



# The Thirteenth Report to Congress

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

A report of the

**National Committee on Vital and Health Statistics**

*A public advisory body to the Secretary of Health and Human Services*

U.S. Department of Health and Human Services



# NCVHS

## NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

March 14, 2019

The Honorable Nancy Pelosi  
Speaker  
House of Representatives  
1236 Longworth House Office Building  
Washington, D.C. 20515

Dear Madam Speaker:

I am pleased to transmit our *13<sup>th</sup> 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 HHS on health data, statistics, privacy, and national health information policy. It covers the period January 2016 through December 2018.

HIPAA was a visionary law that put the country on a path toward standardizing electronic health care transactions and protecting patients' health care information. The Administrative Simplification provisions of HIPAA require the Secretary of Health and Human Services (HHS) to adopt standards to support electronic information exchange for an efficient, effective healthcare system, including standards for security and privacy to protect individually identifiable health information. It has achieved considerable success with the basic claim, payment, eligibility, and pharmacy adopted standards and significant protections for patients' health information.

Our central message in this report is that revisions to the current HIPAA rules would facilitate the agility industry needs to keep pace with the opportunities and challenges of today's ever-changing health care landscape. While the processes HIPAA set in motion were absolutely essential at the time, they have not kept pace with the rate of change in policy, health care, and technology. Indeed, they actually have come to constrain complete administrative simplification and clinical interoperability. In short, the U.S. needs more agile ways to advance the goals of the Act.

A modernized HIPAA, combined with other necessary changes, can contribute to achieving health care value and optimal national health. Thus, the heart of this 2019 Report to Congress is a *Call for Action* to help usher in that future. We draw on our assessment of the current status of HIPAA implementation to identify actions that government's legislative and executive branches together with private sector and community-level entities might take, separately or preferably jointly, to introduce into HIPAA the flexibility and pace that today's rapidly-evolving environment demands. While separate actions by Congress, the Executive branch, or the private sector will make a difference, concerted action across all of them will produce compounding effects that are more likely to achieve true transformation on the scale that is needed.

The Committee's assessment of HIPAA implementation through 2018 points the way toward new strategies that would support administrative simplification, clinical delivery, public health, and research objectives and keep pace with rapidly-evolving business models and technologies. These strategies would promote the interoperability of health data, reduce the proportion of health spending attributable to administrative processes, provide the necessary agility for national standards upgrades to support innovation, and protect the privacy and security of personal health information. The convergence of computing and communications technologies has made such goals achievable.

As a Federal advisory committee to HHS, NCVHS works in close partnership with other agencies and advisory bodies, including the Health Information Technology Advisory Committee (HITAC). NCVHS also serves a unique role in providing a forum for stakeholders in the private sector to contribute observations and recommendations to the Committee's deliberations. It is this unique, collaborative and transparent process that has enabled these advances to date and the acquisition of knowledge to provide a vision for the future.

As reflected in this report's *Call for Action*, the Committee continues its 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 look forward to continued progress on these important issues for the benefit of the nation's health system. If your staff would like a briefing presentation on this or any of our past or anticipated activities, the Committee would be pleased to provide this information.

Sincerely,

/s/

William W. Stead, M.D., Chair  
National Committee on Vital and Health Statistics

CC: The Honorable Alex Azar, II  
HHS Data Council Co-Chairs

Enclosure

**Identical letter to:**

Honorable Mike Pence  
President  
United States Senate

Honorable Chuck Grassley  
President Pro Tempore  
United States Senate

Chuck Grassley, Chairman and Ron Wyden, Ranking Member  
Senate Finance Committee

Patrick J. Toomey, Chair, and Debbie Stabenow, Ranking Member  
Finance/Subcommittee on Healthcare

Lamar Alexander, Chair, and Patty Murray, Ranking Member  
Senate HELP Committee

Richard Shelby, Chair, and Patrick Leahy, Vice Chair  
Senate Committee on Appropriations

Roy Blunt, Chair, and Patty Murray, Ranking Member  
Appropriations/Subcommittee on Labor, Health and Human Services, Education, and Related  
Agencies

Richard Neal, Chair, and Kevin Brady, Ranking Member  
House Committee on Ways and Means

Lloyd Doggett, Chair, and Ranking Member, Devin Nunes  
Ways and Means/Subcommittee on Health

Frank Pallone, Chair, and Greg Walden, Ranking Member  
House Committee on Energy and Commerce

Anna Eshoo, Chair, and Michael Burgess, Ranking Member  
Energy and Commerce/Subcommittee on Health

Nita Lowey, Chair, and Kay Granger, Ranking Member  
House Committee on Appropriations

Rosa DeLauro, Chair, and Tom Cole, Ranking Member  
Appropriations/Subcommittee on Labor, Health and Human Services, Education and Related  
Agencies

## **About the 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 (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C.242k[k]). In that capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues. The Committee is composed of eighteen 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 of 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 HHS for terms of four years each, with about four new members being appointed each year. Two additional members are selected by Congress. See the NCVHS membership roster in Appendix 6. [www.ncvhs.hhs.gov](http://www.ncvhs.hhs.gov)

This report was prepared by Susan Baird Kanaan, Rose Li and Associates, Inc., in collaboration with NCVHS members and staff.

## **NCVHS Membership and Lead Staff**

*See detailed NCVHS membership roster in Appendix 6*

### **William W. Stead, MD, Chair**

Bruce Cohen, PhD

Nicholas Coussoule

Llewellyn Cornelius, PhD, LCSW

Alexandra Goss

Linda Kloss, MA, RHIA, CAE, FAHIMA

Richard Landen, MPH, MBA

Denise Love, BSN, MBA

Vickie Mays, PhD, MSPH

Jacki Monson, JD

Bob Philips, MD, MSPH

David Ross, ScD

Debra Strickland, MS

Roland Thorpe, PhD

### **Sharon B. Arnold, PhD, Executive Staff Director**

Associate Deputy Assistant Secretary for Planning and Evaluation/Science and Data Policy

Office of the Assistant Secretary for Planning and Evaluation

U.S. Department of Health and Human Services

### **Rebecca S. Hines, MHS, Executive Secretary/Designated Federal Officer**

Health Scientist

Office of Planning, Budget and Legislation

National Center for Health Statistics

Centers for Disease Control and Prevention

U.S. Department of Health and Human Services

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## EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 directed the National Committee on Vital and Health Statistics (NCVHS) to report to Congress regularly on the implementation status of the HIPAA administrative simplification provisions. This 13<sup>th</sup> NCVHS Report to Congress provides that status report and outlines ways in which HIPAA needs modernizing to enable the now much-evolved digital health system to more fully support needed improvements and innovation in health care and health while reducing costs and administrative burden.

HIPAA was a visionary Law that put the country on a path toward standardizing electronic health care transactions and protecting patients' health care information. It has achieved considerable success with the basic claim, payment, eligibility, and pharmacy adopted standards and significant protections for patients' health information. However, the regulatory processes it put in place have not kept up with changes in technology and health care. The world has changed considerably over the ensuing 22 years; and it is clear to NCVHS that the time has come to accelerate the pace, close critical gaps, and increase the flexibility with which HIPAA is applied to align the trajectory it set with the rapid rate of change in today's health care and technology environments.

The Committee's work in recent years has revealed not just this need but also a clear path toward a future in which a modernized HIPAA, combined with other necessary changes, can contribute to achieving health care value and optimal national health. Thus, the heart of this 2019 Report to Congress is a *Call for Action* to help usher in that future. We draw on our assessment of the current status of HIPAA implementation to identify actions that the government's legislative and executive branches together with private sector and community-level entities might take, separately or preferably jointly, to introduce into HIPAA the flexibility and pace that today's rapidly-evolving environment demands. While separate actions by Congress, the Executive branch, or the private sector will make a difference, concerted action across all of them will produce compounding effects that are more likely to achieve true transformation on the scale that is needed.

### Part 1. Call for Action

#### 1.1 *The World Has Changed*

Since HIPAA legislation was passed in 1996, the world of health care and health information has changed to an extraordinary degree. **Our central message in this report is that revisions to the current HIPAA Rules would facilitate the agility industry needs to keep pace with the opportunities and challenges of today's ever-changing health care landscape.** While the processes HIPAA set in motion were absolutely essential at the time, they have not kept pace with the rate of change in policy, health care, and technology. Indeed, they actually have come to constrain complete administrative simplification and clinical interoperability. In short, the U.S. needs more agile ways to advance the goals of the Act.

Many of the challenges faced by the health care industry since 1996 are a function of the massive task of moving from paper to electronic processes, which Congress has tried to facilitate



through a series of laws that began with HIPAA. While the challenges to the health care industry today have multiple causes, we believe that the HIPAA-related changes proposed in this report would go a long way toward removing barriers and streamlining health care processes. Such changes have the potential to deliver significant economic benefits to the U.S. in the form of savings: There is a \$312 billion *annual* opportunity—the current estimated cost of administrative complexity—to be realized from complete administrative simplification.

### 1.3 Looking Ahead

It is instructive to consider what would be possible – and is technically possible now – if HIPAA administrative simplification and privacy protection did more to enable the health care system to take advantage of opportunities to enhance efficiency, add value, and improve population health. In view of myriad advances in health care, health policy, and information technology, imagine these very real possibilities:

- **What if** every administrative transaction were fully digital? (Analogy: PayPal)
- **What if** every patient and provider could see the status of their transactions? (Analogy: FlightAware)
- **What if** every local public health department in the U.S. could see who died in their jurisdiction in the past week and be alerted to emerging problems such as a new drug overdose hot spot? (Analogy: weather reporting/forecasting)
- **What if** standards updates were automated, schedulable, and non-intrusive into provider workflows? (Analogy: computer operating system and smartphone app updates)
- **What if** the standards ecosystem enabled collaborative innovation? (Analogy: Salesforce.com)
- **What if** patients could conveniently see how their health information was being used and who was using it? (Analogy: Google privacy checkup)

### 1.4 Resetting the Trajectory: New Strategies for New Opportunities

Our assessment of HIPAA implementation through 2018 points the way toward new strategies that would support administrative simplification, clinical delivery, public health, and research objectives and keep pace with rapidly-evolving business models and technologies. These strategies would promote the interoperability of health data, reduce the proportion of health spending attributable to administrative processes, provide the necessary agility for national standards upgrades to support innovation, and protect the privacy and security of personal health information. The convergence of computing and communications technologies has made such goals achievable.

Part 1 of this report describes the present opportunity with respect to HIPAA and issues a *Call for Action* that outlines the type of complementary steps we believe are needed to create a path on which HIPAA can achieve the goals Congress initially set for it. This section of the Executive Summary briefly summarizes the intended net effect of the suggested actions. Taken together, these actions would remove some of the main constraints built into the HIPAA regulations, encourage innovation, and clarify accountability so that government, the health care industry,

and communities will have the flexibility to take greater advantage of potential opportunities. Many of the ideas the Committee presents in this report emerged as findings in the NCVHS projects described in Parts 2 and 3; and some represent areas in which NCVHS is still developing recommendations.

Our suggestions are predicated on distinct roles for Congress, the Executive branch, and multiple private sector actors that we believe will facilitate efficiency and coordination. To be specific, Congress would be responsible for laying out policy and resources and establishing accountability; HHS and other executive agencies would be responsible for writing and enforcing regulations and managing budgets and programs; and the private sector, including the health care industry and Standards Development Organizations (SDOs), would be empowered to innovate, develop technical specifications for existing standards, test possible new standards and operating rules for usability and fitness in accord with business needs, and improve data protection practice across all entities that hold or process health information. The specific strategies we suggest can help reset the HIPAA trajectory so it can again be an instrument of positive and timely change.

#### **1.4.1 Actions Needed to Effect Change: Transaction Standards, Operating Rules, and Terminologies and Vocabularies**

In [Table 1](#), (page 10), we suggest a set of coordinated actions related to standards for transactions, operating rules, and their associated terminologies and vocabularies. The general thrust of these actions is to modernize HIPAA, clarify roles and responsibilities, increase timeliness, give industry greater flexibility, and strengthen regulatory enforcement where needed. Although actions for improvement can be taken separately by Congress, the Executive branch, or the private sector, coordinated action can compound their overall impact.

#### **1.4.2 Actions Needed to Effect Change: Privacy, Confidentiality, and Security**

Taken together, the priorities for privacy, confidentiality, and security that are described in [Table 2](#) (page 12) will strengthen enforcement and protections, extend the rights of data subjects, increase education and guidance, support research, and catalyze communities of practice. As in the other areas, the benefits derived from these actions will compound if they are taken jointly by Congress, the Executive branch, and the private sector.

## **Part 2. Status Report on Administrative Simplification Implementation**

NCVHS has been actively involved in advising HHS on the adoption and implementation of standards, identifiers, and code sets, and on protection of the privacy and security of personal health information, since the passage of HIPAA in 1996. The Committee works in close consultation with the health care industry and standards organizations to fulfill its statutory duties with respect to administrative simplification. Part 2 of this report, which supports our *Call for Action*, reviews the status of administrative simplification and the work of NCVHS in three areas of HIPAA: transaction standards and operating rules; terminology and vocabulary standards; and privacy, confidentiality, and security.

## ***2.1 Transaction Standards and Operating Rules***

NCVHS embarked on a series of information-gathering activities in 2017 with SDOs, federal partners including the HHS Office of the National Coordinator for Health Information Technology (ONC), and advisors, leading to a May 2018 forum with chief information officers, vendors, and other end-users of standards. The Committee's information-gathering culminated in a December 2018 hearing during which participants shared their perspectives on 23 draft NCVHS recommendations pursuant to the information gathered by the NCVHS Subcommittee on Standards. The hearing testimony stressed that current transaction standards and operating rules, and especially the related federal rule promulgation and enforcement processes, fail to support emerging business needs and technologies in a timely manner, thus stifling innovation and driving up administrative costs. On the basis of the findings from the two-year intensive process, NCVHS submitted initial recommendations to the HHS Secretary for a Predictability Roadmap in early 2019.<sup>1</sup>

### **2.1.2 Major Themes and Takeaways on Transaction Standards and Operating Rules, 2017-18**

1. Current standards promulgation impedes the full utilization of technology.
2. The timing for the availability of new versions of transaction standards or operating rules for administrative transactions is unpredictable.
3. Covered entities cannot use new technology or standards voluntarily and at their own pace, due to constraints in existing HIPAA statutes and regulations.
4. HHS enforcement of the standards and code sets provisions of the HIPAA statute and regulations is ineffective in their impact on industry compliance.
5. The lack of HHS-sponsored or -supported education and technical guidance on the appropriate use of the adopted transactions and operating rules hinders industry's successful adoption and implementation of standards.

## ***2.2 Health Terminology and Vocabulary Standards***

In 2017, NCVHS undertook a project to advise the HHS Secretary on 1) the changing environment and implications for timing and an approach to terminologies and vocabularies standards adoption; 2) the needs, opportunities, and problems with development, dissemination, maintenance, and adoption of these standards; and 3) actions HHS might take to improve these practices. The National Institutes of Health/National Library of Medicine has been an important partner to NCVHS in this work. Major issues related to terminologies and vocabularies include the opportunity to coordinate scope of content and curation, the need to streamline regulatory adoption, and the need for a pathway to the convergence of clinical and

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<sup>1</sup> NCVHS Letter to the HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," February 13, 2019: <https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf>

administrative data standards. NCVHS submitted recommendations to the HHS Secretary on health terminologies and vocabularies in early 2019.<sup>2</sup>

### **2.2.2 Major Themes and Takeaways on Health Terminologies and Vocabularies, 2017-18**

1. The U.S. named standards for terminologies and vocabularies are in place, but coordination across standards is lacking and under-resourced, presenting a barrier to interoperability.
2. The HHS regulatory process is applied unevenly for named health terminology and vocabulary standards, causing costly delays and complexity in adopting revised versions of some standards.
3. Greater coordination across terminology and vocabulary standards is needed to ensure that redundant terminology and vocabulary concepts are purposeful and useful, and that gaps are addressed.
4. A deliberate pathway toward convergence of clinical and administrative data domains is key to realizing health transformation goals and administrative simplification.

## **2.3 Privacy, Confidentiality, and Security**

NCVHS works closely with the HHS Office for Civil Rights and other partners to advise the Secretary on protections and needed improvements in the complex area of privacy, confidentiality, and security. Part 2 of this report, which supports our *Call for Action*, reviews the status of privacy, confidentiality, and security protections under HIPAA and the work of NCVHS in this area. During the period covered by this report, NCVHS made recommendations on de-identification of protected health information under HIPAA. The Committee's chief focus in 2017 and 2018 was to examine the health information privacy environment beyond the scope of the HIPAA law. NCVHS is now considering recommendations for the Secretary based on study of data stewardship models and regulatory levers that will extend protections for health data. This will require coordinated action by Congress, the Executive branch, and the private sector.

### **2.3.2 Major Themes and Takeaways on Privacy, Confidentiality, and Security, 2017-18**

1. Today, there are two health information worlds. One is regulated by HIPAA; the other is largely unregulated (that is, "beyond HIPAA").
2. De-identified health data carry real risk of re-identification, a risk that grows into the future as datasets are combined and data tools become more sophisticated.

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<sup>2</sup> NCVHS Letter to the HHS Secretary, "Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards," February 13, 2019: <https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf>

3. Protection of privacy and security requires management, compliance, and enforcement across the lifecycle of the information.
4. Data protections grounded in Fair Information Practice Principles remain the essential building blocks for data policy.

## Part 3. Data Essential for Management of Population and Community Health

The ongoing evolution in recent years from a fee-for-service approach to value-based reimbursement has shifted the frame of reference for health care to include community health and population health management. In 2017, NCVHS completed a study of the data needed to manage community and population health that began in 2011 and culminated in development of a *Measurement Framework for Community Health and Well-being*. In 2018, NCVHS conducted a major project on the vulnerabilities of the nation's Vital Registration and Statistics System, the loosely federated system of state, county, and federal agencies that collect and steward birth, death, and other vital statistics data. Also in 2018, the Committee undertook a new project focusing on access to local data, in response to widespread concerns among researchers, public health leaders, community health assessment experts, and other data stakeholders about declining public access to aggregate small-area (local) data.

### 3.1.1 Major Themes and Takeaways on Data on Population and Community Health, 2017-18

1. The NCVHS *Measurement Framework for Community Health and Well-being* offers a practical approach to organizing the data essential to understand the health of populations at national, state, and community levels.
2. Access to small area data is critical for supporting community-focused population health management, reducing the need for health care and associated costs.
3. A sustainable system for vital registration and statistics data is essential to tracking the health of the nation. These data also are critical to establishment of individual identity and the protection of national security, as well as being fundamental building blocks for health surveillance data, such as for tracking opioid and influenza epidemics. Despite its importance, this federated system is fragile.

### 3.2 New Strategies for New Opportunities

With the relationship between individual and community/population health now well-established in public policy and health care, a number of actions are needed to safeguard the continued availability of population and community health data. As in the realms of standards and privacy/security, the actions NCVHS suggests in [Table 3](#) (page 29) could be taken independently by the legislative and executive branches and/or private sector and community-level partners. However, they will have the greatest impact when all these stakeholders act in concert.

## Part 4. Conclusion and Next Steps

Based on lessons learned and input from industry during the two-year period covered by this Report to Congress, the Committee outlines in this report the types of actions we believe will set the country on a course to better achieve interoperability and reduce the burden of adopting and implementing standards and privacy protections. We emphasize that our suggestions are predicated on distinct roles for each stakeholder that we believe will maximize opportunities for efficiency and coordination. For our part, as we carry out our role as a Federal Advisory Committee on national health information and data policy, NCVHS will further explore aspects of this transformation that are within the purview of our Charter. This section outlines three such opportunities. The Committee looks forward to additional guidance from HHS about areas in which NCVHS advice and consultation will be needed in the coming years.

### 4.1 Predictability Roadmap

NCVHS submitted recommendations to the Secretary of HHS on new approaches to improve the adoption of national standards for the health care industry in early 2019.<sup>3</sup> These recommendations will address policy and procedural actions that the Secretary can take to jumpstart predictability and accelerate the pace of the standards adoption process. This jumpstart will improve interoperability and reduce both health care provider burden and regulatory burden.

### 4.2 Health Terminology and Vocabulary Standards/Systems

NCVHS submitted recommendations to the Secretary of HHS in early 2019<sup>4</sup> on selection criteria for adoption of health terminology and vocabulary standards and on guidelines for curation and dissemination of these standards. The recommended criteria and guidelines will be useful to HHS when considering the adoption of standards, and will inform the health industry of the characteristics for contemporary standards and their maintenance. These recommendations will include an approach to simplifying the adoption of future versions of the International Classification of Diseases (ICD) and related health terminology and vocabulary standards.

### 4.3 A Health Privacy and Security Framework for the 21st Century

NCVHS will convene a working session in early 2019 to bring together leading experts to outline principles for stewardship of health data in today's environment; to identify essential public and private levers to ensure appropriate governance; to develop recommendations for a contemporary framework of data stewardship including a pathway for improving private and public sector governance of health information over the next decade; and finally to identify key themes for communications with individuals, policymakers, and stakeholders in the private sector.

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<sup>3</sup> NCVHS Letter to the HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," February 13, 2019:

<https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf>

<sup>4</sup> NCVHS Letter to the HHS Secretary, "Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards," February 13, 2019: <https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf>

## INTRODUCTION

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 directed NCVHS to report to Congress regularly on the implementation status of the HIPAA administrative simplification provisions. This 13<sup>th</sup> NCVHS Report to Congress provides that status report and outlines ways in which HIPAA needs modernizing to enable the now much-evolved digital health system to more fully support needed improvements and innovation in health care and health while reducing costs and administrative burden.

The roots of HIPAA began in the early 1990s, when it first became apparent that the health care industry could become more efficient by computerizing medical records and standardizing routine administrative messaging between providers and payers.<sup>5</sup> In 1992, then Secretary of Health and Human Services Dr. Louis Sullivan convened a gathering of health insurers, hospitals, and physicians in the “Forum on Administrative Costs.” The Forum participants agreed on a future vision in which the health care industry would be linked to electronic health information systems, eliminating the reliance on paperwork and allowing providers, payers, and consumers to communicate over an “electronic highway.” These changes were expected to pave the way for lower administrative costs, less burden, and long-run gains in quality of care.

Congress passed the bipartisan Kennedy-Kassebaum bill in 1996 as the Health Insurance Portability and Accountability Act. The primary goals for HIPAA were to make it easier for people to keep health insurance, to help the health care industry control administrative costs, and to put in place more formal privacy and security protections for patients’ health care information. This Law was visionary, and it put the country on a path toward achieving its stated goals.

However, while HIPAA has achieved considerable success with the basic claim, payment, eligibility, and pharmacy adopted standards and protections for patients’ health care information, the regulatory processes it put in place have not kept up with changes in technology and health care. Core issues are the need for greater flexibility and agility in how the law is applied, and gaps in coverage as digital information changes the landscape. Despite successes, over time the constraints and complexities of the standards adoption process have made it as much of an impediment to progress as an enabler.

In the two years since the 12th NCVHS report to Congress on HIPAA,<sup>6</sup> it has become increasingly clear to us that the time has come to accelerate the pace of change and close critical gaps so that the trajectory HIPAA set in motion aligns with the rapid rate of change in today’s health care and technology environments. The gap must be closed between what has

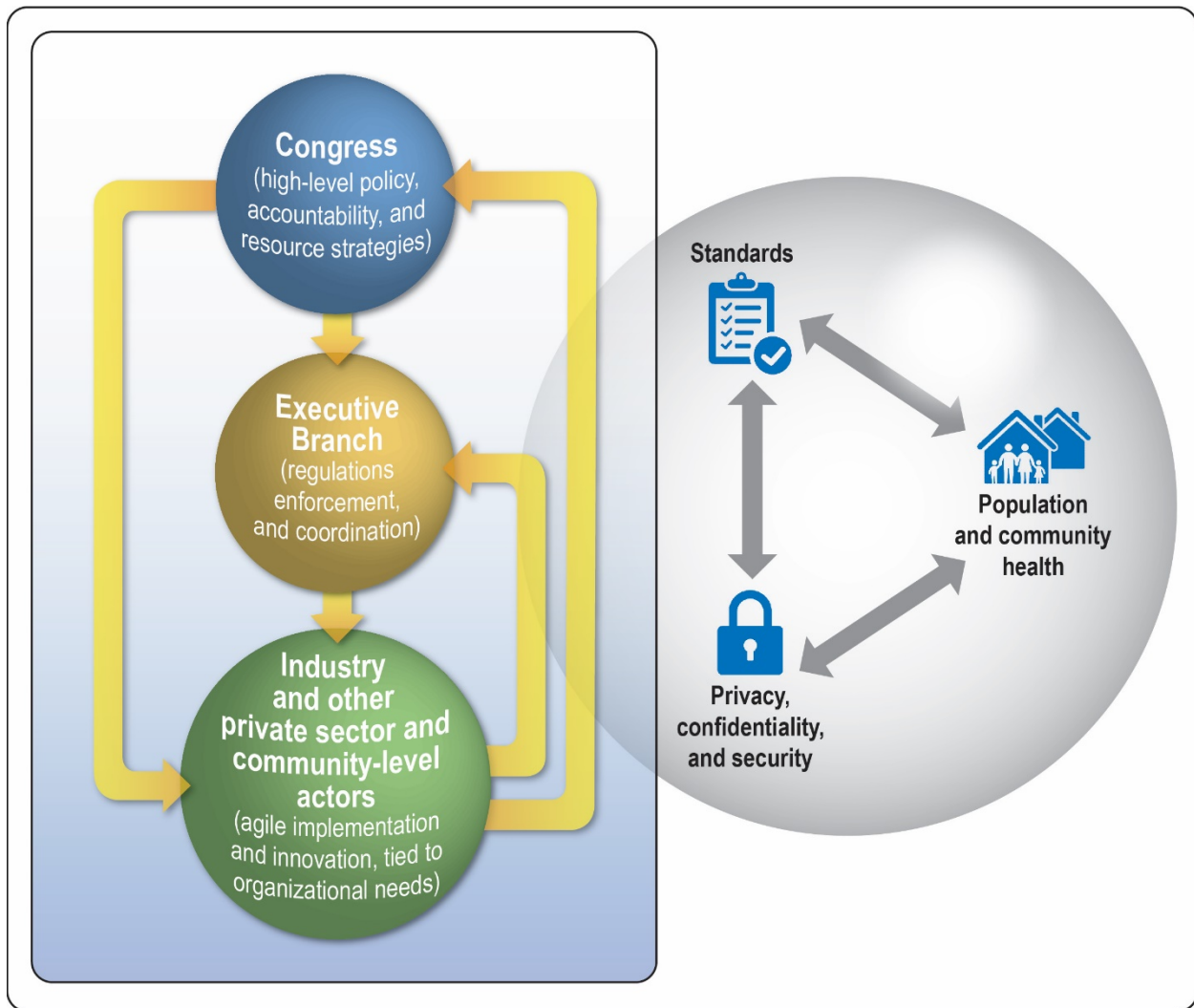
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<sup>5</sup> Institute of Medicine. *Computer-Based Patient Record: An Essential Technology for Health Care*. Washington, DC: The National Academies Press; 1991: <https://www.nap.edu/catalog/18459/computer-based-patient-record-an-essential-technology-for-health-care>

<sup>6</sup> NCVHS, “Twelfth Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act,” May 2017: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/12th-Rpt-to-Congress.pdf>

been achieved to date through HIPAA and what is needed and clearly possible in the 21<sup>st</sup> century. Our work in recent years has revealed not just this need but also a clear path toward a future in which a modernized HIPAA, combined with other necessary changes, can contribute to achieving health care value and optimal national health.

Thus the heart of this 2019 Report to Congress is a *Call for Action*. We draw on our assessment of the status of HIPAA implementation to identify actions that government’s legislative and executive branches along with private sector and community-level entities might take, separately or preferably jointly, to introduce into HIPAA the flexibility and pace that today’s rapidly-evolving environment demands. Our observations are based on careful study of the issues and consultations with a broad swath of leaders in public and private arenas. While actions by Congress, the Executive branch, or the private sector separately will make a difference, concerted action across them all will produce compounding effects that are more likely to achieve true transformation on the scale that is needed. (See Figure 1.)



**Figure 1.** Complementary Actions for Optimal Health Care Value and Health in the U.S.



Our Report draws heavily on recent NCVHS work, including eight letters to the HHS Secretary and 12 reports describing aspects of health information policy related to privacy and security, administrative transaction standards, and vital records. We also draw on relevant work of the HHS Office for the National Coordinator of Health Information Technology (ONC) and Office for Civil Rights (OCR), and of the National Library of Medicine. All three, together with ONC's Health Information Technology Advisory Committee (HITAC), collaborated with NCVHS and provided information or guidance on a range of HIPAA implementation issues during the reporting period.

Following this introduction, **Part 1** (page 4) describes the present opportunity with respect to HIPAA and issues a *Call for Action* that outlines the type of complementary steps we believe are needed to create a path on which HIPAA can achieve the goals Congress set for it.

To fulfill the Congressional mandate for this report, **Part 2** (page 14) reviews the status of administrative simplification and the work of NCVHS in three areas of HIPAA: transaction standards and operating rules; terminology and vocabulary standards; and privacy, confidentiality, and security. Our assessment of this status supports the *Call for Action*.

**Part 3** (page 26) broadens the perspective to include community and population health, which has become an explicit frame of reference for health care with the shift toward value-based reimbursement. Our focus in this section is the data needed to manage community and population health.

Finally, **Part 4** (page 31) summarizes our key messages and briefly describes the major issues with which the Committee expects to concern itself in 2019-20, working in close collaboration with HHS and other partners to optimize information for health.

Throughout the report are links to NCVHS documents on the Committee's website where readers can delve more deeply into topics of particular interest and learn more about NCVHS work and recommendations. The **Appendices** (pages 34-47) contain documents that support the contents of the report.

## PART 1. CALL FOR ACTION

### 1.1 The World Has Changed

Since HIPAA legislation was passed in 1996, the world of health care and health information has changed to an extraordinary degree, far beyond what the authors of that legislation could have envisioned. Here are just a few examples that apply equally to health care providers, health insurance companies, and public/population health authorities:

- In 1996, almost all health care records were paper-based. Transactions moved by snail-mail, hand delivery, and fax. Today, health care information is largely digital; and care delivery, communication, and record-keeping use mobile devices, cloud computing, intelligent medical devices, and other forms of digital technology. Access to much of the data is nearly real-time. Technological innovation, the ever-expanding volume of information, and ongoing discovery of new opportunities to use data for health all drive the intense rate of change.

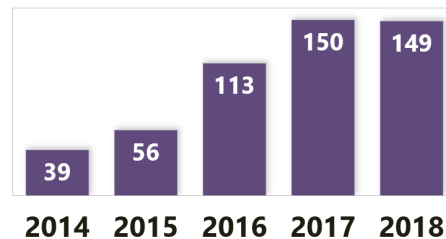
The volume of health care data has multiplied 8 times since 2013 and is projected to grow at a compound annual rate of 36 percent between 2018 and 2025.

**Source:** IDC White Paper, *The Digitization of the World from Edge to Core*, #US44413318 November 2018

- In 1996, health care reimbursement was based on paying fees for services delivered. Today, it is increasingly framed in terms of paying for outcomes achieved through value-based purchasing and population health management. This change has increased the pressure for care coordination and quality and price transparency across all sectors of health care, and for comprehensive and timely data on population health.

- The types of security breaches of health care information have shifted over the years from misplaced laptops to major cyber-attacks. In 2018, 43 percent of breaches of unsecured protected health information were the result of hacking. Lax security practices in health care make this valuable information particularly vulnerable.

**BREACHES AFFECTING 500 OR MORE INDIVIDUALS  
REPORTS RECEIVED INVOLVING  
HACKING/IT INCIDENTS**



**Source:** HHS Office for Civil Rights, *Breaches Affecting 500 or More Individuals Involving Hacking/IT Incidents, calendar years 2014-2018*. March 2018.

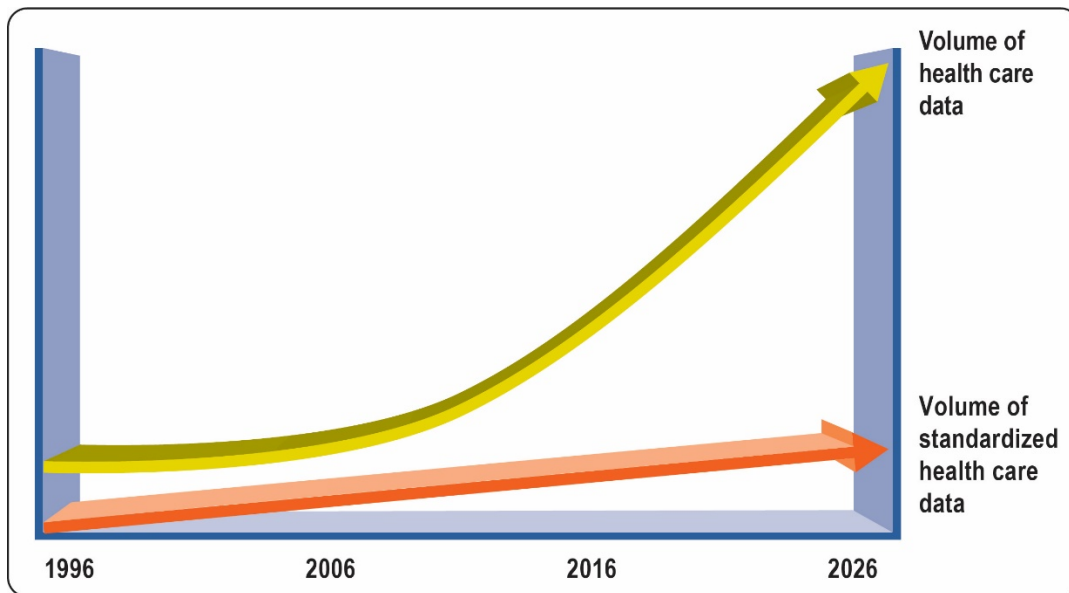
- Today, individuals are more engaged in their health and wellness decisions and have a far greater stake in accessing and using their own health information than they did in 1996. Individuals are also generating data about their own health using biomedical monitoring devices, genetic profiling services, mobile apps, and the Internet of Things.

- In recent years, there is growing public awareness and concern about how personal information is being used by second and third parties, along with interest in individuals' privacy rights to have a say about such downstream uses.
- Anonymized health data are being analyzed, with the help of sophisticated and proprietary algorithms derived from artificial intelligence, to develop new knowledge but with little control over how the information is used or whether individuals can be re-identified as data sets are merged and manipulated.

Between 2011 and 2016, the mid-point of estimates of the annual cost of administrative complexity to the U.S. health care system increased from \$248B to \$312B. This represents the savings that could be realized through administrative simplification.

**Source:** [Health Affairs blog, May 2018](#), based on [Berwick: JAMA, 2012; 307\(14\):1513-1516](#)

Our chief message in this report is that revisions to the current HIPAA Rules could help facilitate greater agility much needed by the industry to keep pace with the opportunities and challenges of today's ever-changing health care landscape. While the processes HIPAA set in motion were absolutely essential at the time, they have not kept pace with the rate of change in policy, health care, and technology. Indeed, they actually have come to constrain complete administrative simplification and clinical interoperability. As the volume of health data and data uses grows exponentially, the slow pace of administrative simplification creates a growing gap between the two trajectories, as illustrated in Figure 2.



**Figure 2.** Growing Gap Between the Volume of Health Care Data and the Volume that Is Standardized.

**Sources:** Top line: Adapted from [IDC White Paper, The Digitization of the World from Edge to Core, #US44413318 November 2018](#). Bottom line: Adapted from [CAQH 2018 Index](#).

As currently constituted, HIPAA regulatory processes force the health care industry to cope with obsolete and sometimes conflicting statutory or regulatory requirements, arbitrary barriers between clinical and administrative standards, slow updates to standards, and slow regulatory

process or non-responsiveness to industry needs and NCVHS recommendations.<sup>7</sup> As a result of lengthy and uncertain lead times for promulgating rules for standards updates, the industry has found it necessary to create workarounds to meet business needs. The time and investment required to develop and implement those workarounds limits the bandwidth available to industry for other, more beneficial changes. This is a significant opportunity cost of the HIPAA regulatory process in its present form. The missed opportunities can lead to inefficient care, disappointing health outcomes, and higher health care costs. As such, they obstruct the achievement of our national health care priorities and goals, compared both to our own goals and to health outcomes and costs in other industrialized countries.

In short, the U.S. needs more agile ways to advance the goals of the Act.

## 1.2 A Developmental View

It is useful to look at HIPAA developmentally and in the context of related laws that have been passed since 1996. Collectively, these laws and policies have had mixed results in the ongoing effort to simplify health care information and financial management. HIPAA does not exist in a vacuum; and the health care industry must juggle its requirements with many other requirements of federal and state legislation and regulation as well as the complex operational requirements of Medicare, Medicaid, and private health insurance contracts. Broadly speaking, many of the challenges faced by the health care industry since 1996 are a function of the massive task of moving from paper to electronic processes, which Congress has tried to facilitate through this series of laws. While the challenges to the health care industry have multiple causes, we believe that the HIPAA-related changes we propose can go a long way toward removing barriers and streamlining health care processes.

In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act mandated standards for prescription drug transactions that were consistent with HIPAA. In 2017, 4 billion pharmacy claims were submitted digitally with an estimated 10 million residual paper claims,<sup>8</sup> and 1.4 billion prescriptions were processed digitally.<sup>9</sup>

Congress passed HITECH—the Health Information Technology for Economic and Clinical Health Act—as part of the American Recovery and Reinvestment Act in 2009. HITECH enacted incentives for health care providers to implement electronic health records (EHRs) and supporting technology. HITECH also established what were originally known as Meaningful Use regulations (now known as Promoting Interoperability) that included adoption and

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<sup>7</sup> For example, the National Council for Prescription Drug Programs (NCPDP) developed and published an update of the U.S. pharmacy standards in 2009. There is overwhelming industry support for adopting updated versions as HIPAA standards. However, under the current HHS regulatory process, the adoption rules have not yet been promulgated. Even after promulgation, implementation of those three standards will require three years.

<sup>8</sup> IQVIA National Prescription Audit database—IQVIA (formerly IMS Health and Quintiles).

<sup>9</sup> Surescripts LLC 2017 National Progress Report: [https://surescripts.com/docs/default-source/national-progress-reports/2151\\_npr\\_2017\\_finalB.pdf](https://surescripts.com/docs/default-source/national-progress-reports/2151_npr_2017_finalB.pdf)

implementation of standards for the clinical information in EHRs, supported by substantial federal incentives. These standards increase clinical interoperability while adding friction between the standards adoption and implementation processes originating in HITECH and those originating in HIPAA.

The Patient Protection and Affordable Care Act (ACA), passed in 2010, expanded HIPAA by mandating processes to adopt standard operating rules to supplement certain of the HIPAA transactions. Operating rules seek to reduce the ambiguity of the information content of the HIPAA transactions and improve business processability for health care providers and payers.<sup>10</sup> They reduce the error rate of transaction processing and thereby reduce the cost of investigating and resolving failed transactions. The processes for development, regulatory adoption, and industry implementation of operating rules are very similar to those used for the HIPAA transactions.

The 21<sup>st</sup> Century Cures Act (2016) took an important step toward modernization of HIPAA and HITECH by making interoperability an explicit goal, reducing barriers to patient access and use of data for research while increasing privacy protection.<sup>11</sup>

In view of this series of laws and their consequences for the health care industry, the United States is faced with a compelling need to continue to evolve its laws and improve its regulatory processes and business practices to create a more responsive health data ecosystem for the future that can better support health care efficiency, value, and patient care.

Such changes have the potential to deliver significant economic benefits to the U.S. in the form of savings. There is a \$312 billion *annual* opportunity—the current estimated cost of administrative complexity—to be realized from complete administrative simplification.<sup>12</sup> Over the two decades since HIPAA shifted the health care industry toward standardized digital administrative transactions, six of the 11 administrative transaction standards named in HIPAA have been widely implemented across the health care industry (see Figure 3). In 2018, the national volume of these six transactions for medical and dental claims was 32.2 billion transmissions, resulting in an estimated savings of \$68 billion per year. A residual opportunity of

<b>Percent Industry Implementation of Six Transaction Standards</b>	<b>2013</b>	<b>2018</b>
Health care claim submission	90%	96%
Eligibility for a health plan	65%	85%
Coordination of benefits	NR	80%
Health care claim status	48%	71%
Claim payment	50%	63%
Remittance advice	43%	48%

**Figure 3.** Implementation of Six Transaction Standards (**Source:** [CAQH 2018 Index](#))

<sup>10</sup> For example, an operating rule might specify whether the transaction is exchanged as an asynchronous batch, synchronously in near real time, or both, and whether an acknowledgement is required to ensure receipt of the transaction.

<sup>11</sup> See Appendix 3, which outlines the improvements introduced by the 21st Century Cures Act in relation to actions outlined in this report.

<sup>12</sup> See the text box on page 12.

another \$10 billion in savings per year is estimated if the remaining five standard transactions were widely implemented. Further, these estimated savings consider only the cost of labor related to the transmission; they do not include the time required to pull the data together for transmission because of the historic separation of administrative systems (e.g., revenue cycle) and clinical systems (e.g., electronic health records). In sum, the cost savings to date are less than 25 percent of the opportunity of complete administrative simplification.

Prior authorization and health care attachments are two of the HIPAA named transactions that underscore the need to modernize the HIPAA standard development, adoption, and implementation processes and to harmonize administrative and clinical standards. Prior authorization transactions support communication between provider and payer to obtain approval for coverage for a specific service such as a hospitalization, test, or treatment, for a patient under a circumstance. The national prior authorization standard was adopted with a 2012 compliance date, but in 2018 had been fully implemented for only 12 percent of authorization requests. The health care attachment allows the provider to communicate to the payer why the service is needed. To date, no regulation requiring adoption of this attachment standard has been released or published by HHS. These transactions have significant business potential value but have not progressed towards implementation in any predictable way or at a rapid pace.

### 1.3 Looking Ahead

It is instructive to consider what would be possible—and is technically possible now—if HIPAA administrative simplification and privacy protection did more to enable the health care system to take advantage of opportunities to enhance efficiency, add value, and improve population health. The opportunities available in the health care and health policy world include better support of value-based payment methodologies, easier patient access to their personal health information, innovations in health care, growing alignment of administrative and clinical information, and new ways to exchange and harness the power of available data. The information technologies driving interoperability and transformation include application-programming interfaces (APIs), mobile health, telehealth, machine learning, artificial intelligence, and enhanced security and privacy capabilities such as blockchain.

In view of advances such as these, imagine these very real possibilities:

- **What if** every administrative transaction were fully digital? (Analogy: PayPal)
- **What if** every patient and provider could see the status of their transactions? (Analogy: FlightAware)
- **What if** every local public health department in the U.S. could see who died in their jurisdiction in the past week and be alerted to emerging problems such as a new drug overdose hot spot? (Analogy: weather reporting/forecasting)
- **What if** standards updates were automated, schedulable, and non-intrusive into provider workflows? (Analogy: computer operating system and smartphone app updates)

- **What if** the standards platform enabled collaborative innovation? (Analogy: Salesforce.com)
- **What if** patients could conveniently see how their health information was being used and who was using it? (Analogy: Google privacy checkup)

## 1.4 Resetting the Trajectory: New Strategies for New Opportunities

As described in the previous sections, there exist both a compelling need and a clear opportunity for new strategies that support administrative simplification, clinical delivery, public health, and research objectives and keep pace with rapidly-evolving business models and technologies. The desired strategies would promote the interoperability of health data, reduce the proportion of health spending attributable to administrative processes, provide the necessary agility for national standards upgrades to support innovation, and protect the privacy and security of personal health information. The convergence of computing and communications technologies has made such goals achievable.

We want to emphasize that we see a path forward to resetting the HIPAA trajectory so it can again be an instrument of positive and timely change. In this section, we suggest the types of actions we believe will help to achieve these goals. The actions would remove some of the constraints built into the HIPAA regulations, encourage innovation, and clarify accountability so that government, the health care industry, and communities have the flexibility to take greater advantage of available opportunities. Many of the ideas we present in this report emerged as findings in the NCVHS projects described in Parts 2 and 3 of this report, and some represent areas in which NCVHS is still developing recommendations.

Our suggestions are predicated on distinct roles for Congress, the Executive branch, and multiple private sector actors that we believe will facilitate efficiency and coordination. To be specific, Congress would be responsible for laying out policy and resources and establishing accountability; HHS and other executive agencies would be responsible for writing and enforcing regulations and managing budgets and programs; and the private sector, including the health care industry and Standards Development Organizations, would be empowered to innovate, develop technical specifications for existing standards, and test possible new standards and operating rules for usability and fitness in accord with business needs. This view has emerged from NCVHS work on the Predictability Roadmap, which favors a fundamental shift in HHS regulation from a focus on technical details to a focus on policy and enforcement, leaving much of the implementation detail and responsibility up to the industry itself. This does not diminish the essential overarching government role of setting and enforcing policy. Following this reasoning, the actions suggested below for standards and privacy will be most effective in enhancing health care value and national health when they are adopted in concert and linked to actions to enhance information on community and population health, as described in Part 3.

### 1.4.1 Actions Needed to Effect Change: Transaction Standards, Operating Rules, and Terminologies and Vocabularies

The actions suggested in this section relate to standards for transactions, operating rules, and their associated terminologies and vocabularies. The general thrust of the actions is to modernize HIPAA, clarify roles and responsibilities, increase timeliness, give industry greater flexibility, and strengthen regulatory enforcement where needed. Although actions for improvement can be taken separately by Congress, the Executive branch, or the private sector, coordinated action is likely to compound their overall impact.

**Table 1.** Actions to Enhance Transaction Standards, Operating Rules, and Terminologies and Vocabularies

<b>Actor</b>	<b>Actions to Enhance Transaction Standards, Operating Rules, and Terminologies and Vocabularies</b>
Congress	<ul style="list-style-type: none"> <li>• Modernize HIPAA and related legislation:                             <ul style="list-style-type: none"> <li>○ Direct HHS to streamline regulatory processes for administrative transaction standards, codes sets, and operating rules, replacing them as appropriate with agile, value-based rulemaking, adoption, and enforcement processes.</li> <li>○ Authorize HHS to expand the standards mandate to require all entities that send or receive an adopted administrative transaction (not just those now defined as covered entities) to implement the related standards, code sets, and operating rules within three years of adoption.</li> </ul> </li> <li>• Require and fund HHS to develop a process and a public-private oversight body for collaborating in the development, updating, curation, integration, and dissemination of standards, code sets, and operating rules. Such oversight body would be the successor to the Designated Standards Maintenance Organizations (DSMOs), with an updated scope of responsibilities. Include an appropriation for appropriately funding the program.</li> <li>• Assign joint responsibility to NCVHS and HITAC for recommending to Congress by the end of 2020 a path toward convergence of administrative and clinical standards over the subsequent decade.</li> </ul>
Executive Branch (HHS)	<ul style="list-style-type: none"> <li>• Modernize the HIPAA regulations to eliminate the requirement for new rulemaking each time an adopted standard is updated. Work with NCVHS, WEDI, the DSMOs, SDOs, code set curators, and industry to develop the new update procedures.</li> <li>• Conduct or fund an independent cost-benefit study to estimate the value from adoption of administrative standards, code sets, and operating rules, comparing the status prior to adoption to the status two years after the mandatory compliance date.</li> <li>• Enforce implementation of adopted, standards and updates after the mandatory compliance date. Ensure a level playing field by levying significant penalties against proven bad-faith actors.</li> </ul>



Actor	Actions to Enhance Transaction Standards, Operating Rules, and Terminologies and Vocabularies
	<ul style="list-style-type: none"> <li>Collaborate with industry groups and SDOs to ensure that operational and technical guidance are available and recognized, and that broad awareness exists, to assist in implementation of adopted standards, code sets and operating rules. Diverse tools, technologies, and promotional vehicles should be used to reach small and rural providers and entities with other time or resource limitations.</li> </ul>
Private sector entities (primarily the health care industry)	<ul style="list-style-type: none"> <li>The industry should catalyze communities of practice to innovate standards-based health care business processes. A community of practice should consist of willing partners; have a defined purpose and scope; and test extensions or alternatives to adopted standards, code sets, and operating rules.</li> <li>The industry should promote proven standards for dissemination through sub-regulatory guidance, followed by adoption if they prove to have generalized benefit.</li> <li>SDOs should adjust their processes to deliver updates at the pace their segment of the industry needs to meet changing business requirements and to improve outreach to incorporate and address small end user (e.g., physician and hospital) input about their standard transaction pain points and adoption challenges. NCVHS notes that almost all the SDOs have adjusted their processes to ensure capability for better timeliness or are in process of doing so.</li> </ul>

**1.4.2 Actions Needed to Effect Change: Privacy, Confidentiality, and Security**

The protections suggested below are intended to augment the comprehensive Privacy and Security Rules initially set forth under HIPAA for covered entities and business associates. Digital health data can no longer be segregated into two distinct worlds, one that is regulated by HIPAA and one that is largely unregulated, that is beyond the scope of HIPAA. Taken together, the priorities described in the following table will strengthen enforcement and protections, extend the rights of data subjects, increase education and guidance, support research, and catalyze communities of practice. As in the other areas, the benefits derived from these actions will compound when they are taken jointly by Congress, the Executive branch, and the private sector.

**Table 2.** Actions to Enhance Privacy, Confidentiality, and Security

<b>Actor</b>	<b>Actions to Enhance Privacy, Confidentiality, and Security</b>
Congress	<ul style="list-style-type: none"> <li>• Establish federal standards for organizations holding individually identifiable data outside of the scope of HIPAA to have in place reasonable and appropriate privacy and security protections for consumer data.</li> <li>• Call for a federal study to examine the creation of a consumer right of action allowing individuals to seek redress in the case of unauthorized access, misuse, or harm attributable to how their identifiable health information was used.</li> <li>• Establish federal standards for medical device and mobile application manufacturers to implement reasonable and appropriate health data security and privacy practices.</li> </ul>
Executive Branch (HHS)	<ul style="list-style-type: none"> <li>• Develop and promulgate guidance requiring covered entities and business associates to take reasonable and responsible steps to protect identifiable and de-identified health information when releasing it to entities that are not covered by HIPAA, or other privacy law. Reasonable and responsible steps include establishing data sharing agreements, business associate agreements, improved notice, consent and authorization practices, encryption, information security, and breach detection protocols.</li> <li>• Work with other federal agencies and States to develop and promulgate reasonable privacy and security guidance that applies to all individuals and entities that hold or process health information but are not subject to HIPAA. This guidance should reinforce the obligation to uphold fair information privacy principles.<sup>13</sup></li> <li>• Support a research agenda on methods for de-identifying data and mitigating risks of re-identification. The research agenda should include:             <ul style="list-style-type: none"> <li>○ Measurement of the effectiveness of the Safe Harbor method of de-identification in protecting against re-identification;</li> <li>○ Study of the value of applying statistical disclosure limitation techniques in concert with Safe Harbor; and</li> <li>○ Techniques for evaluating risks of re-identification and inference.</li> </ul> </li> <li>• Establish information security and privacy standards and protocols for use by medical devices and apps that collect, process and transmit health data.</li> </ul>

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<sup>13</sup> U.S. Department of Health, Education & Welfare, "Records, Computers, and the Rights of Citizens, Report of the Advisory Committee on Automated Personal Data Systems," July 1973: <https://www.justice.gov/opcl/docs/rec-com-rights.pdf>

<b>Actor</b>	<b>Actions to Enhance Privacy, Confidentiality, and Security</b>
	<ul style="list-style-type: none"> <li>• Establish avenues for reporting, investigating and preparing rapid response guidance on emerging threats to health information privacy and information security.</li> </ul>
Private sector entities	<ul style="list-style-type: none"> <li>• Partner with government to raise public awareness and understanding of individuals’ information rights, how to exercise them, and recourses when avenues are blocked.</li> <li>• Work with government to leverage policy and technology to help patients gain access to their health information, and to help individuals understand responsible steps in protecting the privacy and security of the information in their possession about their own and their families’ health.</li> <li>• Become more transparent about the actual uses being made of personally identifiable and de-identified health information.</li> <li>• Step up vigilance and proactive response for emerging threats and work collaboratively across the industry to respond quickly and comprehensively.</li> <li>• Catalyze communities of practice to share best practices to improve data protection across all entities that hold identified and de-identified health information, whether or not the entity is covered by HIPAA. Examples include improving informed consent practices, adopting data sharing and data use agreements prohibiting or limiting re-disclosure, and improving assessment of the risks associated with disclosure of protected health information.</li> </ul>

## PART 2. STATUS REPORT ON ADMINISTRATIVE SIMPLIFICATION IMPLEMENTATION

The Administrative Simplification provisions of HIPAA were intended to help the health care industry control administrative costs, speed up processing, and protect the privacy and security of health information. These provisions included standards to move the health care industry from manual and paper-based administrative transactions to electronic exchange and required the Secretary of HHS to create standards to protect individual health information. These provisions apply to HIPAA-covered entities – health care providers, health plans, health care clearinghouses, and business associates of covered entities.

Briefly, standardization of administrative transactions is carried out in three steps:

- 1) **Legislation:** HIPAA named the transactions for which standards should be adopted by the health care industry. The ACA added the mandate to adopt operating rules for each transaction.
- 2) **Rulemaking:** HIPAA authorized HHS to adopt standards, code sets, and identifiers. Later, the ACA added operating rules.
- 3) **Implementation by the health care industry:** Covered entities are required to implement and use the standards, along with specified privacy and security safeguards.

NCVHS has been actively involved in advising HHS on the adoption and implementation of standards, identifiers, and code sets since the passage of HIPAA in 1996. In 2010, the ACA established a new requirement to name an entity to author operating rules and adopt them for each of the adopted standard transactions (such as claims, eligibility, and electronic funds transfer). Based on NCVHS recommendations, HHS designated CAQH CORE (Committee on Operating Rules for Information Exchange) to serve in that capacity for medical standards. The ACA required that the Secretary name a Review Committee to review and make recommendations on adopted standards and operating rules, and HHS designated NCVHS to serve in that capacity. The Review Committee's reports and recommendations, which are based on extensive consultations with industry, inform NCVHS recommendations to HHS and its reports to Congress on the status of HIPAA implementation. In 2018, the 21<sup>st</sup> Century Cures Act established the Health Information Technology Advisory Committee (HITAC) to advise ONC, and also directed ONC to "ensure that the relevant and available recommendations and comments from NCVHS are considered in the development of policies."<sup>14</sup>

The Secretary of HHS responded to the requirement to create national standards to protect individual health information with the HIPAA Privacy and Security Rules. The HIPAA Privacy Rule established the first-ever federal privacy protections for the personal health information for all Americans. It set boundaries on the use and release of that information, and required important safeguards. The Privacy Rule also established accountability for inappropriate use and release, and balanced privacy protections with public safety. (See Appendix 4) The Security Rule required

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<sup>14</sup> 21st Century Cures Act, Sec. 3002 (d)(7).

appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. Subsequently, HITECH Act standards were incorporated into HIPAA regulations in the 2013 Final Omnibus Rule, which required breach notifications, extended liability for the HIPAA Security Rule to business associates and included a robust penalty scheme for enforcement.<sup>15,16</sup> HHS's Office for Civil Rights has from time to time issued sub-regulatory guidance to address emerging issues such as removing barriers to patient access to health information.<sup>17</sup> Support for interoperability has led to initiatives to apply HIPAA while moving data for care continuity and for research.

## 2.1 Transaction Standards and Operating Rules

### 2.1.1 Overview

NCVHS works in close consultation with the health care industry, standards organizations, and federal partners including the HHS Centers for Medicare and Medicaid Services and Office of the National Coordinator for Health Information Technology to fulfill the statutory duties described above. The Committee's recent work in this area was given impetus by the findings from a June 2015 NCVHS Review Committee hearing that there is significant variation in the level of implementation of various transaction and operating rules standards, and that inconsistency still exists within the industry in the ways the standards and operating rules are being implemented. In 2017 and 2018, NCVHS focused on developing a Predictability Roadmap in consultation with expert stakeholders, with the goal of improving the processes for updating, adopting, and using transaction and operating rules standards for administrative health care transactions. The major needs in this area relate to increasing predictability, facilitating innovation, promoting convergence between administrative and clinical information, and enabling health care to manage complexity and rapid change without reintroducing problems HIPAA set out to address. The clear request heard from industry is for greater responsiveness, timeliness, and transparency from HHS to further the goal of administrative simplification.

### 2.1.2 Major Themes and Takeaways, 2017-18

NCVHS embarked on a series of information-gathering activities in 2017 with Standards Development Organizations, federal partners, and advisors, leading to a May 2018 forum with chief information officers (CIOs), vendors, and other end-users of standards. The information-gathering culminated in a December 2018 hearing at which participants shared their perspectives on 23 draft NCVHS recommendations pursuant to the information gathered by the NCVHS Subcommittee on Standards. The hearing testimony stressed that current transaction standards and operating rules, and especially the related federal rule promulgation and enforcement processes, fail to support their emerging business needs and technologies in a

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<sup>15</sup> 45 CFR §§ 164.400-414.

<sup>16</sup> HIPAA Omnibus Rule, 45 CFR Parts 160 and 164: <https://www.govinfo.gov/content/pkg/FR-2013-01-25/pdf/2013-01073.pdf>

<sup>17</sup> On December 12, 2018, HHS issued a request for information on reducing the regulatory burdens of the HIPAA Rules: <https://www.hhs.gov/about/news/2018/12/12/hhs-seeks-public-input-improving-care-coordination-and-reducing-regulatory-burdens-hipaa-rules.html>

timely manner, thus stifling innovation and driving up administrative costs. On the basis of the findings from the two-year intensive process, NCVHS finalized initial recommendations for a Predictability Roadmap in early 2019.<sup>18</sup>

**1. Current standards promulgation impedes the full utilization of technology.**

As discussed above, HHS regulatory activities are not keeping pace with evolving business requirements, emerging technology, or innovation opportunities. If current processes remain in place, providers and health plans will continue to use HIPAA-allowed but non-standard workarounds or rely on portals for information exchange. In this event, all entities will miss opportunities to achieve efficiencies and leverage innovation. NCVHS informants point to the need to ensure a level playing field among exchange partners, promote more effective industry stewardship of standards, and remove the barriers to use and adoption of new technology and of transactions that could improve the efficiency of the health care system and the effectiveness of patient care, as envisioned in the original HIPAA legislation.

**2. The timing for the availability of new versions of transaction standards or operating rules for administrative transactions is unpredictable.**

Schedules for updates from some SDOs are inconsistent and unpredictable, making industry participation difficult. Compounding the problem, the HHS rule promulgation process is unpredictable, open-ended, and non-transparent. The result is hindering providers, health plans, and their clearinghouses and software vendors from planning for system and business process changes. Industry representatives have told NCVHS that they need appropriately available and appropriately sized updates of transactions, based on business cases that they provide. Essentially, they are asking for smaller but more frequent updates to standards, without prolonged HHS rulemaking.

**Featured NCVHS Report**

[Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules: Paving the Way to a Predictability Roadmap](#) (September 2018)

**3. Covered entities cannot use new technology or standards voluntarily and at their own pace, due to constraints in existing HIPAA statutes and regulations.**

Current statutory and regulatory language requires that new standards or modifications to implemented standards be adopted through formal rulemaking. Because of the lengthiness of the rule-making process, this poses a barrier to innovation and progress. As described in Part 1 of this Report to Congress, NCVHS has heard industry consensus calls for Congress to

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<sup>18</sup> NCVHS Letter to the HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," February 13, 2019: <https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf>

evaluate the statutory language in the administrative simplification provisions of Title II and identify opportunities to enable innovation. Similarly, HHS needs to evaluate regulatory barriers to the use of updated or new standards and restructure them to achieve timeliness and predictability with appropriate guidance and updating.

**4. HHS enforcement of the standards and code sets provisions of the HIPAA statute and regulations is ineffective in its impact on industry compliance.**

NCVHS agrees with industry representative reports that the enforcement of administrative transaction standards and operating rules is weak and ineffective, particularly when compared to the volume of corrective actions and resolutions that the HHS Office for Civil Rights has executed for privacy and security violations. Covered entities may not file complaints because of the fear of retribution from their trading partners involved in the complaint. Further, stakeholders do not believe that submitting a complaint will have an impact, as HHS currently provides only high-level data on complaints and does not share information about Corrective Action Plans nor about types of complaints or their resolution. Participants in NCVHS roundtables and hearings express the need for HHS to more actively pursue the statutory and regulatory enforcement provisions and to substantially increase the transparency of its actions and share the lessons learned from compliance reviews. A related issue is the need for proactive education, which would decrease the need for enforcement action.

**5. The lack of HHS-sponsored or -supported education and technical guidance on the appropriate use of the adopted transactions and operating rules hinders industry's successful adoption and implementation of standards.**

Providers and other covered entities describe the common use of thousands of work-arounds necessary to adapt the adopted HIPAA transactions to accommodate changing business requirements. As a result, the transaction standards are used inconsistently. This is inefficient, costly, and contrary to the goal of administrative simplification, and will continue to stifle innovation. NCVHS constituents have suggested that HHS convene an industry-wide work group in collaboration with appropriate parties to determine necessary programming and appropriate communication methods and timing.

### Letters and Reports on Transaction Standards and Operating Rules, 2017-18

- [Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules: Paving the Way to a Predictability Roadmap](#) (September 30, 2018)
- [Letter to the HHS Secretary: NCVHS Recommendations on National Council for Prescription Drugs Programs \(NCPDP\) Pharmacy Standards Updates](#) (May 17, 2018)
- [CIO Forum Meeting Summary](#) (May 17, 2018)
- [Letter to the Office of the Coordinator for Health IT: Recommendations on U.S. Core Data for Interoperability \(USCDI\) Proposed Expansion Process](#) (March 15, 2018)
- [Letter to the Secretary: CMS Transition from Social Security Numbers to a Medicare Beneficiary Identifier](#) (September 14, 2017)
- [Summary Report of the Appreciative Inquiry Workshop on the Predictability Roadmap](#) (August 21, 2017)
- [Letter to the Secretary: Recommendations on Rescinding the U.S. Health Plan Identifier \(HPID\)](#) (June 21, 2017)

## 2.2 Health Terminology and Vocabulary Standards

### 2.2.1 Overview

Health terminology and vocabulary standards serve as the language of medicine and health and are foundational to patient care, research, and public health.<sup>19</sup> These standards are a necessary precondition for interoperability. The interoperability goals of the 21<sup>st</sup> Century Cures Act cannot be realized without terminology and vocabulary curation practices that bridge these environments. In 2017, NCVHS undertook a project to advise the HHS Secretary on 1) the changing environment and implications for timing and an approach to terminologies and vocabularies standards adoption; 2) the needs, opportunities, and problems with development, dissemination, maintenance, and adoption of these standards; and 3) actions HHS might take to improve these practices. The National Library of Medicine has been an important partner to NCVHS in this work.

An environmental scan outlined the complexity of the health vocabulary and terminology domain in terms of the number of systems, their purposes and uses, ownership, and ways in which systems are maintained and disseminated. These complexities impact the timely adoption and cost-effective use of uniform standards. They also impact the validity and reliability of data

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<sup>19</sup> "Clinical vocabularies, terminologies or coding systems, are structured lists of terms which together with their definitions are designed to describe unambiguously the care and treatment of patients. Terms cover diseases, diagnoses, findings, operations, treatments, drugs, administrative items etc., and can be used to support recording and reporting a patient's care at varying levels of detail, whether on paper or, increasingly, via an electronic medical record": <http://www.openclinical.org/medicalterminologies.html>



to support the range of uses including interoperability and exchange of health information, clinical innovation, public health, valid vital and health statistics, and biomedical research. A limited number of terminology and vocabulary systems are “named standards” under HIPAA and Promoting Interoperability. As with administrative transaction standards, the scan identified areas in which the regulatory process impedes timely updates reflecting changing medical and scientific knowledge. The scan also documented variability in the ways that terminology and vocabulary standards are developed, curated, disseminated, and adopted. There is currently no stewardship body to advance the science and enable more effective management of the disparate terminologies and vocabularies serving as named standards, nor to consider the most effective ways to handle redundancies and gaps reflecting advances in science, medical knowledge, therapeutics, and health of populations.

Major issues in this area include the opportunity to coordinate scope of content and curation, the need to streamline regulatory adoption, and a pathway to the convergence of clinical and administrative data standards.

### ***2.2.2 Major Themes and Takeaways, 2017-18***

#### **1. The U.S. named standards for terminologies and vocabularies are in place, but coordination across standards is lacking and under-resourced, presenting a barrier to interoperability.**

HHS used principles for selecting terminologies and vocabularies in 2000, as required by HIPAA, and the first set of named standards was adopted in 2003. Since that time, while standards have been updated to require use of the current version of each standard, there has been no systematic planning for advancing their use to take full advantage of new technologies and lessons learned about the design, curation, implementation, and use of health terminologies and vocabularies. This lack of coordination leads to inefficient curation and dissemination practices that add cost to the system with no offsetting benefits. The current fragmented approach creates redundancy and duplication in codes and terms, with no mechanism for identifying areas where overlap is purposeful and of value. Redundant terminologies present a barrier to interoperability. Tools and methods to improve the current process are available, but they need to be coordinated and supported. The environmental scan of terminologies and vocabularies in 2017-18 identified five themes for evaluation and improvement. NCVHS presented these to a July 2018 roundtable of experts, who identified areas of opportunity for the near, mid, and long terms. The Committee plans to submit recommendations on this subject in 2019.

#### **Featured NCVHS Report**

[Health Terminologies and Vocabularies Environmental Scan](#) (September 2018)

**2. HHS regulatory process is applied unevenly for named health terminology and vocabulary standards, causing costly delays and complexity in adopting revised versions of some standards.**

The International Classification of Diseases (ICD), a cornerstone named standard, is updated approximately every decade by the World Health Organization (WHO). While the U.S. makes annual maintenance and updates as needed, entirely new WHO versions (e.g., the replacement of ICD-9 by ICD-10) are handled through a full regulatory rule promulgation process, slowing adoption by years. In the recent move from ICD-9 to ICD-10, adoption in the U.S. took 26 years.<sup>20</sup> In this era of regulatory simplification, the process should be handled through a streamlined adoption process that follows incremental updates used by other standards. NCVHS has recommended a streamlined process to the Secretary of HHS.

Guided by the findings from the health terminologies and vocabularies environmental scan report and expert roundtable, NCVHS is also developing a project to evaluate ICD-11 with respect to topics including the fitness for U.S. adoption of ICD-11 for mortality and morbidity, and the purpose and return on investment of a U.S. clinical modification.

**3. Greater coordination across terminology and vocabulary standards is needed to ensure that redundant terminology and vocabulary concepts are purposeful and useful, and that gaps are addressed.**

Coordination among the developers or custodians of the various terminologies and vocabularies is not currently supported with the level of resourcing required to handle the full scope and complexity of the issues. Research terminologies must be bridged with clinical/administrative domains. In addition, the scope of terminology and vocabulary standards should be expanded to include vitals and public health, population health and social and behavioral determinants, and mental health and substance abuse. In and across all domains, it is important to balance the parsimony of named standards with flexibility and extensibility and also to achieve balance between stability and versioning.

**4. A deliberate pathway toward convergence of clinical and administrative data domains is key to realizing health transformation goals and administrative simplification.**

Digital health creates the opportunity to capture data once and use it many times for a variety of purposes including administration, clinical care, biomedical research, and public health. It also supports direct use of data by the patient. This vision of capturing data once for multiple purposes drove adoption of health information technology. With adoption nearly universal for both practice management/billing software and electronic health records, the industry has reached the point where this vision is feasible. However, this will not happen without a coordinated public-private effort to lay out the pathway and align clinical and administrative data standards. There are many calls today to bridge clinical and administrative domains. NCVHS has identified this need through its administrative standards

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<sup>20</sup> WHO adopted ICD-10 in 1989. The U.S. implemented ICD-10 for mortality reporting in 1999 but did not implement ICD-10 for morbidity (ICD-10-CM) until October 1, 2015. (Source: National Center for Health Statistics).

work, its health terminology and vocabulary standards work, and its work in public and population health. Full support from HHS to advance this goal should be the work of the next decade.

#### NCVHS Letters and Reports on Terminologies and Vocabularies, 2017-2018

- [NCVHS Health Terminologies and Vocabularies Environmental Scan.](#)
- [NCVHS Health Terminologies and Vocabularies Expert Roundtable Meeting Report, July 17-18, 2018.](#)

## 2.3 Privacy, Confidentiality, and Security

### 2.3.1 Overview

Privacy and security are relevant to all the ways in which information about individuals is collected, analyzed, and used in our increasingly digital society. The HIPAA Privacy and Security Rules<sup>21</sup> protect individuals' medical records and other individually identifiable health information (known as "protected health information" or PHI) that is created or received by or on behalf of covered entities and their business associates. While HIPAA Privacy and Security Rules have unquestionably raised the bar, the challenges of protecting privacy and security, even using information that has been anonymized or de-identified, are far greater today than when the Privacy and Security Rules went into effect.

First, digital data cannot easily be confined to the environments addressed by the HIPAA law—the covered entities (health care providers, payers, and clearinghouses) and their business associates. Digital data move from covered entities to non-covered entities; health data is being created by non-covered entities. HIPAA's Privacy and Security Rules apply to limited parts of the health sector; and when data move beyond the health sector, they move beyond the scope of the law, and the legal protections may or may not adequately cover the protection of health data. Some states have enacted laws that build upon or extend the federal protections of HIPAA. More recently, California adopted the first broad consumer data protection law, modeled on the European Union's General Data Protection Regulation.<sup>22,23</sup>

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<sup>21</sup> 45 CFR Parts 160, 162, and 164: <https://www.hhs.gov/sites/default/files/hipaa-simplification-201303.pdf?language=en>

<sup>22</sup> California legislature AB 375, California Consumer Privacy Act of 2018: [https://leginfo.ca.gov/faces/billTextClient.xhtml?bill\\_id=201720180AB375](https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB375)

<sup>23</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation): [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC)

Secondly, certain provisions of the Privacy Rule have yet to be implemented and other provisions may have outlived their useful life. HHS is currently collecting industry feedback through a Request for Information to identify ways to reduce the regulatory burdens of the Rules and opportunities to promote information sharing for treatment and care coordination. These opportunities include promoting parental and caregiver involvement in the opioid crisis and the care of people with serious mental health disease, expansion of accounting for disclosures of health information to include treatment, payment and operations (a provision of the HITECH law yet to be implemented), and improved procedures for handling the required notice of privacy practices.<sup>24</sup> The planned comprehensive review is intended to serve as the basis for a refresh of the Privacy Rule.

Sub-regulatory guidance and other resources have been used to bridge the gap of regulatory updates. For example, during 2017 and 2018, the HHS Office for Civil Rights published guidance for covered entities and business associates on patient access to health information, aimed at removing barriers that may be preventing patients from seeking and obtaining their medical records for continuity of care.<sup>25</sup> In coordination with this policy release, OCR issued a web-based training for health care professionals to help individuals gain access to their health information, available for free continuing medical education credit.<sup>26</sup> OCR also issued guidance for information sharing to address the opioid crisis.<sup>27</sup> On the security front, the HHS Health Care Industry Cybersecurity Task Force issued its *Report on Improving Cybersecurity in the Health Care Industry* (2017), laying out guidelines for covered entities and business associates and steps that HHS can take to expand the scope and potency of security practices in the face of cybercrime.<sup>28</sup>

NCVHS works closely with OCR and other partners to advise the Secretary on protections and needed improvements in this complex area. During the period covered by this report, NCVHS made recommendations on de-identification of PHI under HIPAA.<sup>29</sup> The Committee sought to increase awareness of practices involving PHI and to consider how well the current de-identification standard stands up in light of these practices. To address this important topic, the Committee held a hearing on “De-identification and HIPAA,” at which it heard testimony from public and private sector computer science, legal, data analytic, informatics, and privacy experts. Through the hearing and deliberations, NCVHS also sought to develop practical

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<sup>24</sup> RFI published in the *Federal Register*: <https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf>

<sup>25</sup> HHS patient access guidance: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>

<sup>26</sup> Patient access web training: [http://www.medscape.org/viewarticle/876110?src=acdm-part\\_ocr-hhs\\_876110](http://www.medscape.org/viewarticle/876110?src=acdm-part_ocr-hhs_876110)

<sup>27</sup> HHS Office for Civil Rights: <https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html>

<sup>28</sup> Healthcare Industry Cybersecurity Taskforce, “Report on Improving Cybersecurity in the Health Care Industry,” June 2017: <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>

<sup>29</sup> NCVHS Letter to HHS Secretary, “Recommendations on De-identification of Protected Health Information under HIPAA,” February 23, 2017: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2017-Ltr-Privacy-Deidentification-Feb-23-Final-w-sig.pdf>

recommendations in areas of guidance, research, education, and useful policy change. In its February 2017 letter to the Secretary, the Committee did not recommend that the current standard for de-identification be revised, but it identified a number of actions that HHS could take to improve the way the current standard is applied. These included a set of actions to formalize research into how emerging methods to improve de-identification could be adopted. Finally, the Committee urged greater focus on potential harms of misuse of de-identified data and a process to make these uses more transparent.

The Committee's chief focus in 2017 and 2018 was to examine the health information privacy environment beyond the scope of the HIPAA law. This work is informed by its study of methods and policies for de-identification of health information, described above, and its previous work on enhancing protections for uses of health data and stewardship frameworks.<sup>30, 31, 32</sup> NCVHS' Beyond HIPAA initiative is examining emerging health information privacy and security issues in the largely unregulated worlds of big data and analytics, personal health devices, and the Internet of Things. It also has considered emerging technologies for privacy and security, and changing consumer attitudes regarding health information privacy. The Committee held several hearings throughout 2017 and presented detailed findings from the hearings and broad review of related work by other government and private entities in a report (see theme 1 below). The environmental scan in this area illustrates the dichotomy of the HIPAA-regulated health industry and the largely unregulated worlds of digital health data that have passed beyond the control of regulated entities. Building on the environmental scan, the Committee is now considering recommendations for the Secretary based on study of data stewardship models and regulatory levers that will extend protections for health data in motion. As discussed above, this will require coordinated action by Congress, the Executive branch, and the private sector.

### ***2.3.2 Major Themes and Takeaways, 2017-18***

#### **1. Today, there are two health information worlds. One is regulated by HIPAA; the other is largely unregulated (that is, beyond HIPAA).**

The current legal framework for privacy has not kept pace with the development of technologies and uses for health information, which are exploding outside of these protections. Health data are protected by the HIPAA Privacy or Security Rules when they are created by, or in the custody of, a covered entity. HIPAA sets a federal floor for the privacy of health information. In addition, a patchwork of state and federal laws governs data use in a variety of contexts such as education and substance abuse; however, these laws are neither comprehensive nor consistently enforced. The unregulated world is virtually limitless, and

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<sup>30</sup> NCVHS Report, "Enhanced Protections for Uses of Health Data: A Stewardship Framework for 'Secondary Uses' of Electronically Collected and Transmitted Health Data," December 19, 2007: <https://ncvhs.hhs.gov/wp-content/uploads/2007/12/December-22-2007-Enhanced-Protections-for-Uses-of-Health-Data-A-Stewardship-Framework-for-%E2%80%9CSecondary-Uses%E2%80%9D-of-Electronically-Collected-and-Transmitted-Health-Data.pdf>

<sup>31</sup> NCVHS Report, "Enhancing Protections for Uses of Health Data, A Stewardship Framework: A Summary for Policy Makers," April 2008: <https://ncvhs.hhs.gov/wp-content/uploads/2014/05/080424rpt.pdf>

<sup>32</sup> NCVHS Letter to the HHS Secretary, "A Stewardship Framework for the Use of Community Health Data," December 5, 2012: <https://ncvhs.hhs.gov/wp-content/uploads/2014/05/121205lt.pdf>

includes companies engaged in health data analytics, marketing, health device manufacturing, consumer health applications development, and the range of Internet of Things applications that include health information. The NCVHS *Beyond HIPAA* initiative focuses on health-related data that are often unprotected, whether disclosed or originating outside of the regulated environment, and the Committee is studying and developing recommendations on these issues.

**Featured NCVHS Report**

[Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges.](#)

**2. De-identified health data carry real risk of re-identification, a risk that grows into the future as datasets are combined and data tools become more sophisticated.**

The standard for de-identification is an essential component of the HIPAA Privacy Rule and has generally provided a reasonable level of protection. Once again, however, the challenges of protecting privacy using even de-identified health information are far more complex today than when HIPAA was enacted two decades ago or when the Privacy Rule went into effect in 2003.

There is a general presumption that data stripped of personal identifiers are no longer a privacy risk; but experts who testified before the Committee agree that there is a real likelihood that personal health data can be and are being re-identified and re-disclosed. This work also revealed that information subjects have little idea about the range of uses for their de-identified information or the risk of re-identification. They also have little or no opportunity to assert privacy rights when information moves beyond the bounds of HIPAA. NCVHS describes these complex issues in its *Environmental Scan Report on Health Information Privacy Beyond HIPAA*, released in early 2018, and in its letter to the Secretary about de-identification of protected health information. These concepts are reinforced in the 21<sup>st</sup> Century Cures Act.<sup>33</sup>

As noted above, HHS is currently gathering broad industry input on aspects of the Privacy Rule including the de-identification provisions in order to identify how the Rule can better address current challenges.

**3. Protection of privacy and security requires management, compliance, and enforcement across the lifecycle of the information.**

Compliance with HIPAA Privacy and Security Rules requires sound information management practices spanning the lifecycle of the information, no matter where it resides. Without HIPAA, there may be few incentives for data custodians or HIT developers to go the extra mile to invest in sound practices and governance for privacy and security. Compliance

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<sup>33</sup> Section 2013 of the 21st Century Cures Act, Protection of Identifiable and Sensitive Information, supports the need for research on de-identification.

enforcement is one lever that sound government policy can provide. It is in place for covered entities and business associates, and OCR has notably captured industry's attention with the headline-level fines it has levied for breaches and other failures to carry out the Rules. 2018 was a record year for HIPAA enforcement actions by OCR.<sup>34</sup> While settlements are large and numerous, impacting reputation and finances, cases of willful neglect are more troublesome given the amount of time that organizations have had to get this in place. Today, the stakes are greater because of cyber theft. Criminals understand that healthcare is information-rich and the industry is less mature in its information protection safeguards.

The unregulated, beyond-HIPAA world requires thoughtful federal prohibitions and sanctions—both civil and criminal—for actions by any individual or entity that intentionally accesses identifiable health information without authorization or misuses it in specific ways such as discrimination in employment, insurance underwriting, loans, identity fraud, and other harms, intended or unintended. Policy should require at least foundational stewardship practices for all entities that generate, hold, and process identifiable and de-identified health data.

#### **4. Data protections grounded in Fair Information Practice Principles remain the essential building blocks for data policy.**

HIPAA has its foundations in a Code of Fair Information Practice originated with a predecessor Advisory Committee to the Secretary of Health, Education, and Welfare in 1973.<sup>35</sup> These are sometimes reformulated and referred to as Fair Information Practice Principles (FIPPs), a set of internationally recognized practices for addressing the protection of data about individuals. FIPPs are also the underlying policy for many national laws addressing privacy and data protection matters.<sup>36</sup> The European Union's General Data Protection Regulation (GDPR), enacted in 2016, focuses on the rights of data subjects and imposes greater jurisdiction and enforcement of these rights by all data holders. Data protection laws are being passed or are under consideration in several U.S. states and are being deliberated in the U.S. Congress. Data subjects are demanding more complete protection and the ability to exercise the types of rights laid out in the FIPPs.

Addressing the issues laid out by NCVHS in its Beyond HIPAA work challenges policy makers and data stewards to look again to FIPPs to find the right balance between appropriate rights and protections for individuals and the potential for important health breakthroughs

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<sup>34</sup> Three examples: (1) OCR's collections, settlement, and judgments totaled more than \$25.6 million (record). It resolved 28,006 civil rights and HIPAA complaints (record) and conducted 372 breach reviews, 98 civil rights and HIPAA compliance reviews, and 320 outreach events for consumers and covered entities. (2) In 2018, OCR completed audits of 166 covered entities and 41 business associates and sent individual reports to each audited entity pursuant to Phase 2 of its audit program under the HITECH Act. (3) In October 2018, OCR settled the largest U.S. health data breach in history with the largest settlement in OCR history when Anthem, Inc. paid OCR \$16 million.

<sup>35</sup> U.S. Department of Health, Education & Welfare, "Records, Computers, and the Rights of Citizens, Report of the Advisory Committee on Automated Personal Data Systems," July 1973:

<https://www.justice.gov/opcl/docs/rec-com-rights.pdf>

<sup>36</sup> The Privacy Act of 1975, 5 U.S.C. § 552a, was the first law to incorporate all of the principles.

from responsible and ethical use of health data.

#### **NCVHS Letters and Reports on Privacy, Confidentiality and Security, 2017-18**

- [Health Information Privacy Beyond HIPAA: A 2018 Environmental Scan of Major Trends and Challenges.](#)
- [Letter to the Secretary: Recommendations on De-identification of Protected Health Information under HIPAA](#) (2017).

## **PART 3. DATA ESSENTIAL FOR MANAGEMENT OF POPULATION AND COMMUNITY HEALTH**

### **3.1 Overview**

The ongoing evolution from a fee-for-service approach to value-based reimbursement in recent years has shifted the frame of reference for health care to include community health and population health management.<sup>37</sup> In 2017, NCVHS completed a study of the data needed to manage community and population health that began in 2011 and culminated in development of a measurement framework described below. As is the case with administrative and clinical data, improvements in administrative simplification and interoperability improve population health data, ultimately increasing the quality, accessibility, and usefulness of these data. While HIPAA focuses on discrete transactions and privacy and security for individuals, the aggregate of these health care transactions contributes data to the management of the health of the U.S. population.

Vital statistics data, primarily birth and death, are a critical component of population health data. In this reporting period, NCVHS conducted a major project on the vulnerabilities of the nation's Vital Registration and Statistics System—the loosely federated system of state, county, and federal agencies that collect and steward birth, death, and other vital statistics data. This system is fragile even though the information it produces is foundational for health care, population health surveillance, and identity establishment. The Committee's work in this area included a

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<sup>37</sup> The ACA section on "Additional Requirements for Charitable Hospitals" requires tax-exempt hospitals to conduct community health needs assessments and implementation strategies. The Internal Revenue Service published final rules implementing this section on December 31, 2014.



hearing<sup>38</sup> and an analysis of users and uses of these data,<sup>39</sup> culminating in a 2018 letter with recommendations to the HHS Secretary.<sup>40</sup>

Also in 2018, the Committee undertook a new project focusing on access to data in response to concerns among researchers, public health leaders, community health assessment experts, and other data stakeholders about declining public access to aggregate small-area (local) data.

### **3.1.1 Major Themes and Takeaways, 2017-18**

#### **1. The NCVHS Measurement Framework for Community Health and Well-being offers a practical approach to organizing the data essential to understand the health of populations at national, state, and community levels.**

In recognition of the need for more comprehensive, higher quality data with which to understand and improve community health, NCVHS conducted a project focused on measuring the health and well-being of communities to improve access to and integration of data for this purpose. Through a series of meetings over a number of years, NCVHS developed the *NCVHS Measurement Framework for Community Health and Well-being*. This tool is designed to be flexible and comprehensive, covering multiple factors known to influence health such as education, public safety, housing, and access to health services. Some of these data are aggregated from individual health data that are HIPAA-protected. The Framework enables communities to identify and use locally relevant measures while also generating a parsimonious set of core measures to guide federal, state, and local policy development including resource allocation. With this Framework, the Committee developed a systematic approach to integrating data on the social and behavioral determinants of health—information whose importance is increasingly recognized by health care providers—together with other data essential for health assessment and improvement. In 2017, NCVHS recommended that the Secretary provide leadership to implement the use of this Framework within HHS, across federal departments, and among non-federal community data efforts. A nationally recognized organization, the Institute for Healthcare Improvement (IHI) 100 Million Healthier Lives program, assumed leadership of the tool and continues to advance its

#### **Featured NCVHS Report**

[NCVHS Measurement Framework for Community Health and Well-being](#)

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<sup>38</sup> NCVHS, “Next Generation Vital Statistics: A Hearing on Current Status, Issues, and Future Possibilities,” May 21, 2018: <https://ncvhs.hhs.gov/wp-content/uploads/2018/05/Summary-Report-Next-Generation-Vitals-Sept-2017-Hearing-Final.pdf>

<sup>39</sup> NCVHS, “Vital Records and Vital Statistics in the United States: Uses, Users, Systems, and Sources of Revenue,” January 10, 2018: [https://ncvhs.hhs.gov/wp-content/uploads/2018/01/NCVHS\\_Vital\\_Records\\_Uses\\_Costs\\_Feb\\_23\\_2018-1.pdf](https://ncvhs.hhs.gov/wp-content/uploads/2018/01/NCVHS_Vital_Records_Uses_Costs_Feb_23_2018-1.pdf)

<sup>40</sup> NCVHS Letter to the HHS Secretary, “U.S. Vital Registration and Vital Statistics System—Critical Challenges and Opportunities,” May 21, 2018: <https://ncvhs.hhs.gov/wp-content/uploads/2018/05/Letter-to-the-Secretary-US-Vital-Registration-and-Vital-Statistics-System-Recommendations.pdf>

development and use. As a result of the Committee's work, the *NCVHS Measurement Framework for Community Health and Well-being* continues to evolve as a dynamic national resource. *U.S. News and World Report* has adapted the Framework for its Healthiest Communities ranking project.<sup>41</sup> IHI's 100 Million Healthier Lives program is now stewarding a process to identify specific measures for the Framework, including measures that track population health and well-being, and developing a public platform to make the data available to all communities nationwide. The Framework project is an excellent example of the way in which coordination and collaborative action between government and the private sector can achieve scale.

## **2. Access to small area data is critical for managing health care costs and supporting community-focused population health management.**

The measurement of health at the community or neighborhood level using standardized, aggregate data is necessary for identifying and prioritizing health needs within communities, and it potentially may be used for adjusting payment for health care using social risk factors.<sup>42,43, 44</sup> However, some established federal sources of essential small area data have recently been eliminated or narrowed in scope. NCVHS sponsored a panel discussion among data users and stakeholders to identify the needs for these data and federal efforts to create such data. Those panels substantiated the importance of the Federal Data Strategy (FDS) for increasing access to federal data assets by researchers; they also confirmed, however, that the FDS has inadvertently reduced communities' access to previously public, small-area health data. The loss of three data sources from the Health Resources and Services Administration (HRSA) and CDC also contributed to the recent reduction in access. NCVHS is developing plans for future work on this issue.

## **3. A sustainable system for vital registration and statistics data is essential to tracking the health of the nation. These data also are critical to establishment of individual identity and the protection of national security, as well as being fundamental building blocks for health surveillance data, such as for tracking opioid and influenza epidemics. Despite its importance, this federated system is fragile.**

After obtaining extensive input through a public hearing and issuing a follow-up report,<sup>45</sup> NCVHS confirmed that the federated vital records system is the foundation for essential

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<sup>41</sup> U.S. News & World Report, "Healthiest Communities: How They Were Ranked," March 26, 2018: <https://www.usnews.com/news/healthiest-communities/articles/methodology>

<sup>42</sup> National Academy of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment: Data*. Washington, DC: The National Academies Press; 2016.

<sup>43</sup> Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, Section 2(d)(1)(A).

<sup>44</sup> Office of the Assistant Secretary for Planning and Evaluation. *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*. Washington, DC: U.S. Department of Health and Human Services; 2016: <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>

<sup>45</sup> NCVHS, "Vital Records and Vital Statistics in the United States: Uses, Users, Systems, and Sources of Revenue," January 10, 2018: [https://ncvhs.hhs.gov/wp-content/uploads/2018/01/NCVHS\\_Vital\\_Records\\_Uses\\_Costs\\_Feb\\_23\\_2018-1.pdf](https://ncvhs.hhs.gov/wp-content/uploads/2018/01/NCVHS_Vital_Records_Uses_Costs_Feb_23_2018-1.pdf)

functions at local, state, territorial, and federal levels and in the private sector, as well as essential to achieving interoperability in health data. NCVHS also determined that this system requires attention to maintain and improve its quality, timeliness, reliability, and utility so that continuance of its essential mission is assured. NCVHS has identified the need for federal leadership to modernize and secure the vital records and vital statistics data collection network as the critical, foundational identity and health resource in the United States.

### 3.2 New Strategies for New Opportunities

With the relationship between individual and community/population health now well-established in public policy and health care, a number of actions are needed to safeguard the continued availability of population and community health data. As in the realms of standards and privacy/security, the actions NCVHS suggests here could be taken independently by the legislative and executive branches and/or private sector and community-level partners; however, they will have the greatest impact when all these stakeholders act in concert.

**Table 3.** Actions to Safeguard and Improve Data on Population and Community Health

Actor	Actions to Safeguard and Improve Data on Population and Community Health
Congress	<ul style="list-style-type: none"> <li>• Enact legislation that would form a federal, interagency office whose mission is to make community health data publicly available, including support for data linkage and integration.</li> <li>• Enact legislation and provide funding to ensure the sustainability of the federated Vital Registration and Statistics system.</li> <li>• Revise legislation to expand the collection of commercial self-funded claims data and generate standardized claims data in all states to support policy/population health applications.<sup>46,47</sup></li> </ul>
Executive Branch	<ul style="list-style-type: none"> <li>• Create guidelines/policies for both intra-departmental and inter-departmental data use, collection, access, and sharing that returns public access to federal data assets routinely used by state and local entities to assess and improve health.</li> <li>• Address the weaknesses of the federated Vital Registration and Statistics system to ensure long-term sustainability.</li> <li>• Fill critical information gaps to support policy/population health applications.</li> <li>• Integrate the collection of Medicaid data with other population-based data.</li> </ul>

<sup>46</sup> National Academy for State Health Policy, "Comments on Department of Labor Notice of Proposed Rulemaking," September 20, 2016: <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB63/00030.pdf>

<sup>47</sup> APCD Council, Common Data Layout: <https://www.apcdouncil.org/common-data-layout>

<b>Actor</b>	<b>Actions to Safeguard and Improve Data on Population and Community Health</b>
Community-level stakeholders and private sector partners	<ul style="list-style-type: none"> <li>• Build upon the <i>NCVHS Measurement Framework for Community Health and Well Being</i> and offer input on barriers to accessing related data.</li> <li>• Generate and expand access to health and well-being data for small geographic areas and small population subgroups.</li> <li>• Form health and community use-case collaborations to inform:                             <ul style="list-style-type: none"> <li>○ The Federal Data Strategy on data needs; and</li> <li>○ Value-based purchasing and price transparency initiatives.</li> </ul> </li> </ul>

<b>NCVHS Letters and Reports on Population and Community Health, 2017-2018</b>
<ul style="list-style-type: none"> <li>• <a href="#"><u>Letter to the Secretary – Recommendations on Measuring Health at the Community Level – Opportunities for HHS Leadership</u></a> (May 22, 2017)</li> <li>• <a href="#"><u>Summary Report: Next Generation Vital Statistics: A Hearing on Current Status, Issues and Future Possibilities</u></a> (May 21, 2018)</li> <li>• <a href="#"><u>Report – Vital Records and Vital Statistics in the United States: Uses, Users, Systems, and Sources of Revenue</u></a> (January 10, 2018)</li> <li>• <a href="#"><u>Letter to the Secretary – U.S. Vital Registration and Vital Statistics System Recommendations</u></a> (May 21, 2018)</li> <li>• <a href="#"><u>Workshop Summary and Project Overview – Measuring Health at the Community Level: Data Gaps and Opportunities</u></a> (March 1, 2017)</li> <li>• <a href="#"><u>NCVHS Measurement Framework for Community Health and Well-being</u></a></li> </ul>

## PART 4. CONCLUSION AND NEXT STEPS

Based on lessons learned and input from industry during the two-year period the Report to Congress covers, NCVHS made the decision to issue a *Call for Action* that would reset the trajectory established by HIPAA and subsequent legislation. In this Report to Congress, we have outlined the types of actions we believe will set the country on a course to better achieve interoperability and reduce the burden of adopting and implementing standards and privacy protections.

Importantly, the Committee's suggestions for resetting the trajectory are predicated on distinct roles for each stakeholder that we believe will maximize opportunities for efficiency and coordination: specifically, **Congress** would be responsible for laying out policy and resources, and establishing accountability; **HHS and other executive agencies** would be responsible for defining and enforcing regulations and managing budgets and programs; and **the private sector**, including the health care industry and standards development organizations, would be charged to innovate, develop technical specifications for existing standards, and test possible new standards and operating rules for usability and fitness in accordance with business needs. NCVHS' *Call for Action* seeks to advance the conversation to concentrate on opportunities to work together to effect this much-needed transformation.

For our part, as we carry out our role as a Federal Advisory Committee on national health information and data policy, NCVHS will further explore aspects of this transformation that are within the purview of our Charter. This section outlines three such opportunities. The Committee looks forward to additional guidance from HHS about areas in which NCVHS advice and consultation will be needed in the coming years.

### 4.1 Predictability Roadmap

Part 2 of this report describes NCVHS' work over the past two years to draft a "Predictability Roadmap" to support industry's need for a clear and explicit pathway for standards that keep pace with changing business needs and opportunities to innovate. We evaluated barriers to the efficient and timely update and adoption of transaction standards and operating rules by engaging with health care providers, health plans (private, state and federal), clearinghouses, Standards Development Organizations, practice management and electronic health record systems vendors, pharmacies, health information exchanges, and our federal partners, such as the Office of the National Coordinator for Health Information Technology.

NCVHS submitted initial recommendations to the Secretary of HHS in early 2019<sup>48</sup> on new approaches to improve the adoption of national standards for the health care industry based on this work. These recommendations address policy and procedural actions that the Secretary can take to jumpstart predictability and accelerate the pace of the standards adoption process. This

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<sup>48</sup> NCVHS Letter to the HHS Secretary, "NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry," February 13, 2019:

<https://ncvhs.hhs.gov/wp-content/uploads/2019/02/Recommendation-Letter-Predictability-Roadmap.pdf>

jumpstart will improve interoperability and reduce both health care provider burden and regulatory burden.

The Committee believes that the Designated Standards Maintenance Organizations (DSMOs) have accomplished their original mission. Changes in the health care standards environment and the need for harmonization of administrative and clinical standards require an updated mission for the DSMOs and a new stewardship role which will necessitate participation by additional organizations and wider collaboration. Further evaluation is needed to determine the best approach. NCVHS plans to develop a new scope of work for a project focused on supporting HHS in this evaluation.

The Predictability Roadmap will set the stage for convergence and harmonization of administrative, i.e., HIPAA and the Affordable Care Act of 2010 (ACA), and clinical, i.e., HITECH standards. NCVHS and HITAC, established by the 21<sup>st</sup> Century Cures Act, began conversations in 2018 to align the work of the two federal advisory committees. NCVHS posed an essential question on the road to harmonization to the members of HITAC. Is it in the best interests of patients, the U.S. health care business community and health statistics and research to maintain an HL7 CDA/FHIR/XML system for clinical interoperability and an X12/NCPDP EDI system for administration and payment? This question resonates with most stakeholders, but the path forward is unclear, and the journey will be difficult. NCVHS plans to continue to collaborate with HITAC, HHS, Standards Development Organizations, and others in the private sector to further this exploration.

## 4.2 Health Terminology and Vocabulary Standards/Systems

Health terminology and vocabulary standards/systems are the backbone of interoperable health information, health statistics, and research. They define data elements and ensure consistency of meaning as data are exchanged and used for a broad range of essential purposes. They are the content foundation for administrative transactions and for use by electronic health record and other health information systems. As described in Part 2, NCVHS conducted an environmental scan and convened an expert roundtable to assess the changing environment and implications for timing and approach to terminologies and vocabularies standards adoption, curation and dissemination.

NCVHS submitted recommendations to the Secretary of HHS in early 2019<sup>49</sup> on selection criteria for adoption of health terminology and vocabulary standards and guidelines for curation and dissemination of these standards based on this work. The recommended criteria and guidelines will be useful to HHS when considering the adoption of standards and will inform the health industry of the characteristics for contemporary standards and their maintenance.

These recommendations include an approach to simplifying the adoption of future versions of the International Classification of Diseases and related health terminology and vocabulary

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<sup>49</sup> NCVHS Letter to the HHS Secretary, "Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards," February 13, 2019: <https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf>

standards. There has been one update to ICD since HIPAA Code Set standards were put in place. This was the 2015 transition from ICD-9 to ICD-10. The timeline and experience of this update illustrates why the process must be simplified. In May 2019, the World Health Organization will adopt ICD-11 for worldwide use. This in turn starts the clock ticking on a series of critical decisions for the U.S. such as when ICD-11 should replace ICD-10 for cause of death coding, whether ICD-11 includes sufficient detail to meet the U.S. needs for morbidity classification without a clinical modification, the cost-benefit of a version update, and an assessment of optimal timing considering other standards updates. NCVHS is developing a new scope of work for a project to assist HHS in this evaluation of ICD-11.

### **4.3 A Health Privacy and Security Framework for the 21<sup>st</sup> Century**

The HIPAA privacy and security rules protect individuals' identifiable health information that is created or received by or on behalf of covered entities and their business associates. As described in Part 2, NCVHS convened a hearing, held several panels and conducted an environmental scan to examine emerging health information privacy and security issues in the largely unregulated worlds of big data and analytics, personal health devices, and the Internet of Things.

Based on this work, NCVHS will convene a working session in early 2019 to bring together leading experts to outline principles for stewardship of health data in today's environment; to identify essential public and private levers to ensure appropriate governance; to develop recommendations for a contemporary framework of data stewardship including a pathway for improving private and public sector governance of health information over the next decade; and finally to identify key themes for communications with individuals, policymakers, and stakeholders in the private sector.

## APPENDIX 1. 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 stipulate:<sup>50</sup>

“Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

- 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.
- 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.”

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<sup>50</sup> Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Health Insurance Portability and Accountability Act of 1996:

<https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996>



## APPENDIX 2. ABOUT ADMINISTRATIVE SIMPLIFICATION

This appendix begins with an overview in [Table 4](#) of the regulations and related laws published under the HIPAA legislation since its release. It is followed by information on financial and administrative transactions and code sets, unique health identifiers and operating rules.

**Table 4:** History of HIPAA and ACA Regulations, as of December 31, 2016

Year	Date	Law or Reg	Topic of Law/Reg	Description
1996	Aug 21	Law	HIPAA, Health Insurance Portability and Accountability Act	The law requires Health and Human Services (HHS) to adopt national standards and code sets for electronic transactions. The provisions become known as Administrative Simplification HIPAA added a new Part C – Administrative Simplification to the Social Security Act of 1935
2000	Aug 17	Reg	Standards and Code Sets for Electronic Transactions and DSMO Process	HHS adopts code sets (ICD-9, CPT-4, National Drug Codes, Code on Dental Procedures and Nomenclature, and HCPCS) and standards for electronic transactions: ASC X12 Version 4010 and NCPDP Version 5.1. HHS publishes a regulation outlining the process for standards development organizations to collaborate on the review of proposed. Modifications to standards and code sets, including the execution of a Memorandum of Understanding on which HHS is a signatory. The mandatory collaboration is called the Designated Standards Maintenance Organization (DSMO). Adoption of the standards and code sets is required by Oct 16, 2002 for all HIPAA-covered entities, except small health plans, which were required to comply on Oct 16, 2003.
2001	Jan 3	Law	ASCA, Administrative Simplification Compliance Act	Congress requires electronic submission of Medicare claims.
2002	May 31	Reg	Employer Identification Number (EIN)	HHS adopts standard for Employer Identifier Standard (EIN) which becomes mandatory for use on July 30, 2002.
2003	Feb 20	Reg	Transaction Standards and Code Sets	HHS modified specifications for 1) transaction standards, and 2) how HIPAA-covered entities use standards, effective Mar 24, 2003.

<b>Year</b>	<b>Date</b>	<b>Law or Reg</b>	<b>Topic of Law/Reg</b>	<b>Description</b>
2003	Aug 15	Reg	Electronic Submission of Medicare Claims	HHS published regulation implementing ASCA, requiring electronic submission of Medicare claims, effective Oct 16, 2003.
2004	Jan 23	Reg	National Provider Identifier (NPI)	HHS published regulation adopting the National Provider Identifier (NPI) under HIPAA, effective May 23, 2007, except for small health plans, which had until May 23, 2008, to comply.
2005	Sept 05	Reg	Electronic Health Care Claims Attachments	Proposed Rule to adopt standards for sending and receiving solicited and unsolicited health care attachments. Rule proposed use of Version 4050 X12 and HL7 standards. Rule was withdrawn and final rule has not been published. Updated versions of X12 and HL7 standards are under development.
2006	Feb 16	Reg	Enforcement of Administrative Simplification	HHS extended civil monetary penalties for privacy violations to apply to all Administrative Simplification violations, effective Mar 16, 2006.
2009	Jan 16	Reg	Version 5010/D.0 Final Rule	HHS adopted updated versions of the standards: ASC X12 Version 5010, NCPCP D.0 and NCPDP 3.0 and required adoption by Jan 1, 2012.
2009	Jan 16	Reg	ICD-10 Final Rule	HHS required HIPAA-covered entities to transition from ICD-9 to ICD-10 codes for medical diagnosis and inpatient hospital procedures on Oct 1, 2013. After two delays, ICD-10 became effective Oct 1, 2015.
2009	Feb 17	Law	HITECH Act and Civil Penalties	Part of the American Reinvestment and Recovery Act, HITECH adjusted civil monetary penalties for HIPAA violations, including Administrative Simplification
2009	Oct 30	Reg	Enforcement and Civil Penalties	HHS released interim final rule on civil monetary penalties effective Nov 30, 2009.
2010	Mar 23	Law	ACA, Patient Protection and Affordable Care Act ACA Administrative Simplification Provisions	Congress expanded on HIPAA to require operating rules for transactions, standards for electronic funds transfer (EFT) and claims attachments, adoption of the unique health plan identifier (HPID) as required in the 1996 law, health plan certification of compliance, and HHS outreach to advisory bodies for input on potential improvements to Administrative Simplification. ACA also required the ICD-9-CM Coordination and Maintenance Committee to solicit input on and revise ICD-9 to ICD-10 crosswalk posted on CMS website.

Year	Date	Law or Reg	Topic of Law/Reg	Description
2011	Jul 8	Reg	Operating Rules for Eligibility for a Health Plan and Claim Status	HHS adopted operating rules for eligibility and claim status transactions effective Jan 1, 2013.
2011	Dec 7	Reg	ICD-10 Medical Loss Ratio Update	HHS updated medical loss ratio requirements under ACA to help payers cover costs of ICD-10 transition.
2012	Jan 10	Reg	Standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA)	HHS published interim final rule for EFT standard, then announced, on Jul 10, 2012, that the Jan 10 standards rule is final.
2012	Aug 10	Reg	Operating Rules for EFT and ERA	HHS adopted operating rules for EFT/ERA, effective Jan 1, 2014

## Financial and Administrative Transactions and Code Sets

Financial and administrative transactions and code sets were the second set of HIPAA Administrative Simplification provisions to be implemented after the HIPAA Privacy rules. As of December 2016, most of the original requirements related to Electronic Data Interchange (EDI) standards -or transactions and code sets -have been implemented. Under the 2010 Affordable Care Act, Congress required the adoption of new standards and operating rules, increased enforcement authority, and reiterated the requirement to adopt a standard for health care attachments and an identifier for health plans.

As noted, [Table 4](#) (above) provides an overview of the regulations and related laws that have been published under the HIPAA legislation since its release.

Although covered entities have implemented the adopted standards to varying degrees, depending on the usefulness, business value and efficiency value of the transaction, there has not been a marked decrease in the use of companion guides as predicted. In spite of adopting standards to simplify the process of conducting certain business processes, there are still individual health plan business rules. NCVHS believed that the transition to the next version of the standards and implementation specifications would significantly eliminate the optionality of the current version of the standard, and reduce or in most cases eliminate the need for companion guides. With the transition to Version 5010 and NCPDP Version D.0 in 2012, this did not occur. In addition, the Affordable Care Act sought to further address the gaps and optionality issues associated with the implementation of electronic transactions by calling for the adoption of operating rules for each transaction. In the past four years, these rules have also not decreased the use of companion guides by health plans.

## Unique Health Identifiers

HIPAA called for four unique health identifiers: Employer, Provider, Patient and Health Plan. Two of the four have been adopted and implemented. HHS is prohibited by law from expending funds on the development of a patient identifier. HHS had not adopted the Health Plan Identifier by the time the Affordable Care Act passed in 2010, and it was included as a mandate for HHS, to be adopted by October 1, 2012. NCVHS held hearings on this subject, and the WorkGroup for Electronic Data Interchange (WEDI) held a Policy Advisory Group (PAG). Both organizations submitted recommendations to HHS. When HHS released its proposed and final rules to industry in 2012, it required all health plans, including self-funded plans, to obtain an identifier, and to determine if they would enumerate as either a controlling or sub-health plan or both, and suggesting that clearinghouses and vendors be permitted to obtain identifiers called "other entity identifiers." The regulation also required health plans to use the identifier in transactions. Industry found the requirements confusing, the inclusion of self-funded plans onerous, and reported that identifiers were already effectively being used for routing transactions and identifying health plans. NCVHS held additional hearings in 2014, and based on industry input, provided additional recommendations to HHS. As a result of NCVHS recommendations and concern from industry, the Secretary imposed enforcement discretion for the HPID rule, which remains in effect.

A proposed rule to rescind the HPID was published on December 18, 2018. NCVHS recommendations to the HHS Secretary provided substantive support for the HHS action.<sup>51</sup> A final rule is anticipated in 2019.

## Operating Rules

The Affordable Care Act required HHS to adopt operating rules for each of the transactions to create greater consistency in their usage. Operating rules include business rules such as response time, security, use of the internet, system availability and certain content and format elements companion guides. NCVHS has recommended the adoption of three "phases" of operating rules which have infrastructure rules to support transactions for eligibility, claim status, electronic funds transfer and remittance advice. The Secretary has adopted these three operating rules. Operating rules for the other transactions have been drafted and presented to NCVHS but not yet recommended to the Secretary for adoption due to testimony from industry indicating that these operating rules do not meet industry business needs.

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<sup>51</sup> NCVHS Letter to the HHS Secretary, "Findings and Recommendations from the May 3, 2017 NCVHS Standards Subcommittee Hearing on the Health Plan Identifier," June 21, 2017: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2017-Ltr-HPID-June-21-wws-w-sig.pdf>

## APPENDIX 3. 21<sup>ST</sup> CENTURY CURES ACT AND THE REPORT TO CONGRESS: PART 1 ACTIONS

Section	Description	Relation to 13 <sup>th</sup> Report to Congress
Sec. 2013. Protection of Identifiable and Sensitive Information	<ul style="list-style-type: none"> <li>• Allows the Secretary of HHS to exempt individual biomedical research data from being disclosed if the data is identifiable or could be used for identification.</li> <li>• Requires the Secretary of HHS to submit written basis for each disclosure exemption, made available to the public upon request to the Chief Freedom of Information Act Officer at HHS.</li> </ul>	Supports need for de-id/re-id research
Sec. 2014. Data Sharing	<ul style="list-style-type: none"> <li>• Allows the Director of the NIH to require grant recipients to share the data that is generated from the NIH-funded research.</li> <li>• Requires the data to be shared in a manner that is consistent with Federal laws and regulations, including laws and regulations for protection of human research participants, proprietary data, and national security interest.</li> </ul>	Clarifies that HIPAA does not prohibit this data sharing
Sec. 2012. Privacy Protection for Human Subjects	<ul style="list-style-type: none"> <li>• Directs the Secretary of HHS to issue certificates of confidentiality to researchers that receive federal funding. Allows the Secretary of HHS to also issue certificates to privately funded researchers.</li> <li>• Prohibits researchers to whom certificates are issued from disclosing the name of participants or any other identifiable data gathered during research, except when:                             <ul style="list-style-type: none"> <li>○ Required by federal, state, or local law;</li> <li>○ Necessary to treat the individual in question;</li> <li>○ The individual gives consent; or</li> <li>○ Disclosure of information is for the purposes of other research in compliance with privacy laws.</li> </ul> </li> <li>• Prohibits researchers who are issued certificates from being compelled to disclose identifiable, sensitive information about participants that was gathered during research.</li> <li>• Grants immunity from the legal process to all identifiable, sensitive information gathered during research. Such information can only be used in legal proceedings with the consent of the research participant.</li> </ul>	Adds protection for data that may not be covered by HIPAA, complements section 2014

<b>Section</b>	<b>Description</b>	<b>Relation to 13<sup>th</sup> Report to Congress</b>
	<ul style="list-style-type: none"> <li>• The protections of this section are afforded in perpetuity.</li> <li>• Directs the Secretary of HHS to minimize the burden of compliance for researchers. The requirements of this section apply</li> </ul>	
<p>Sec. 2063. Accessing, Sharing, and Using Health Data for Research Purposes</p>	<ul style="list-style-type: none"> <li>• Requires the Secretary of HHS to issue guidance clarifying that certain researchers may remotely access protected health information if specific security and privacy safeguards are maintained.</li> <li>• Requires the Secretary of HHS to issue guidance clarifying circumstances under which an authorization to use and disclose protected health information for future research purposes contains sufficient information.</li> <li>• Establishes a working group to study and report on whether the uses and disclosures of protected health information for research purposes should be modified</li> </ul>	<p>Seeks clarifying guidance</p>
<p>Sec. 4001. Assisting Doctors and Hospitals in Improving Quality of Care for Patients</p>	<p>This provision amends the HITECH Act by adding language to the end of part 1 of subtitle A to direct the Secretary to establish a goal, strategy, and provide recommendations for reducing regulatory and administrative burden relating to the use of EHRs within 1 year of enactment. It also eases EHR documentation requirements by allowing physicians, as consistent with state law, to delegate electronic medical record documentation to non-physicians. The strategy must prioritize current initiatives such as Meaningful Use, MIPS, APMs, other value- based payment systems, and activities related to using and protecting electronic information.</p>	<p>We could re-frame the exec branch cost-benefit requirement along these lines</p>
<p>Sec. 4002. Transparent Reporting on electronic health record transparency, usability, security, and functionality - electronic health record significant hardship.</p>	<p>Section 1848(a)(7)(B) of the Social Security Act is amended to provide an EHR hardship exemption for eligible professionals from the application of payment adjustment, subject to annual renewal, due to decertification. Section 1848(o)(2)(D) of the Social Security Act is amended to apply the hardship exemption to MIPS eligible professionals. Section 1886(b)(3)(B)(ix)(II) of the Social Security Act is amended to apply the hardship exemption to eligible hospitals.</p>	<p>Example of reducing burden</p>

<b>Section</b>	<b>Description</b>	<b>Relation to 13<sup>th</sup> Report to Congress</b>
<p>Sec. 4003. Transparent Reporting on EHR Transparency, Usability, Security, and Functionality – Interoperability</p>	<p>This is a new provision. Within 3 years, the Secretary must establish a provider digital contact information index for health professionals and health facilities.</p>	<p>Example of assigning responsibility, but not budget for developing and maintaining a standard resource</p>
<p>Sec. 4005. Leveraging EHRs to Improve Patient Care</p>	<p>To be certified in accordance with title XXX of the PHS Act:</p> <ul style="list-style-type: none"> <li>• Requires, as part of certification, that EHRs are capable of transmitting to, and where applicable, receiving and accepting data from, registries, including clinician-led clinical data registries.</li> <li>• Registries will also be certified to be technically capable of receiving and accepting, and where applicable, transmitting data to, certified EHRs. A health IT developer will be treated as a provider for purposes of reporting and conducting patient safety activities related to improving clinical care through the use of health IT that result in improved patient safety or health care outcomes.</li> <li>• Within 4 years, the Secretary must submit a report to Congress on best practices and current trends by patient safety organization to improve the integration of health into clinical practice</li> </ul>	<p>Intersects beyond HIPAA registry example</p>
<p>Sec. 4006. Empowering Patients and Improving Patient Access to Electronic Health Information</p>	<p>Amends Section 3009 of the PHS Act by adding: Promoting Patient Access to Electronic Health Information through Health Information Exchanges:</p> <ul style="list-style-type: none"> <li>• The Secretary must encourage partnerships to help patients access their electronic health information in a single, longitudinal format.</li> <li>• The Secretary must undertake a variety of educational efforts targeted at providers on leveraging capabilities of health information exchanges and clarifying misunderstandings about using health information exchanges for patient access.</li> </ul> <p>Promoting Access to Health Information:</p>	<p>Establishes policy objective of reducing barriers to patient access</p>

<b>Section</b>	<b>Description</b>	<b>Relation to 13<sup>th</sup> Report to Congress</b>
	<ul style="list-style-type: none"> <li>• ONC must promote patient access to health information in a manner that would ensure the information is available in a form convenient for the patient.</li> </ul> <p>Accessibility of Patient Records:</p> <ul style="list-style-type: none"> <li>• The Secretary must promote policies that ensure accessibility by the patient and/or the patient’s designee.</li> <li>• OCR must assist individuals and providers in understanding a patient’s rights to access and protect personal health information under HIPAA.</li> <li>• ONC may require that certification criteria support patient access, patient’s ability to communicate patient-reported information electronically, and patient access to their personal electronic health information for research.</li> </ul>	
<p>Sec. 11002. Confidentiality of Records</p>	<p>Requires the Secretary to, within a year of finalizing updated rules related to the confidentiality of health records related to alcohol and drug abuse, convene relevant stakeholders to determine the effect of the regulation on patient care, health outcomes, and patient privacy.</p>	<p>Relates to pop health ERISA &amp; 42 CFR legislative lever</p>
<p>Sec. 11003. Clarification on Permitted Uses and Disclosures of Protected Health Information</p>	<p>Directs the Secretary through the Director of the Office for Civil rights to clarify circumstances when a health care provider or covered entity may use or disclosure protected health information related to the treatment of an adult with a mental or substance use disorder.</p>	<p>Relates to pop health ERISA &amp; 42 CFR legislative lever</p>
<p>Sec. 9013. National Violent Death System</p>	<p>Encourages the Director of the Centers for Disease Control and Prevention (CDC) to improve, particularly through the inclusion of other states, the existing National Violent Death Reporting System. The reporting system was created in 2002 and currently collects surveillance data from 32 states</p>	<p>Relates to Vitals</p>



## APPENDIX 4. THE PRIVACY RULE'S FOUR TIERS OF PROTECTION

The HIPAA Privacy Rule established the first-ever federal privacy protections for the personal health information for all Americans. This Rule set national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically. It set boundaries on the use and release of that information and required important safeguards. The Privacy Rule also established accountability for inappropriate use and release, and balanced privacy protections with public safety.

The Privacy Rule tailors the four distinct tiers of privacy protections to specific circumstances:

**Tier 1** reflects HIPAA's base-line protection: disclosing a person's PHI requires individual authorization, and the individual's expressed will, rather than the minimum necessary standard, governs the scope of disclosure.

In **Tier 2**, the Privacy Rule recognizes that certain discrete uses of data offer societal benefits so compelling as to justify the use or disclosure even without the individual's authorization. Here, the individual receives the protection of the minimum necessary standard, which allows disclosure only to the extent necessary to serve the beneficial use, and no more.

**Tier 3** addresses certain disclosures required by law. Here, applying the minimum necessary standard could obstruct justice, so the Privacy Rule sets out alternative due-process standards to protect the individual.

**Tier 4** outlines a very narrow set of circumstances (treatment and regulatory compliance) where covered entities may disclose data with neither authorization nor minimum necessary limitations.

## APPENDIX 5. ACRONYMS USED IN THIS REPORT

Acronym	Definition
<b>ACA</b>	Affordable Care Act
<b>CAQH CORE</b>	CAQH Committee on Operating Rules for Information Exchange
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>DSMO</b>	Designated Standards Maintenance Organization
<b>HHS</b>	Department of Health and Human Services
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>ICD</b>	International Classification of Diseases
<b>NCVHS</b>	National Committee on Vital and Health Statistics
<b>OCR</b>	HHS Office for Civil Rights
<b>ONC</b>	HHS Office for the National Coordinator of Health Information Technology
<b>ORAE</b>	Operating Rule Authoring Entity
<b>SDO</b>	Standards Development Organization
<b>WEDI</b>	Workgroup for Electronic Data Interchange

## APPENDIX 6. NCVHS MEMBERSHIP

### HHS EXECUTIVE STAFF DIRECTOR

**Sharon B. Arnold, PhD**

Associate Deputy Assistant Secretary for Planning and Evaluation  
Office of Science and Data Policy/Office of the Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services  
Washington, DC

### EXECUTIVE SECRETARY/DESIGNATED FEDERAL OFFICER

**Rebecca Hines, MHS**

Health Scientist  
Office of Planning, Budget and Legislation  
National Center for Health Statistics  
Centers for Disease Control and Prevention  
Hyattsville, MD

### MEMBERSHIP

**Bruce B. Cohen, PhD**

Consultant  
Massachusetts Gaming Commission  
Boston, MA

**Llewellyn J. Cornelius, PhD, LCSW**

Donald Lee Hollowell Distinguished Professor of Civil Rights and Social Justice Studies  
Director, Center for Social Justice, Human, & Civil Rights  
Editor- Journal of Poverty  
University of Georgia, Athens  
School of Social Work  
Athens, GA

**Nicholas L. Coussoule**

Senior Vice President & Chief Information Officer  
BlueCross BlueShield of Tennessee  
Chattanooga, TN

**Alexandra (Alix) Goss**

Vice President and Senior Consultant  
Imprado/Dynavet Solutions  
Harrisburg, PA

**Linda L. Kloss, MA**

President  
Kloss Strategic Advisors, Ltd.  
Vero Beach, FL

**Richard W. Landen, MPH, MBA**

Bonita Springs, FL

**Denise E. Love, BSN, MBA**

Executive Director  
National Association of Health Data Organizations (NAHDO)  
Salt Lake City, UT

**Vickie M. Mays, PhD, MSPH**

Professor and Director  
Department of Psychology & Health Services  
University of California, Los Angeles  
Los Angeles, CA

**Jacki Monson, JD**

Vice President and Privacy & Information Security Officer  
Sutter Health  
Sacramento, CA

**Robert L. Phillips, Jr., MD, MSPH**

Executive Director  
Center for Professionalism and Value in Health Care  
American Board of Family Medicine Foundation  
Washington, D.C.

**David A. Ross, ScD**

President and CEO  
The Task Force for Global Health  
Decatur, GA  
*(term ended December 14, 2018)*

**Debra Strickland, MS**

Director of Integration and Client Services  
XeoHealth Corporation  
Middletown, MD

**Roland J. Thorpe, Jr., PhD**

Associate Professor

Department of Health, Behavior and Society

Director, Program for Research on Men's Health

Deputy Director, Hopkins Center for Health Disparities Solutions

Johns Hopkins Bloomberg School of Public Health

Baltimore, MD

For further information regarding NCVHS membership, visit

<https://ncvhs.hhs.gov/membership/full-committee/>