National Committee on Vital and Health Statistics

Report to Congress on the Implementation of the
Administrative Simplification Provisions of the
Health Insurance Portability and Accountability Act

May, 2017

[1-page executive summary will be added.]

I – Introduction

This report by the National Committee on Vital and Health Statistics (NCVHS)\(^1\) is the 12th such report to Congress on the status of implementation of the Health Insurance Portability and Accountability Act (HIPAA), which was passed in 1996 to enable electronic information exchange for an efficient and effective healthcare system. To mark this important 20-year milestone, NCVHS offers a high-level overview of the major advances, issues, and opportunities related to the two goals advanced by HIPAA, administrative simplification and information privacy and security.\(^2\) The report reviews HIPAA and the progress toward its full implementation in the broad context in which HIPAA provisions operate.

Administrative efficiency and information privacy and security are closely linked to, and indeed dependent on, continued progress in the accessibility and usefulness of health data as well as the adequacy of information on the population’s health. Accordingly, this report describes the National Committee’s work in all these areas and identifies cross-cutting priorities. This broad context encompasses all the topics on which NCVHS advises the Department of Health and

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\(^1\) Established in 1949, the National Committee on Vital and Health Statistics (NCVHS) serves as the advisory committee to the Secretary of Health and Human Services on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42U.S.C.242k[k]). In that capacity, it provides advice and assistance to the Department and serves as a forum for interaction with interested groups on key issues related to population health, standards, privacy and confidentiality, and data access and use. Its members have distinction in such fields as health statistics, electronic interchange of healthcare information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing healthcare services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. HIPAA requires NCVHS to report regularly to Congress on the status of HIPAA implementation. NCVHS reports and recommendations are posted on its website, http://ncvhs.hhs.gov/. See Appendix 4 for the NCVHS Charter and a roster of current members.

\(^2\) The goal of administrative simplification is to enable electronic information exchange for an efficient and effective healthcare system. Appendix 1 presents an overview of key concepts in administrative simplification.
Human Services (HHS), including standards; privacy, confidentiality, and security; population and community health data; and data access and use. The report is primarily retrospective, offering a synthesis of the cross-cutting themes identified through review of recent NCVHS recommendations, summarization of the progress of HIPAA implementation, and a forward look to future areas that NCVHS views as ripe for study, assessment, and development of recommendations.

The landmark HIPAA legislation was a bipartisan effort to meet the healthcare industry’s need to simplify information exchange in administrative transactions, among other goals. Since its passage in 1996, information technology and healthcare delivery have changed in ways and to degrees that the Law’s authors could not have foreseen. The health system has accommodated the dramatic changes that took place over that 20-year period while gradually implementing and adhering to HIPAA and the laws that augmented it. As the law of the land, HIPAA has had a profound impact, and it continues to do so. It has been regularly updated, and its implementation is actively advanced by HHS. NCVHS sources generally agree, with evidence and qualifications explored below, that HIPAA’s standards and operating rules have made the health system’s administrative and business practices more efficient and cost-effective, while its privacy and security protections have helped to protect the privacy rights of individuals and the security of personal health information. At the same time, more needs to be done because the environment in which HIPAA operates is continually and rapidly changing.

During the period covered by this report (2014-2016), NCVHS held 12 full Committee meetings and 10 hearings and workshops, resulting in 15 letters and 6 reports on various aspects of health information policy. The present report draws on this work in addition to relevant work of the HHS Office for the National Coordinator of Health Information Technology (ONC) and HHS Office for Civil Rights (OCR), which provided guidance on a range of HIPAA implementation issues during the reporting period.

The next section (Section II) outlines four complementary priorities related to data and information that must be pursued simultaneously to achieve maximum benefit for Americans. They concern balancing standardization and innovation, practicing data stewardship, educating and supporting health data users, and leveraging the power of partnerships. Section III then describes specific policy goals and themes in the areas of standards, privacy and security, population health, and data access and use. References and links to NCVHS letters, recommendations, and reports on each topic are provided to enable further exploration.

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3 https://www.ncvhs.hhs.gov/recommendations-reports-presentations/
Finally, **Section IV** outlines the steps that NCVHS plans to take in 2017-18 to envision the optimal policy environment for continuing to advance HIPAA, advise on making the impacts of HIPAA more predictable for covered entities,\(^4\) and enhance the vulnerable vital statistics system. Throughout this report, the Committee hopes to convey its judgment that HIPAA’s administrative simplification and privacy and security provisions can have the most positive impact when (1) they are based on standards and operating rules that are consistently implemented by all users; (2) they are an integral part of a predictable and coordinated ecosystem of laws, regulations, and guidance; and (3) they function within a policy environment that also encourages innovation and assures the availability of information to enable improvements in the health of all Americans.

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\(^4\) Covered entities under HIPAA include healthcare clearinghouses, health plans, and providers who perform electronic transactions. (HIPAA Title 45, Subtitle A, Subchapter C, Part 164, Subpart A, §164.104)
II – Cross Cutting Themes

Four themes emerge as essential approaches to achieving continued improvement in implementing HIPAA and advancing the public good. The themes concern balancing standardization and innovation, practicing effective data stewardship, educating and supporting health data users, and leveraging partnerships—all for the purpose of realizing the maximum return on the large investments in data and optimizing the efficiency of the health system. The four themes are expressed below as general principles, as a guide for the future. The Federal government has a pivotal role to play in helping to ensure that the data it collects are used responsibly and appropriately. Moreover, Federal guidance and expertise will help assure that data collected by others such as states and communities meet the conceptual standards set by HIPAA.

1. Balance standardization and innovation to improve efficiency.

In an interdependent and interoperable system, standards enable information to flow and be understood once received. To be most effective, such standards should be implemented completely and consistently. At the same time, though, the environment in which HIPAA is implemented is changing so rapidly that policy approaches must be dynamic and agile. As healthcare delivery and information technology evolve, the levers of administrative simplification and privacy and security protection must evolve, as well.

To adapt to this ever-changing environment, NCVHS suggests that future HIPAA implementation efforts focus first on the handful of transactions that can be universally implemented. Thus, NCVHS has recommended a focus on achieving consistent implementation of the standards related to the five transactions that are already widely implemented by all participants in those transactions. This will be accomplished by broadened participation and greater understanding of the value of consistent implementation, reinforced by enforcement efforts. NCVHS will continue to advise HHS on adapting HIPAA regulations to evolving conditions in consultation with industry representatives, standards development organizations, and others.

Building on this platform of standardized transactions, NCVHS has urged the Federal government to encourage the health system to experiment with new methods for achieving the administrative simplification goals of HIPAA, and to leverage the innovative approaches of others. Healthcare transactions and privacy and security protections need to keep pace with the rapid changes in information technology and clinical practice as well as with system and payment reform, new policy priorities, the progress toward open data, increasing risks of

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5 The five transactions for which standards are now widely implemented are eligibility, claim, claim status, remittance advice, and coordination of benefits.
inappropriate or harmful use, and other areas. The healthcare industry and other partners in health are continuously developing new solutions in response to new challenges and opportunities, and they should be encouraged to do so. When appropriate, the learnings from these innovations can then be woven back into existing processes for consideration in subsequent standards development.

The same principle of balancing standardization and innovation applies in the arena of population and community health. As discussed below, NCVHS developed a consensus Measurement Framework for community-level health and well-being indicators, to facilitate local data access and use. The two-fold goal of that effort is to provide 1) a parsimonious measurement tool that enables national-scale coordination and benchmarking and 2) an adaptable menu of metrics to meet diverse local needs. The creation of learning communities in this arena, as in others, will facilitate sharing of the lessons and benefits of innovation.

Finally, it is important to coordinate all of the standards and policies supporting administrative simplification and privacy and security protection so they work together for public good. These standards, policies, and related activities include rule-making, guidance, operating rules, robust testing and pilots, tool kits, technical assistance, methods research, measurement, and enforcement as well as the successful results of voluntary experiments.

2. Practice consistent data stewardship to facilitate information use.

Effective health data stewardship supports efficient information exchange by promoting data quality and creating an atmosphere of accountability and trust. While advances in information technology capabilities make health data more accessible and useful in ways that can significantly benefit Americans, the same capabilities also heighten the risk that inappropriate, unexpected, or unauthorized uses of the information may harm individuals or communities and undermine trust in healthcare and public health providers. Health data stewardship is a responsibility, guided by principles and practices, to ensure the purposeful and appropriate use of data derived from individuals' personal health information. The stewardship principles (which NCVHS culled from authoritative sources to create the reports referenced below) include accountability, transparency, individual participation and control, purpose specification, data integrity and quality, security safeguards, de-identification of data, and oversight of data uses. These principles are designed to protect the rights and privacy of the persons whose data are involved, to assure the quality and integrity of the data, and to encourage the appropriate and innovative use of the data. To ensure that data are of optimal quality and appropriately safeguarded, everyone who collects, uses, protects, and/or shares health data must practice data stewardship.

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6 Pages 19-20
The expanded data access sought by many stakeholders must be pursued within a context of strict adherence to data stewardship principles, using the best technology and practices available to protect privacy. The natural tension between data-sharing and individual privacy protection has had an impact on the progress of administrative simplification. While data stewardship practices may impede information flow in some ways, a failure to practice data stewardship could undermine trust in information exchange and, ultimately, the functioning of the health system. To enable care coordination, analytics, and other critical uses of data, it is essential to find ways to protect data privacy and security while preserving data access for the uses that benefit the American people.

NCVHS has stressed the need to extend the chain of trust and accountability addressed in HIPAA to encompass all uses of individually identifiable health data by all users. In 2015, NCVHS released a toolkit to facilitate data stewardship by those using data related to community health. This toolkit is a model of the kind of practical resource that can be useful for data users, as discussed below.

3. Take advantage of technology to educate and support the multiplicity of health data users.

The power of technology can be used more fully and effectively to offer more resources tailored to specific use cases and user needs. Health information and data have many users and uses across the realms of personal health management, healthcare, financing, policy, governance, public and community health and wellness, research, and technology, among others. While the interests, needs, and capacities of these data users vary greatly, most need some form of support to help them find and appropriately use needed information. The complexity of data and the diversity of formats can be challenging for the communities, businesses, and non-profits that rely on health data. The absence of best-practice guidance in the governmental and non-governmental platforms offering access to data and support can undermine the use of those data, because of the burden and cost of figuring out how to use each source. For these reasons, many NCVHS recommendations focus on providing education and guidance and optimizing interfaces, standards, and services to meet the needs of diverse users.

There are many excellent models of such resources. The Committee commends ONC and OCR for developing and disseminating highly effective educational resources for their constituents.

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7 NCVHS reports on data stewardship: Health data stewardship: An NCVHS primer (September 2009); Enhancing protections for uses of health data: a stewardship framework (April 2008); Enhanced protections for uses of health data: a stewardship framework for “secondary uses” of electronically collected and transmitted health data (December 2007)

8 Toolkit for communities using health data: How to collect, use, protect, and share data responsibly (May 2015)
through web pages, FAQs, videos, and other forms of targeted resources. In the realm of community health data, many intermediary organizations have developed online resources that make such data accessible and usable for community health improvement efforts. The National Committee’s own contributions to these resources include the toolkit on data stewardship for community users described above and the Measurement Framework described below. Additional targeted resources continue to be needed, to ensure that data are accessible and usable for public benefit while the rights of individuals are protected.

4. Leverage partnerships to get the most out of data resources.

As complexity increases and the demands on resources intensify, there is growing interest in strengthening partnerships as a strategy for optimizing data investments. This theme was prominent in the Committee’s work in 2014-16. NCVHS has a unique vantage point on the evolution of partnerships through its role as convener and interface between the Federal government and information policy stakeholders. Every arena in which it advises the Federal government contains multiple constituencies. And in every one, NCVHS has seen growing recognition of common interests, appreciation for the value of achieving alignment and economies of scale, and determination to avoid duplication of effort. The opportunities for partnership exist on many axes: between governmental and non-governmental organizations (public and private sectors); across geographic levels (nation, state, county, community, and neighborhood); and among sectors (health, commerce, labor, education, transportation, agriculture, environment, justice, and so on).

It is not surprising, then, that a vibrant conversation about partnership and collaboration is taking place in all the arenas on which NCVHS advises the Federal government. The conversations are taking place within the standards and provider communities and between health plans and providers, among other entities. In the community health context, local health and well-being cannot be achieved without joint efforts across domains, using information about and from all of them. In these community health efforts, healthcare organizations are increasingly active partners with public health and community organizations. Their involvement stems from the fact that policy-makers now define healthcare outcomes in terms of the health of entire populations, and recognize that the health of individuals is affected not just by medical care but also by education, housing, socioeconomic status, and many other factors. To cite a few examples of collaboratives, the Committee’s recent work has highlighted the creative joint

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efforts of the Workgroup for Electronic Data Interchange (WEDI), the Health Datapalooza, the
100 Million Healthier Lives Initiative of the Institute for Healthcare Improvement, and the non-
governmental stewardship group formed to continue the work on the NCVHS Measurement
Framework for Community Health and Well-being.

NCVHS anticipates that partnerships and the role of partners will be an increasingly essential
part of the American health story in the years to come. Potential partners can consider where
their interests and goals converge and how they might engage in joint efforts and form learning
communities. In such endeavors, it will be critically important for the Federal government to be
at the table as a contributing partner, crossing sectors and helping to remove the incentives to
form silos.
III – Progress and Status

Administrative Simplification

Overview

Administrative Simplification includes laws, rules, and initiatives intended to move the health care industry from manual and paper-based billing, payment, and administrative transactions to an electronic exchange that will improve security, lower administrative costs, and reduce billing errors. Briefly, administrative simplification is carried out in three steps:

1) Legislation: HIPAA named the transactions for which standards should be adopted by the health care industry. The Affordable Care Act (ACA) added the mandate to adopt operating rules for each transaction.

2) Rulemaking: HHS was authorized to adopt standards, code sets, identifiers and (later) operating rules, and to define business associate, based on recommendations from NCVHS.

3) Implementation by the healthcare industry.

NCVHS has been actively involved in advising and working with 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 (e.g., 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. 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.

Themes and Findings

1. Significant progress has been made with implementation and expanded utilization of the HIPAA standards, identifiers, code sets, and operating rules.

HIPAA administrative simplification provisions have created real value across the healthcare ecosystem. By providing a common set of rules for all entities to follow and increasing the

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10 https://www.cms.gov/eHealth/downloads/eHealthU_IntroAdminSimp.pdf

11 See Appendix 1 for further information about the elements of administrative simplification, including definitions and a table summarizing the history of implementation.
volume of electronic data interchange, the adopted standards have met many core business
needs of healthcare providers and health plans and decreased the cost and complexity of
administrative processes. This progress has enabled the healthcare industry to focus its
resources and technology investments more cost-effectively. For example, the 2016 CAQH Index
estimated that in 2015 alone there were at least $1.5 billion in savings as a result of standards
adoption, and projected potential savings of more than $9 billion if just the seven HIPAA
transactions measured by the Index were routinely utilized.\textsuperscript{12} It also found that 94 percent of
healthcare claims are submitted using the standard, with savings ranging from a low of $1.95
per claim transaction, to industry savings as high as $9.25 per prior authorization transaction.
The CAQH Index estimates providers could save up to 20 minutes per eligibility transaction
conducted using the standard, currently accounting for at least $5 billion in wasted labor costs
each year. In addition, the Veterans Administration found that one of greatest benefits from the
eligibility transaction was the reduced amount of time needed to verify insurance.

Having written the Secretary on two occasions to urge no further delays in the implementation
of ICD-10, NCVHS welcomed the relatively smooth transition to these new code sets in 2015.
This success is a good illustration of the importance of industry education and collaboration,
two of the cross-cutting themes discussed in Section II. Responding to widespread concerns
about impending ICD-10 implementation, the Centers for Medicare & Medicaid Services (CMS)
convened industry partners to explore the challenges and determine how to test between
trading partners and prepare industry for this significant change. As a result, the Federal
government engaged in extensive testing with its Medicare providers, shared the results,
developed guidance on best practices, and conducted aggressive outreach to inform the
healthcare industry about available resources. Many other entities collaborated to provide
extraordinary education and outreach to small providers and to assist in the transition.

2. There continue to be significant challenges in implementing administrative
simplification provisions.

The challenges to HIPAA implementation relate to attaining maximum efficiency and
effectiveness, the overall pace in achieving cross-industry consistency, and the consistent
measurement of value generation. The existence of differing business models and governance
for every component of administrative simplification continues to pose a major challenge. In
addition, regulations and practices are misaligned across sectors; and existing regulations must
be revised to leverage standards and business practice advances that have emerged through

\textsuperscript{12} \texttt{http://www.caqh.org/sites/default/files/explorations/index/report/2016-caqh-index-report.pdf}. It should
be noted that the data used to create this index have not been vetted or validated by any government
actuary. The baseline data are based on a small “n” and do not represent the entire industry, but rather a
small subset of organizations who voluntarily provide their data to CAQH. This information is extrapolated
to come up with the cited figures.
industry collaboration since the passage of HIPAA. NCVHS has heard from industry that maximum value is achieved when all parties to a transaction equally engage in and consistently use the standards. Recognizing these challenges, in February 2016 NCVHS sent a letter to the Secretary with recommendations for HHS, followed by a report in October 2016 that added recommendations for Standards Development Organizations, the Operating Rule Authoring Entity, and the healthcare industry. The recommendations include exploring the feasibility of expanding the definition of HIPAA covered entities,\(^{13}\) broadening education, ensuring consistency, enforcing compliance, and ensuring responsiveness to evolving changes in healthcare.

3. The healthcare industry needs greater predictability over a long time horizon so it can plan for resource use.

In its hearings and consultations with the healthcare industry, NCVHS has heard a strong and consistent need for greater predictability for managing updates and changes. The current processes for proposing, commenting, and promulgating changes to the transactions, code sets, and operating rules are complex, sometimes duplicative, lengthy, and without any dependably predictable end-point. Compounding the unpredictability issue, final rule promulgation frequently includes inadequate implementation lead-times. The industry has clearly told NCVHS that the current processes do not support efficiency or best practices for planning, staffing, and budgeting for change, despite the fact that these objectives are a fundamental premise of HIPAA administrative simplification.

The lack of sufficiently predictable planning and budgeting horizons results in problematic implementations such as inadequate workflow redesign, cross-system coordination, and training as well as insufficient testing and higher-than-normal avoidable “bugs,” to name just some of the more visible downsides. All these factors drive up costs and aggravate operational

\(^{13}\) The current definition of HIPAA Covered Entities: “health plans, health care clearinghouses, and health care providers conducting certain electronic transactions.” 45 C.F.R. 160.103. In its February 2016 letter, NCVHS (Review Committee) recommended that HHS evaluate the following alternative paths with regard to covered entities:

1.1 Explore the feasibility of requesting that Congress amend the definition of a covered entity to include all entities that perform HIPAA-named transactions. As covered entities, they would then be required to comply with the adopted standards and operating rules. This would include but not be limited to employers, workers’ compensation, property and casualty industry, practice management systems (PMS), and other vendors of relevant solutions.

1.2 In the absence of a statutory amendment to the definition of a covered entity, explore other regulatory and non-regulatory mechanisms (including federal procurement and contractual requirements) to require that any entity that performs a HIPAA-named transaction specified in §1104(h)(B)(3) of ACA comply with the standards (including code sets, identifiers) and operating rules adopted for these transactions.
disruptions, adversely affecting implementers’ bottom lines and contributing to the cost of healthcare. Ultimately, such issues are a disservice to the implementers and to the patients/consumers they serve. NCVHS plans to address predictability solutions in 2017, as described in Section IV.

4. The impact of traditionally non-HIPAA covered entities continues to expand as a result of the complexity of the healthcare ecosystem, with growing implications and risks.

The goal of administrative simplification is to maximize system efficiency and cost-effectiveness by getting everyone to follow the same rules and practices. Achievement of this goal is thwarted by the current definition of a HIPAA covered entity. A number of organizational types are currently not included in the definition of a HIPAA covered entity although they engage in exchanging administrative and financial data related to health and/or healthcare. These “uncovered” organizational types include banks and other financial institutions, some employers, worker’s compensation plans, and the property and casualty industry. The failure of these and other entities to use electronic transaction standards could result in increased costs because of the need for more translators, customization and maintenance to capture necessary data, and information from those using proprietary methods.

5. The levers of administrative simplification must evolve along with the healthcare landscape.

As the healthcare landscape continues to change rapidly, increasing integration is needed among clinical and administrative information flows and their supporting standards. Today, healthcare finance policy favors integrated care models, and payment models based on value and quality are being developed across the country. This growing need for integration has significant implications for existing and planned administrative simplification provisions. It is important to learn from a changing market and take advantage of opportunities related to technology and new business processes as well as in various types of data standards. One example of the need for alignment between clinical and administrative information flows and supporting standards is the new policy direction in healthcare that could necessitate the use of clinical data to inform system delivery and care reform efforts. There are also opportunities to support a learning health system, guided by the Shared Nationwide Interoperability Roadmap, in order to build more robust public health and bio-surveillance capabilities to support the government’s critical role in monitoring disease outbreaks and threats. These and other opportunities, such as better care coordination and more efficient transaction processing, will be explored in the forthcoming NCVHS “Beyond HIPAA” project described in Section IV.

\[14\] See note 13 for the current definition of HIPAA Covered Entities and NCVHS recommendations for possible changes.

\[15\] Published by ONC: https://www.healthit.gov/policy-researchers-implementers/interoperability
NCVHS Letters and Reports on HIPAA and Administrative Simplification, 2014-16

NCVHS Letter to the National Coordinator of HIT:
- **ONC’s Draft 2017 Interoperability Standards Advisory** (October 13, 2016)

NCVHS Letters to the Secretary on Administrative Simplification, 2014-16:
- **Findings from the February 2014 NCVHS Hearing on Prior Authorization for the Pharmacy Benefit; Health Plan Identifier (HPID); Electronic Fund Transfer (EFT)/Electronic Remittance Advice (ERA); and, Remaining Operating Rules** (May 15, 2014)
- **ICD-10 Delay** (May 15, 2014)
- **Electronic Standards for Public Health Info Exchange** (June 16, 2014)
- **ASC X12 XML Schemas** (September 23, 2014)
- **Findings from the June 2014 NCVHS Hearing on Virtual Credit Cards and Credit Card Use** (September 23, 2014)
- **Findings from the June 2014 NCVHS Hearing on the Incorporation of the Unique Device Identifier (UDI) in Administrative Transactions** (September 23, 2014)
- **Findings from the June 2014 NCVHS Hearing on Healthcare Claim Attachments** (September 23, 2014)
- **Findings from the June 2014 NCVHS Hearing on Coordination of Benefits, Health Plan Identifier (HPID), and ICD-10 Delay** (September 23, 2014)
- **Recommendations for the Electronic Healthcare Attachment Standard** (July 5, 2016)
- **Recommendations Proposed Phase IV Operating Rules** (July 6, 2016)

Letter and Report from the Review Committee:
- **Review Committee Findings and Recommendations on Adopted Standards and Operating Rules** (October 13, 2016)
Privacy Confidentiality and Security

Overview

The goal of privacy, confidentiality, and security protection of personal health information is to ensure a foundation of trust for all uses of health information. In addition to standards for transactions, code sets, and identifiers, HIPAA also called for standards for security to be adopted, as well as for the development of privacy regulations if Congress did not enact privacy legislation. The HIPAA Privacy and Security Rules\(^\text{16}\) lay out the obligations of covered entities and their business associates, as defined in the Rules. While the Rules have been regularly updated, the health information ecosystem continues to outpace policy, creating significant challenges. The following themes capture these challenges.

Themes and Findings

1. Consumer engagement and trust can be advanced through greater access to information.

Research by ONC found that 75 percent of those surveyed expressed concern about the privacy of their information. An essential premise for earning the trust of the subjects of information is that they have access to the information about them and are informed about how it is being used. The subjects of information also want to know that those who maintain the information deploy sound practices to ensure that it is accurate and secure. In 2016, OCR issued new guidance ensuring that neither price nor process would be barriers to patients seeking access to their health information.\(^\text{17}\) OCR and ONC have stepped up consumer education to help consumers understand the potential risks and benefits of health information exchange as well as their rights with respect to their personal health information.\(^\text{18}\)

2. HIPAA standards for privacy and security protection continue to evolve.

As noted, the HIPAA Privacy and Security Rules detail responsibilities of covered entities (providers, health plans, and clearinghouses) and their business associates (contractors performing specific information duties under explicit agreement with covered entities). Important provisions in both the Privacy and Security Rules have been updated over the years, and they must continue to evolve. For example, Minimum Necessary is a HIPAA standard requiring covered entities and business associates to make reasonable efforts to limit the protected health information that is requested or disclosed to accomplish the intended purpose.

\(^{16}\) The Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164. The Security Rule is located at 45 CFR Part 160 and Subparts A and C of Part 164.

\(^{17}\) https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

of a specific use, disclosure, or request. In November 2016, NCVHS sent recommendations to the HHS Secretary reaffirming the importance of the Minimum Necessary standard as an essential provision of the HIPAA Privacy Rule and offering ten practical recommendations for clarifying the regulation and promulgating guidance and education on its implementation. The recommendations, for example, call upon HHS to develop specific guidance on adherence to the Minimum Necessary standard by business associates. They call for clarification of how the Minimum Necessary standard will be upheld in implementing the previously recommended Attachments standards. They also call upon HHS to issue guidance that will support improved implementation of the standard by both covered entities and business associates.

NCVHS also continues to monitor existing standards and the adequacy of existing guidance in light of changing demands and technology. In September 2015, it sent recommendations to the Secretary on HIPAA Section 1179, which creates a limited exemption from HIPAA requirements for financial institutions engaged in certain healthcare-related financial transactions. These recommendations addressed evolving health-related banking and finance services and stressed the value of greater coordination of regulation across health and finance sectors. NCVHS also advises and collaborates with HHS on priorities such as the important work of OCR on HIPAA rights education and of ONC on the privacy implications of interoperability and technology advancements such as “computable privacy.” The latter effort is designed to capture, communicate, and process individual choice to enhance interoperability and move toward a learning healthcare system.

3. Privacy and security must be strengthened beyond the boundaries of HIPAA.

Digital health information is now more widely available and used by public and private entities for analytics. The May 2014 report by the President’s Council of Advisors on Science and Technology (PCAST) recommended privacy policies for the era of big data. Data for analytics

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19 The HHS Office for Civil Rights has issued guidance on Minimum Necessary in the form of FAQs.
20 Financial institutions offer far more services in support of the healthcare industry today than when Section 1179 exemption was made part of the HIPAA law. This hearing examined the range of services and the application of the exemption. NCVHS offered recommendations calling for guidance and training to ensure that the exemption was limited to claims payment and funds transfer services as Congress intended.
21 https://www.healthit.gov/policy-researchers-implementers/computable-privacy
22 Funded by an ONC grant, the National Governors’ Association produced the report, “Getting the Right Information to the Right Health Care Providers at the Right Time: A Road Map for States to Improve Health Information Flow between Providers.” (https://www.nga.org/cms/home/nga-center-for-best-practices/center-publications/page-health-publications/col2-content/main-content-list/getting-the-right-information-to.html). This report was developed to activate governors and their senior state leaders to drive forward policies that support interoperability.
23 President’s Council of Advisors on Science and Technology, Report to the President: Big Data and Privacy: A Technological Perspective, May 2014.
are generally “de-identified” according to HIPAA standards; but once de-identified, these data
are no longer subject to HIPAA. There remains a persistent risk of re-identification as data sets
are combined and enhanced. NCVHS convened experts in a hearing on de-identification to
address the rapidly-expanding use of de-identified data and the growing risk of re-identification
associated with increasing opportunities to link datasets. In early 2017, NCVHS issued
recommendations calling for improved guidance on de-identification of protected health
information.

Today, health data are frequently collected outside the hospital and doctor’s office, often
placing the data beyond the boundaries of HIPAA protection. For example, biometric devices
collect health information for personal use by individuals and to share with providers. The use of
cloud-based and proprietary applications can raise new privacy concerns. Defining the boundary
between uses and transmissions of data that are within the scope of HIPAA and those that are
not has recently been addressed by guidance from OCR.\textsuperscript{24,25} However, this area remains a
rapidly moving target.

In the areas described above and others, stewardship of privacy and security beyond the
boundaries of HIPAA is a critical issue. Public policy must strive to preserve privacy while also
promoting innovation through the use of information. NCVHS developed its aforementioned
Toolkit to strengthen privacy and security practices in data sharing for community health
purposes.\textsuperscript{26} NCVHS plans to continue its focus on advancing the privacy and security of health
information, both under and beyond the protections of HIPAA.

4. Compliance with the Privacy and Security Rules must remain a top priority for policy-
makers.

Privacy and security remain, and must remain, a top policy priority in the face of the sharp recent
increase in cyber risks and attacks, which include the threat of holding medical information for
ransom. In addition, security breaches by HIPAA covered entities continue to be frequent
despite carrying stiff fines and consequences. Breaches continue to occur, due to the lax security
practices of some covered entities. At the same time, health care information is now also a focus
for external cyber attacks, requiring greater attention to strengthening security practices and
supporting technology in order to be more prepared for rapid response to threats that

\begin{itemize}
\item[26] NCVHS toolkit for community data users (see citation and link in note 8).
\end{itemize}
continually take new forms. OCR has completed the first phase of its HIPAA compliance audits, and it launched Phase 2 in 2016. It also stepped up enforcement activities from 2014-16, regularly reporting to NCVHS on these actions. NCVHS supports the steps being taken by HHS to strengthen understanding of and full compliance with both the Privacy and Security Rules, to ensure the privacy of protected health information. As noted above, the Committee commends the achievements of OCR and ONC in their provision of industry guidance. New guidance documents are announced on the Newsroom page of the OCR website. Privacy and security are foundational to trust; and trust is critical if the nation is fully to use health information to improve the health system and serve the public good.

NCVHS Letters and Reports on Privacy/Confidentiality/Security, 2014-16

- Toolkit for Communities Using Health Data: How to collect, use, protect, and share data responsibly (May 2015)
- Recommendations on the financial services industry and § 1179 of HIPAA (September 16, 2015, Letter to the Secretary)
- Recommendations on the HIPAA Minimum Necessary Standard (November 9, 2016, Letter to the Secretary)

28 https://www.hhs.gov/ocr/newsroom/index.html
Population and Community Health Data

Overview

The goal of health information and data policy related to population and community health is to increase the availability of useful data from both health and non-health sectors, for use by community leaders to assess and improve local residents' health and well-being. Many Federal and non-Federal data sources are critical for health policy and program development at national, state, and local levels. These sources include, for example, data addressing the obesity epidemic,29 the opioid epidemic and the rise of adolescent substance abuse,30 infectious disease and potential biological/chemical terrorism,31 and youth mental health issues.32 As noted in the introduction, the population health goals that motivate administrative simplification and information privacy and security protection cannot be achieved without adequate information about the population's health. The cross-cutting themes discussed in Section II—balancing standardization and innovation, practicing data stewardship, educating and supporting health data users, and leveraging the power of partnerships—are highly relevant to population and community health data.

Themes and Findings

1. Federal data investments that meet community and local health data needs will also meet the health policy needs of state and Federal government.

Recent studies of the poor health performance of the United States compared to other industrialized nations have identified profound place-based disparities in life expectancy as a primary driver. A growing body of evidence suggests that existing national, state, and county health data sources are inadequate for identifying and addressing the precise disparities, or “hot-spots,” that disproportionately drive the increases in healthcare costs. The Federal government has helped galvanize attention to health disparities and awareness of the need to address the broad determinants of health to achieve sustained health improvement. To

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29 Examples: National data from NHANES and NHIS to identify body mass index (BMI) trends and markers of diabetes in the population; state surveys such as BRFSS; records from health plan systems; school health records to track childhood obesity; national state, and community surveys on physical activity and nutrition; hospital discharge and mortality data tracking the prevalence and mortality related to diabetes and other consequences of obesity.

30 Examples: aggregated and state and local mortality data, particularly linked to medical examiner and public safety reporting systems; state prescription monitoring systems for tracking the distribution of medications; adult and youth Federal, state, and community surveys of growing illicit drug use.

31 Examples: DC’s disease surveillance systems, sentinel hospital emergency department reporting systems; rapid mortality surveillance reporting.

32 Examples: mortality data identifying teen suicide clusters; adolescent school based health surveys tracking teen suicide ideation and risk behaviors.
accomplish this, the government has encouraged data sharing and strategic data integration. To a great extent, the health of the nation is achieved cumulatively, through targeted local actions taking place throughout the country. Looking forward, NCVHS sees a vital ongoing role for the Federal government in supporting and informing these local efforts. This is a cost-effective strategy for realizing national policy goals for the health of the American people. The Federal government, with its expertise in data collection initiatives—including the Census, the National Health Interview Survey, the CDC Social Vulnerability Index, the 500 Cities Project, and the cooperative vital statistics system—helps provide technical guidance and support to state and local governments and communities to improve health data available at the community level.

2. States and communities need access to detailed data to inform policy development, resource allocation, and action.

Community leaders and state and local officials find small-area data and comparisons over time and with other communities to be essential for identifying priorities for resource use to improve the well-being of residents. These leaders and officials know that social, behavioral, economic, educational, and other factors play key roles in determining individual life course as well as population health status, making data necessary on the broad range of health determinants. Reduced medical costs, shortened hospital stays, and quicker recoveries are all possible outcomes if local data are more available to develop strategies for prevention and early intervention. However, serious gaps and inconsistencies in the availability of local data hamper decisions and actions on key priorities in all these sectors. While partnerships have formed across sectors to work together to improve local health, the partners often lack the specific, localized data needed to identify the most vulnerable residents, the greatest threats, and the most cost-effective interventions. In NCVHS workshops and roundtables since 2011, community and public health experts have called on HHS to partner with other Federal agencies and other entities to fill these gaps and address the need for greater access to community-level data.33

3. Community health leaders have confirmed that a consistent, clear framework for organizing multi-sectoral health data would benefit everyone, including local and state health planners as well as Federal health policy makers.

In recent years, activities in the areas of public health, mental health, and healthcare have converged in a combined focus on population health. At the local level, this trend is seen in close partnerships among healthcare organizations, local health departments, and other sectors such as education, transportation, and business. This work is based on a common recognition that action, partners, and data must be multi-sectoral because health is a product of multiple determinants. Both Federal agencies and non-governmental coalitions have been working on

33 See references on page 21 and the following NCVHS report, the first of the Committee’s series on community data needs: “The Community as a Learning System for Health: using local data to improve local health” (December 2011).
integrated schema for data on health and its determinants, to enable data-driven decision-making. Leaders in these efforts have told NCVHS that a consensus set of indicators or data domains for indicators would add value.

In 2016, with broad input from experts, NCVHS developed a consensus Measurement Framework for community-level indicators of health and well-being, to address the need for a parsimonious approach to health data in light of a recent proliferation of indicators. The Framework has ten domains (e.g., economy, food and agriculture, health, and housing) and thirty sub-domains (e.g., income/wealth and employment within economy, and food availability and nutrition within food and agriculture). It has a dual purpose of enabling both national-scale coordination and local strategies. State and local leaders have affirmed that the Framework provides a straightforward, easily-understood structure for organizing and collecting data that highlight and identify problems and indicate directions for resources and interventions.

Participants at a September 2016 NCVHS workshop determined that the Measurement Framework is ready for further development and testing by non-Federal entities, with additional input from community leaders. Experts in the non-governmental sector have assumed responsibility for completing development of the Framework and developing specific measures of value at Federal, state, and local levels.

NCVHS will continue to encourage HHS to coordinate and align its community data collection and dissemination efforts internally as well as across Federal Executive agencies and with ongoing private sector initiatives, to improve greater access to community-focused data. The Committee notes that the Measurement Framework has significant overlap with other HHS efforts, including Public Health 3.0 and the HHS Report to Congress on Social Risk Factors and Performance under Medicare’s Value-based Purchasing Program (December 21, 2006). The Committee also found overlap with the 2015 report from the National Academy of Medicine’s Vital Signs: Core Metrics for Health and Health Care Progress report. Viewing them together, NCVHS sees these separate and distinct efforts as pointing toward the need for a more efficient approach to the collection and management of data needed by HHS, states, and communities for population health management and improvement.
NCVHS Letters and Reports on Population and Community Health Data, 2014-16

- **Supporting Community Data Engagement – An NCVHS Roundtable** (October 2014 report)
- **Recommendations on supporting community data engagement by increasing alignment and coordination, technical assistance, and data stewardship education** (May 28, 2015, Letter to the Secretary)
- **NCVHS Seminar at the 2015 National Conference on Health Statistics – Community Health Data, Data Stewardship and Data Access and Use: Tools and Resources** (August 25, 2015)
- **Advancing Community-Level Core Measurement: A Progress Report and Workshop Summary** (February 2016 report)
- **Environmental Scan of Existing Domains and Indicators to Inform Development of a New Measurement Framework for Assessing the Health and Vitality of Communities** (June 2016 report)

See also Toolkit for Communities Using Health Data (May, 2015), listed with Privacy/Confidentiality/Security letters and reports
D. Data Access and Use

Overview

The goal of health information and data policy related to data access and use is to expand appropriate access to and re-use of HHS data assets. Accessible, usable data are the core building block for the nation’s health policies and programs and a precondition for their effectiveness. The benefits from the hard work to advance administrative simplification and protect information privacy and security are magnified by progress toward improving the accessibility and usefulness of health data.

Themes and Findings

1. HHS can learn from the best practices of industry leaders about how to improve the accessibility and usability of HHS data.

The Work Group on Data Access and Use was created within NCVHS at the request of the HHS Chief Technology Officer, to explore innovative uses and applications of HHS data to improve health and healthcare and to provide recommendations for promoting and expanding access to HHS online data. The Work Group is composed of NCVHS members and consultant members who are nationally recognized for their expertise in the development of innovative data applications as well as being active users of government data. The Work Group reviewed available online HHS data (primarily HealthData.gov, the Health Indicators Warehouse, and the Health System Measurement Project) and evaluated the usability, use, and usefulness of the data to which they provide access. In March 2014, NCVHS sent recommendations to the Secretary on three topics: the user-friendliness of HealthData.gov, data documentation and metadata, and improving the timeliness of HHS data. The Committee cited examples of best practices from industry leaders and recommended that HealthData.gov emulate these practices. It also recommended that where practical, HHS data publishers apply elements of the common core metadata schema. Finally, NCVHS noted that the currency and timeliness of HHS data sets vary widely, from the current year to several years old. It offered examples of HHS efforts to accelerate release, and suggested approaches to expediting data release.

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34 HealthData.gov is the HHS website designed to make high-value health data more accessible to entrepreneurs, researchers, and policy makers to support better health outcomes for all Americans. This online health information portal drives economic empowerment, innovation, and transformation in health.

35 Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information resource (NISO 2004, ISBN: 1-880124-62-9).

36 The common core metadata schema provides a standardized format and common vocabulary to facilitate communication about data. https://project-open-data.cio.gov/v1.1/schema/
2. NCVHS has identified recommendations to increase the effectiveness of HealthData.gov.

In late 2016, the NCVHS Work Group on Data Access and Use conducted a more intensive review of HealthData.gov. Since its launch in 2011, this HHS portal has played an increasingly prominent role in facilitating access to data and information used to improve value-based care, the quality of health services, and research on health issues important to a range of communities. HealthData.gov also fosters healthcare innovation by facilitating the discovery, access, and use of publicly-available health data, providing a searchable online directory of data resources from all HHS operating divisions and several state and city open data portals. In addition, HealthData.gov enables the coordination of data stewardship practices to permit data release while minimizing risks.

The Work Group has identified opportunities to further enhance HealthData.gov, building on the portal’s successful implementation and use and on earlier improvements to the site. NCVHS expects to issue recommendations on HealthData.gov by mid-2017, to support the objectives of more effective use of the resource within HHS and by external users and the enhancement of data stewardship and governance.

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**NCVHS Letter on HHS Data Access and Use, 2014-16**

*Steps to Improve the Usability, Use and Usefulness of Selected Online HHS Data Resources* (March 20, 2014, Letter to the Secretary)
IV – Next steps: priorities for 2017-18

Based on lessons learned and input from industry during the reporting period, NCVHS has identified significant areas of opportunity for the next two years. It intends to explore these opportunities in addition to continuing its work in the areas described above. This section outlines three opportunities related to the pressing need for coordinated yet flexible policy levers. The Committee looks forward to additional guidance from HHS about areas in which the Committee’s advice and consultation will be needed in the coming years.

1. Predictability Roadmap for Adopting Standards and Operating Rules

As noted above, the healthcare industry has for many years expressed concern to NCVHS about the lack of predictability in regard to the updating and adoption of standards. The lengthy and complicated processes now associated with these standards make it virtually impossible for affected businesses and organizations to align their planning, budgeting, and work with end-users with the standards process. In 2017-18, NCVHS will assess the more efficient development and testing, adoption, implementation, and evaluation of HIPAA transactions and operating rules. Based on a review of opportunities for efficiency in the overall process and by the organizations responsible for given steps, NCVHS will develop recommendations to HHS aimed at achieving greater predictability in updating HIPAA transaction implementation specifications and operating rules.

NCVHS plans to identify a baseline of existing processes in applicable organizations including Standards Development Organizations (SDOs), the Operating Rule Authoring Entity (ORAE), the Designated Standards Maintenance Organization (DSMO), WEDI, and HHS/CMS. It plans to then identify enhancements from key industry stakeholders and Federal partners. After publicizing the enhancement options identified through stakeholder collaboration, NCVHS will hold a hearing to receive testimony on these options. On that basis, it will develop recommendations to be conveyed in a letter from NCVHS to the HHS Secretary proposing a predictability roadmap. The predictability roadmap is intended to provide the healthcare industry with a degree of certainty in the timing of the development, adoption, or implementation of new or revised standards or operating rules as required under HIPAA.

2. Beyond HIPAA

As described above, HIPAA was designed 20 years ago when healthcare was largely paper-based and providers and health plans were the acknowledged stewards of health information. Prior to the passage of HIPAA, electronic data processing was largely mainframe-based; data storage was expensive; and telecommunication was tape-to-tape. Further, the internet was rudimentary; interoperability did not exist; and electronic data exchange was primarily via claims submission
to payers in non-standard formats. HIPAA has changed the culture of healthcare in ways that now make it possible for private sector stakeholders to take initiative and act in partnership with government to create a more nimble and effective system of care.

Many of the issues commented upon by testifiers during the period covered by this report, and thus facing NCVHS for consideration, extend beyond HIPAA. That is, they concern privacy and security of data about health and healthcare that are maintained and used by entities and individuals that are not covered entities or business associates. A framework that sits alongside HIPAA is needed to enable health data users to deal with new challenges. In its proposed Beyond HIPAA project, NCVHS will explore issues and opportunities, including governance mechanisms and transparency, that can pick up where HIPAA leaves off. With HIPAA and the laws that have modified and enhanced it as the foundation, this project will explore key drivers of health information policy that are beyond the scope of HIPAA or are bumping up against its boundaries. To name a few, these new drivers include technology, APIs, mobile devices, big data and analytics, cybersecurity challenges, population and community health initiatives, personalized medicine and genomics, and the need to track the use of de-identified data.

In the Beyond HIPAA project, NCVHS plans to develop policy guidance in the following areas: guiding principles to advance the governance of health information and inform navigation of the changing landscape beyond HIPAA; consistent privacy policy across federal agencies, states, and the private sector; the shift to predictability and flexibility to enable responsiveness to changing business models; levers such as Quality Payment Programs that HHS can apply; best practices, education, and guidance; and legislative mechanisms such as fines for unauthorized use or misuse of health information.


Although the vital statistics system is a foundational national data system, as currently constituted this federated, state-based data system is vulnerable. The primary components of the vital statistics system are birth data and death data, with additional data systems for fetal deaths and marriage and divorce data. Vital statistics are used for health research, demography, and identity establishment. Individuals use birth certificates for routine activities such as obtaining driver’s licenses and registering children for school. Commercial uses include establishing the basis for insurance benefits and filing claims for death benefits. Vital statistics data are used by the Social Security Administration, Medicare, and other major programs to determine future revenues and costs. Vitals are a critical component of population estimates produced by the Census Bureau, and are used by the Bureau of Labor Standards as a basis for projections of the future labor force. Furthermore, vital statistics are a key component for identity establishment and protection as inputs for protecting individual identity and national security. Despite these and other critical uses, for a host of reasons the vital statistics system has
considerable unrealized potential for enabling public health surveillance, increasing the
effectiveness of the healthcare and health financing system, and being useful to business and
commerce.

NCVHS is charged with helping HHS to strengthen its data enterprise and assure its safety, for
maximum efficiency in assessing and promoting the population’s health. To address the
concerns outlined above, NCVHS plans to convene a two-day hearing in Fall, 2017, to obtain
input from key stakeholders including HHS, other Federal sources, state jurisdictions,
researchers, healthcare providers, and other experts. The hearing will focus on the role of the
vital statistics system, assess its current status and the risks to its viability, look at questions such
as linkage of vital records data with other data systems (e.g., health records), and consider what
actions are needed to protect and improve the vital statistics system. The Committee expects to
release a report on its findings about the next generation of vital statistics in early 2018.
### Appendix 1. About Administrative Simplification

#### Table 1: HISTORY OF HIPAA AND ACA REGULATIONS as of December 31, 2016

<table>
<thead>
<tr>
<th>Year</th>
<th>Date</th>
<th>Law or Reg</th>
<th>Topic of Law/Reg</th>
<th>Description</th>
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<tr>
<td>2000</td>
<td>Aug 17</td>
<td>Reg</td>
<td>Standards and Code Sets for Electronic Transactions and DSMO Process</td>
<td>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.</td>
</tr>
<tr>
<td>2001</td>
<td>Jan 3</td>
<td>Law</td>
<td>ASCA, Administrative Simplification Compliance Act</td>
<td>Congress requires electronic submission of Medicare claims.</td>
</tr>
<tr>
<td>2002</td>
<td>May 31</td>
<td>Reg</td>
<td>Employer Identification Number (EIN)</td>
<td>HHS adopts standard for Employer Identifier Standard (EIN) which becomes mandatory for use on July 30, 2002.</td>
</tr>
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<td>Year</td>
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<tr>
<td>2004</td>
<td>Jan 23</td>
<td>Reg</td>
<td>National Provider Identifier (NPI)</td>
<td>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.</td>
</tr>
<tr>
<td>2005</td>
<td>Sept 05</td>
<td>Reg</td>
<td>Electronic Health Care Claims Attachments</td>
<td>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.</td>
</tr>
<tr>
<td>2006</td>
<td>Feb 16</td>
<td>Reg</td>
<td>Enforcement of Administrative Simplification</td>
<td>HHS extended civil monetary penalties for privacy violations to apply to all Administrative Simplification violations, effective Mar 16, 2006.</td>
</tr>
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<td>Year</td>
<td>Date</td>
<td>Law or Reg</td>
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<tr>
<td>2009</td>
<td>Jan 16</td>
<td>Reg</td>
<td>ICD-10 Final Rule</td>
<td>HHS required <a href="#">HIPAA-covered entities</a> 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.</td>
</tr>
<tr>
<td>2009</td>
<td>Feb 17</td>
<td>Law</td>
<td>HITECH Act and Civil Penalties</td>
<td>Part of the <a href="#">American Reinvestment and Recovery Act</a>, HITECH adjusted civil monetary penalties for <a href="#">HIPAA</a> violations, including Administrative Simplification.</td>
</tr>
<tr>
<td>2010</td>
<td>Mar 23</td>
<td>Law</td>
<td>ACA, Patient Protection and Affordable Care Act</td>
<td>Congress expanded on <a href="#">HIPAA</a> 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.</td>
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<td>Year</td>
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<tr>
<td>2011</td>
<td>Jul 8</td>
<td>Reg</td>
<td>Operating Rules for Eligibility for a Health Plan and Claim Status</td>
<td>HHS adopted operating rules for eligibility and claim status transactions effective Jan 1, 2013.</td>
</tr>
<tr>
<td>2011</td>
<td>Dec 7</td>
<td>Reg</td>
<td>ICD-10 Medical Loss Ratio Update</td>
<td>HHS updated medical loss ratio requirements under ACA to help payers cover costs of ICD-10 transition.</td>
</tr>
<tr>
<td>2012</td>
<td>Jan 10</td>
<td>Reg</td>
<td>Standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA)</td>
<td>HHS published interim final rule for EFT standard, then announced, on Jul 10, 2012, that the Jan 10 standards rule is final.</td>
</tr>
<tr>
<td>Year</td>
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<tr>
<td>2012</td>
<td>Sept 5</td>
<td>Reg</td>
<td>HPID Standard and ICD-10 Compliance Delay to 2014</td>
<td>HHS adopted a standard for the Health Plan Identifier (HPID) and set a Nov 5, 2014, compliance date, while giving small plans until Nov 1, 2015, to comply. Effective Oct 31, 2014, HHS announced a delay until further notice in HPID enforcement.</td>
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</table>

- On Sept 23, 2014, NCVHS recommended HHS issue a rule that exempts the need to use an HPID in HIPAA transactions.
- May 29, 2015, HHS released a Request for Information to solicit industry feedback on three (3) questions. Moderate response received to the request for information. Implementation delay remains in place.

HHS also delayed **ICD-10 compliance date** from Oct 1, 2013, to Oct 1, 2014, to allow providers more time to prepare until 10/1/2015.
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<tr>
<th>Year</th>
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<th>Topic of Law/Reg</th>
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</table>
|      |       |            | Consolidated (Unofficial)                              | • OCR enforces privacy and security regulations on behalf of HHS.  
|      |       |            |                                                        | • CMS Office of Enterprise Information, National Standards Group, enforces all other Administrative Simplification regulations on behalf of HHS. |
|      |       |            |                                                        | HHS is finalizing a revised rule for how HIPAA-covered entities must certify their compliance with Administrative Simplification mandates. |
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.

Table 1 (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 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.

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.
Appendix 2. The Privacy Rule’s Four Tiers of Protection

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 (listed in Appendix A, Table I) 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 3. Acronyms Used in This Report

ACA - Affordable Care Act
BRFSS - Behavioral Risk Factor Surveillance System
CAQH CORE – CAQH Committee on Operating Rules for Information Exchange
CMS - Centers for Medicare & Medicaid Services
DSMO - Designated Standards Maintenance Organization
HHS - Department of Health and Human Services
HIPAA - Health Insurance Portability and Accountability Act
ICD-10 – International Classification of Diseases
NCVHS - National Committee on Vital and Health Statistics
NHANES – National Health and Nutrition Examination Survey
NHIS – National Health Interview Survey
OCR - HHS Office for Civil Rights
ONC - HHS Office for the National Coordinator of Health Information Technology
ORAE - Operating Rule Authoring Entity
PCAST - President’s Council of Advisors on Science and Technology
SDO - Standards Development Organization
WEDI - Workgroup for Electronic Data Interchange
Appendix 4. NCVHS charge and roster