1   <u>**National Committee on Vital and Health Statistics**</u>

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

5   May, 2017

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7   *[1-page executive summary will be added.]*

8   **I – Introduction**

9   This report by the National Committee on Vital and Health Statistics (NCVHS)[1] is the 12th such

10 report to Congress on the status of implementation of the Health Insurance Portability and

11 Accountability Act (HIPAA), which was passed in 1996 to enable electronic information exchange

12 for an efficient and effective healthcare system. To mark this important 20-year milestone,

13 NCVHS offers a high-level overview of the major advances, issues, and opportunities related to

14 the two goals advanced by HIPAA, administrative simplification and information privacy and

15 security.[2] The report reviews HIPAA and the progress toward its full implementation in the

16 broad context in which HIPAA provisions operate.

17 Administrative efficiency and information privacy and security are closely linked to, and indeed

18 dependent on, continued progress in the accessibility and usefulness of health data as well as

19 the adequacy of information on the population's health. Accordingly, this report describes the

20 National Committee's work in all these areas and identifies cross-cutting priorities. This broad

21 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.

22 Human Services (HHS), including standards; privacy, confidentiality, and security; population and
23 community health data; and data access and use. The report is primarily retrospective, offering a
24 synthesis of the cross-cutting themes identified through review of recent NCVHS
25 recommendations, summarization of the progress of HIPAA implementation, and a forward look
26 to future areas that NCVHS views as ripe for study, assessment, and development of
27 recommendations.

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

41 During the period covered by this report (2014-2016), NCVHS held 12 full Committee meetings
42 and 10 hearings and workshops, resulting in 15 letters and 6 reports on various aspects of
43 health information policy.[3] The present report draws on this work in addition to relevant work of
44 the HHS Office for the National Coordinator of Health Information Technology (ONC) and HHS
45 Office for Civil Rights (OCR), which provided guidance on a range of HIPAA implementation
46 issues during the reporting period.

47 The next section **(Section II)** outlines four complementary priorities related to data and
48 information that must be pursued simultaneously to achieve maximum benefit for Americans.
49 They concern balancing standardization and innovation, practicing data stewardship, educating
50 and supporting health data users, and leveraging the power of partnerships. **Section III** then
51 describes specific policy goals and themes in the areas of standards, privacy and security,
52 population health, and data access and use. References and links to NCVHS letters,
53 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/

54   Finally, **Section IV** outlines the steps that NCVHS plans to take in 2017-18 to envision the

55   optimal policy environment for continuing to advance HIPAA, advise on making the impacts of

56   HIPAA more predictable for covered entities,[4] and enhance the vulnerable vital statistics system.

57   Throughout this report, the Committee hopes to convey its judgment that HIPAA's

58   administrative simplification and privacy and security provisions can have the most positive

59   impact when (1) they are based on standards and operating rules that are consistently

60   implemented by all users; (2) they are an integral part of a predictable and coordinated

61   ecosystem of laws, regulations, and guidance; and (3) they function within a policy environment

62   that also encourages innovation and assures the availability of information to enable

63   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

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

1. Balance standardization and innovation to improve efficiency.

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

84   To adapt to this ever-changing environment, NCVHS suggests that future HIPAA
85   implementation efforts focus first on the handful of transactions that can be universally
86   implemented. Thus, NCVHS has recommended a focus on achieving consistent implementation
87   of the standards related to the five transactions that are already widely implemented by all
88   participants in those transactions.[5] This will be accomplished by broadened participation and
89   greater understanding of the value of consistent implementation, reinforced by enforcement
90   efforts. NCVHS will continue to advise HHS on adapting HIPAA regulations to evolving
91   conditions in consultation with industry representatives, standards development organizations,
92   and others.

93   Building on this platform of standardized transactions, NCVHS has urged the Federal
94   government to encourage the health system to experiment with new methods for achieving the
95   administrative simplification goals of HIPAA, and to leverage the innovative approaches of
96   others. Healthcare transactions and privacy and security protections need to keep pace with the
97   rapid changes in information technology and clinical practice as well as with system and
98   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.

99   inappropriate or harmful use, and other areas. The healthcare industry and other partners in
100   health are continuously developing new solutions in response to new challenges and
101   opportunities, and they should be encouraged to do so. When appropriate, the learnings from
102   these innovations can then be woven back into existing processes for consideration in
103   subsequent standards development.

104   The same principle of balancing standardization and innovation applies in the arena of
105   population and community health. As discussed below,[6] NCVHS developed a consensus
106   Measurement Framework for community-level health and well-being indicators, to facilitate
107   local data access and use. The two-fold goal of that effort is to provide 1) a parsimonious
108   measurement tool that enables national-scale coordination and benchmarking and 2) an
109   adaptable menu of metrics to meet diverse local needs. The creation of learning communities in
110   this arena, as in others, will facilitate sharing of the lessons and benefits of innovation.

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

116   ## 2. Practice consistent data stewardship to facilitate information use.

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

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[6] Pages 19-20

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

142   NCVHS has stressed the need to extend the chain of trust and accountability addressed in
143   HIPAA to encompass all uses of individually identifiable health data by all users.[7] In 2015, NCVHS
144   released a toolkit to facilitate data stewardship by those using data related to community
145   health.[8] This toolkit is a model of the kind of practical resource that can be useful for data users,
146   as discussed below.

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

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

161   There are many excellent models of such resources. The Committee commends ONC and OCR
162   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)

163 through web pages, FAQs, videos, and other forms of targeted resources.[9] In the realm of
164 community health data, many intermediary organizations have developed online resources that
165 make such data accessible and usable for community health improvement efforts. The National
166 Committee's own contributions to these resources include the toolkit on data stewardship for
167 community users described above and the Measurement Framework described below.
168 Additional targeted resources continue to be needed, to ensure that data are accessible and
169 usable for public benefit while the rights of individuals are protected.

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

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

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

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[9] ONC resources: https://www.healthit.gov/policy-researchers-implementers/computable-privacy; https://www.healthit.gov/providers-professionals/sharing-phi-electronically; https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html. OCR resources: https://www.hhs.gov/hipaa/index.html; https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

194   efforts of the Workgroup for Electronic Data Interchange (WEDI), the Health Datapalooza, the
195   100 Million Healthier Lives Initiative of the Institute for Healthcare Improvement, and the non-
196   governmental stewardship group formed to continue the work on the NCVHS Measurement
197   Framework for Community Health and Well-being.

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

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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.[10] Briefly, administrative simplification is carried out in three steps:[11]

> 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.

236   volume of electronic data interchange, the adopted standards have met many core business
237   needs of healthcare providers and health plans and decreased the cost and complexity of
238   administrative processes. This progress has enabled the healthcare industry to focus its
239   resources and technology investments more cost-effectively. For example, the 2016 CAQH Index
240   estimated that in 2015 alone there were at least $1.5 billion in savings as a result of standards
241   adoption, and projected potential savings of more than $9 billion if just the seven HIPAA
242   transactions measured by the Index were routinely utilized.[12] It also found that 94 percent of
243   healthcare claims are submitted using the standard, with savings ranging from a low of $1.95
244   per claim transaction, to industry savings as high as $9.25 per prior authorization transaction.
245   The CAQH Index estimates providers could save up to 20 minutes per eligibility transaction
246   conducted using the standard, currently accounting for at least $5 billion in wasted labor costs
247   each year. In addition, the Veterans Administration found that one of greatest benefits from the
248   eligibility transaction was the reduced amount of time needed to verify insurance.

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

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

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

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[12] 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.

268 industry collaboration since the passage of HIPAA. NCVHS has heard from industry that
269 maximum value is achieved when all parties to a transaction equally engage in and consistently
270 use the standards. Recognizing these challenges, in February 2016 NCVHS sent a letter to the
271 Secretary with recommendations for HHS, followed by a report in October 2016 that added
272 recommendations for Standards Development Organizations, the Operating Rule Authoring
273 Entity, and the healthcare industry. The recommendations include exploring the feasibility of
274 expanding the definition of HIPAA covered entities,[13] broadening education, ensuring
275 consistency, enforcing compliance, and ensuring responsiveness to evolving changes in
276 healthcare.

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

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

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

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[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.

292   disruptions, adversely affecting implementers' bottom lines and contributing to the cost of
293   healthcare. Ultimately, such issues are a disservice to the implementers and to the
294   patients/consumers they serve. NCVHS plans to address predictability solutions in 2017, as
295   described in Section IV.

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

298   The goal of administrative simplification is to maximize system efficiency and cost-effectiveness
299   by getting everyone to follow the same rules and practices. Achievement of this goal is thwarted
300   by the current definition of a HIPAA covered entity.[14] A number of organizational types are
301   currently not included in the definition of a HIPAA covered entity although they engage in
302   exchanging administrative and financial data related to health and/or healthcare. These
303   "uncovered" organizational types include banks and other financial institutions, some employers,
304   worker's compensation plans, and the property and casualty industry. The failure of these and
305   other entities to use electronic transaction standards could result in increased costs because of
306   the need for more translators, customization and maintenance to capture necessary data, and
307   information from those using proprietary methods.

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

310   As the healthcare landscape continues to change rapidly, increasing integration is needed
311   among clinical and administrative information flows and their supporting standards. Today,
312   healthcare finance policy favors integrated care models, and payment models based on value
313   and quality are being developed across the country. This growing need for integration has
314   significant implications for existing and planned administrative simplification provisions. It is
315   important to learn from a changing market and take advantage of opportunities related to
316   technology and new business processes as well as in various types of data standards. One
317   example of the need for alignment between clinical and administrative information flows and
318   supporting standards is the new policy direction in healthcare that could necessitate the use of
319   clinical data to inform system delivery and care reform efforts. There are also opportunities to
320   support a learning health system, guided by the Shared Nationwide Interoperability Roadmap,[15]
321   in order to build more robust public health and bio-surveillance capabilities to support the
322   government's critical role in monitoring disease outbreaks and threats. These and other
323   opportunities, such as better care coordination and more efficient transaction processing, will be
324   explored in the forthcoming NCVHS "Beyond HIPAA" project described in Section IV.

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[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

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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:

- http://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/2016-Ltr-to-Burwell-Findings-of-RC-Adm-Simp-June-2015-Hearing-Word.pdf (February 29, 2016)
- 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[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.[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.[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

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[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
[18] https://www.hhs.gov/ocr/; https://www.healthit.gov/providers-professionals/sharing-phi-electronically; https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html.

361   of a specific use, disclosure, or request.[19] In November 2016, NCVHS sent recommendations to

362   the HHS Secretary reaffirming the importance of the Minimum Necessary standard as an

363   essential provision of the HIPAA Privacy Rule and offering ten practical recommendations for

364   clarifying the regulation and promulgating guidance and education on its implementation. The

365   recommendations, for example, call upon HHS to develop specific guidance on adherence to the

366   Minimum Necessary standard by business associates. They call for clarification of how the

367   Minimum Necessary standard will be upheld in implementing the previously recommended

368   Attachments standards. They also call upon HHS to issue guidance that will support improved

369   implementation of the standard by both covered entities and business associates.

370   NCVHS also continues to monitor existing standards and the adequacy of existing guidance in

371   light of changing demands and technology. In September 2015, it sent recommendations to the

372   Secretary on HIPAA Section 1179, which creates a limited exemption from HIPAA requirements

373   for financial institutions engaged in certain healthcare-related financial transactions.[20] These

374   recommendations addressed evolving health-related banking and finance services and stressed

375   the value of greater coordination of regulation across health and finance sectors. NCVHS also

376   advises and collaborates with HHS on priorities such as the important work of OCR on HIPAA

377   rights education and of ONC on the privacy implications of interoperability and technology

378   advancements such as "computable privacy." The latter effort is designed to capture,

379   communicate, and process individual choice to enhance interoperability and move toward a

380   learning healthcare system.[21,22]

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

382   Digital health information is now more widely available and used by public and private entities

383   for analytics. The May 2014 report by the President's Council of Advisors on Science and

384   Technology (PCAST) recommended privacy policies for the era of big data.[23] 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.

385 are generally "de-identified" according to HIPAA standards; but once de-identified, these data
386 are no longer subject to HIPAA. There remains a persistent risk of re-identification as data sets
387 are combined and enhanced. NCVHS convened experts in a hearing on de-identification to
388 address the rapidly-expanding use of de-identified data and the growing risk of re-identification
389 associated with increasing opportunities to link datasets. In early 2017, NCVHS issued
390 recommendations calling for improved guidance on de-identification of protected health
391 information.

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

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

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

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

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[24] https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html and https://hipaaqsportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf

[25] ONC's report to Congress, *Examining Oversight of the Privacy and Security of Health Data Collected by Entities Not Regulated by HIPAA*, published in July of 2016, highlights key gaps and confusion among consumers on privacy and security of non-HIPAA covered entities, available at: https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.

[26] NCVHS toolkit for community data users (see citation and link in note 8).

414   continually take new forms. OCR has completed the first phase of its HIPAA compliance audits,
415   and it launched Phase 2 in 2016. It also stepped up enforcement activities from 2014-16,
416   regularly reporting to NCVHS on these actions. NCVHS supports the steps being taken by HHS
417   to strengthen understanding of and full compliance with both the Privacy and Security Rules, to
418   ensure the privacy of protected health information. As noted above, the Committee commends
419   the achievements of OCR and ONC in their provision of industry guidance.[27] New guidance
420   documents are announced on the Newsroom page of the OCR website.[28] Privacy and security
421   are foundational to trust; and trust is critical if the nation is fully to use health information to
422   improve the health system and serve the public good.

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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)

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[27] For example: https://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf.
[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 disproportionally 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.

452 accomplish this, the government has encouraged data sharing and strategic data integration. To
453 a great extent, the health of the nation is achieved cumulatively, through targeted local actions
454 taking place throughout the country. Looking forward, NCVHS sees a vital ongoing role for the
455 Federal government in supporting and informing these local efforts. This is a cost-effective
456 strategy for realizing national policy goals for the health of the American people. The Federal
457 government, with its expertise in data collection initiatives—including the Census, the National
458 Health Interview Survey, the CDC Social Vulnerability Index, the 500 Cities Project, and the
459 cooperative vital statistics system—helps provide technical guidance and support to state and
460 local governments and communities to improve health data available at the community level.

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

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

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

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

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[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).

486   integrated schema for data on health and its determinants, to enable data-driven decision-
487   making. Leaders in these efforts have told NCVHS that a consensus set of indicators or data
488   domains for indicators would add value.

489   In 2016, with broad input from experts, NCVHS developed a consensus Measurement
490   Framework for community-level indicators of health and well-being, to address the need for a
491   parsimonious approach to health data in light of a recent proliferation of indicators. The
492   Framework has ten domains (e.g., economy, food and agriculture, health, and housing) and
493   thirty sub-domains (e.g., income/wealth and employment within economy, and food availability
494   and nutrition within food and agriculture). It has a dual purpose of enabling both national-scale
495   coordination and local strategies. State and local leaders have affirmed that the Framework
496   provides a straightforward, easily-understood structure for organizing and collecting data that
497   highlight and identify problems and indicate directions for resources and interventions.
498   Participants at a September 2016 NCVHS workshop determined that the Measurement
499   Framework is ready for further development and testing by non-Federal entities, with additional
500   input from community leaders. Experts in the non-governmental sector have assumed
501   responsibility for completing development of the Framework and developing specific measures
502   of value at Federal, state, and local levels.

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

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> **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

526 ## D. Data Access and Use

527 *Overview*

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

534 *Themes and Findings*

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

537 The Work Group on Data Access and Use was created within NCVHS at the request of the HHS
538 Chief Technology Officer, to explore innovative uses and applications of HHS data to improve
539 health and healthcare and to provide recommendations for promoting and expanding access to
540 HHS online data. The Work Group is composed of NCVHS members and consultant members
541 who are nationally recognized for their expertise in the development of innovative data
542 applications as well as being active users of government data. The Work Group reviewed
543 available online HHS data (primarily HealthData.gov,[34] the Health Indicators Warehouse, and the
544 Health System Measurement Project) and evaluated the usability, use, and usefulness of the data
545 to which they provide access. In March 2014, NCVHS sent recommendations to the Secretary on
546 three topics: the user-friendliness of HealthData.gov, data documentation and metadata,[35] and
547 improving the timeliness of HHS data. The Committee cited examples of best practices from
548 industry leaders and recommended that HealthData.gov emulate these practices. It also
549 recommended that where practical, HHS data publishers apply elements of the common core
550 metadata schema.[36] Finally, NCVHS noted that the currency and timeliness of HHS data sets vary
551 widely, from the current year to several years old. It offered examples of HHS efforts to
552 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/

554   **2. NCVHS has identified recommendations to increase the effectiveness of**
555   **HealthData.gov.**

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

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

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

572   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

607   to payers in non-standard formats. HIPAA has changed the culture of healthcare in ways that
608   now make it possible for private sector stakeholders to take initiative and act in partnership with
609   government to create a more nimble and effective system of care.

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

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

3. Next-Generation Vital Statistics

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630   Although the vital statistics system is a foundational national data system, as currently
631   constituted this federated, state-based data system is vulnerable. The primary components of
632   the vital statistics system are birth data and death data, with additional data systems for fetal
633   deaths and marriage and divorce data. Vital statistics are used for health research, demography,
634   and identity establishment. Individuals use birth certificates for routine activities such as
635   obtaining driver's licenses and registering children for school. Commercial uses include
636   establishing the basis for insurance benefits and filing claims for death benefits. Vital statistics
637   data are used by the Social Security Administration, Medicare, and other major programs to
638   determine future revenues and costs. Vitals are a critical component of population estimates
639   produced by the Census Bureau, and are used by the Bureau of Labor Standards as a basis for
640   projections of the future labor force. Furthermore, vital statistics are a key component for
641   identity establishment and protection as inputs for protecting individual identity and national
642   security. Despite these and other critical uses, for a host of reasons the vital statistics system has

643   considerable unrealized potential for enabling public health surveillance, increasing the
644   effectiveness of the healthcare and health financing system, and being useful to business and
645   commerce.

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

655

656   APPENDICES

657   **Appendix 1. About Administrative Simplification**

658

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

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661

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

Year	Date	Law or Reg	Topic of Law/Reg	Description
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.

Year	Date	Law or Reg	Topic of Law/Reg	Description
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.
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.

Year	Date	Law or Reg	Topic of Law/Reg	Description
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.

Year	Date	Law or Reg	Topic of Law/Reg	Description
2012	Sept 5	Reg	HPID Standard and ICD-10 Compliance Delay to 2014	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**. - 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.

Year	Date	Law or Reg	Topic of Law/Reg	Description
2013	Mar 26	Reg	Administrative Simplification Regulations Consolidated (Unofficial)	HHS Office for Civil Rights (OCR) published unofficial combined version of Administrative Simplification regulations, updated through Mar 26, 2013. • 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.
2014	Jan 2	Reg	Certification of Compliance for Health Plans	HHS published a Notice of Proposed Rule Making (NPRM) for Certification of Compliance on Dec 31, 2013.). Technicalities prevented its implementation and made that NPRM obsolete. HHS is finalizing a revised rule for how HIPAA-covered entities must certify their compliance with Administrative Simplification mandates.
2014	Apr 1	Law	PAMA, Protecting Access to Medicare Act	Congress prohibited HHS from requiring ICD-10 compliance before Oct 1, 2015.
2014	Aug 4	Reg	ICD-10 Compliance Delay to 2015	HHS implemented PAMA, changing ICD-10 compliance date from Oct 1, 2014, to Oct 1, 2015.

Financial and Administrative Transactions and Code Sets

663

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

671 Table 1 (above) provides an overview of the regulations and related laws that have been
672 published under the HIPAA legislation since its release.

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

Unique Health Identifiers

685

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

701   recommendations and concern from industry, the Secretary imposed enforcement discretion for
702   the HPID rule, which remains in effect.

703   ## Operating Rules

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

713

714 **Appendix 2. The Privacy Rule's Four Tiers of Protection**

715

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

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

720 • In Tier 2, the Privacy Rule recognizes that certain discrete uses of data (listed in Appendix
721   A, Table I) offer societal benefits so compelling as to justify the use or disclosure even
722   without the individual's authorization. Here, the individual receives the protection of the
723   minimum necessary standard, which allows disclosure only to the extent necessary to
724   serve the beneficial use, and no more.

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

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

731

732

733   **Appendix 3. Acronyms Used in This Report**

734

735   ACA - Affordable Care Act

736   BRFSS - Behavioral Risk Factor Surveillance System

737   CAQH CORE – CAQH Committee on Operating Rules for Information Exchange

738   CMS - Centers for Medicare & Medicaid Services

739   DSMO - Designated Standards Maintenance Organization

740   HHS - Department of Health and Human Services

741   HIPAA - Health Insurance Portability and Accountability Act

742   ICD-10 – International Classification of Diseases

743   NCVHS - National Committee on Vital and Health Statistics

744   NHANES – National Health and Nutrition Examination Survey

745   NHIS – National Health Interview Survey

746   OCR - HHS Office for Civil Rights

747   ONC - HHS Office for the National Coordinator of Health Information Technology

748   ORAE - Operating Rule Authoring Entity

749   PCAST - President's Council of Advisors on Science and Technology

750   SDO - Standards Development Organization

751   WEDI - Workgroup for Electronic Data Interchange

752

753

754   **Appendix 4. NCVHS charge and roster**

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