



NCVHS 2021 Report to Congress

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

A report of the
National Committee on Vital and Health Statistics
A public advisory body to the Secretary of Health and Human Services



U.S. Department of Health and Human Services



NCVHS

National Committee on Vital and Health Statistics

October 7, 2021

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Madam Speaker:

I am pleased to transmit our *2021 Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA)*. In compliance with section 263, Subtitle F of Public Law 104-191, this report was developed by the National Committee on Vital and Health Statistics (NCVHS), the public advisory committee to HHS on health data, data standards, statistics, privacy, and national health information policy. It covers the period January 2019 through December 2020.

HIPAA was a visionary law that put the country on a path toward standardizing electronic health care transactions and protecting patients' health care information. At the time of its passage virtually all patient information was paper-based. Since then much has changed.

In this year's Report to Congress, NCVHS identified important trends that have impacted and continue to impact not only administrative simplification but all aspects of health information exchange. The COVID-19 pandemic exposed critical weaknesses in the nation's public health information infrastructure illustrating the need for greater harmonization of standards across data systems and improved data sharing. Patients' roles in accessing and using their health data have expanded and evolved as have new technologies, platforms, and models for managing health information.

In this report, the Committee outlines these trends and issues in detail along with highlighting several major challenges facing all sectors of the nation's health system today for which significant improvement opportunities remain.

The Committee serves a unique role in providing a forum for stakeholders, including from the private sector and across the health care industry, to contribute real-world facts-on-the-ground input to inform the Committee's deliberations and recommendations to HHS, all of which are available online.¹ As a Federal advisory committee to HHS, NCVHS also works in partnership with federal agencies and advisory bodies, including the Office of the National Coordinator (ONC) and its Health Information Technology Advisory Committee (HITAC) to ensure that the Committee's work is synergistic and in alignment with administration priorities.

¹ NCVHS website: <https://ncvhs.hhs.gov/reports/>

We hope that you will find the Committee's 2021 report informative and useful. The Committee looks forward to continue advancing these important issues for the benefit of the nation's health system and ultimately patient care and well-being. If your staff would like a briefing presentation on this or any of our past or anticipated activities, the Committee would be pleased to provide this information.

Sincerely,

/s/

Nick Coussoule, Chair
National Committee on Vital and Health Statistics

CC: Secretary Xavier Becerra
HHS Data Council

Enclosure

Identical letter to:

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Chairman
Committee on Finance
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Washington, D.C. 20510

The Honorable Patrick J. Leahy
President Pro Tempore
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The Honorable Patty Murray
Chairwoman
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The Honorable Richard Neal
Chairman
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U.S. House of Representatives
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The Honorable Robert C. Scott
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U.S. House of Representatives
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The Honorable Frank Pallone Jr.
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The National Committee on Vital and Health Statistics

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C.242(k)] public advisory body to the Secretary of the Department of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA). In that capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues. The Committee is composed of eighteen individuals from the private sector who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the members are appointed by the Secretary of HHS for terms of four years each. Two additional members are selected by Congress. See the NCVHS membership roster in Appendix 5 or visit <https://ncvhs.hhs.gov/>

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Executive Summary

The National Committee on Vital and Health Statistics (NCVHS) is charged with assisting and advising the Secretary of the Department of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Department's strategy to best address these issues. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 further directed NCVHS to report to Congress regularly on the implementation status of the HIPAA administrative simplification provisions. This 2021 NCVHS Report to Congress provides that status report. It provides reporting context by outlining major trends in health information that have contributed to the current status, as well as challenges and opportunities that can materially impact the continued advancement of the HIPAA administrative simplification provisions.

To provide context for the updated status, Section II of the report identifies the following five significant trends in the health information landscape:

1. New technologies, platforms, and models for managing health information—with varying degrees of maturity and implementation—have emerged to meet pressing business needs.
2. Patients' roles in accessing and using their health data have expanded and evolved.
3. The convergence of clinical and administrative data standards is gaining recognition and crossing the boundaries of traditional data and program silos.
4. Critical weaknesses in the public health information infrastructure were exposed by the pandemic.
5. Health information privacy and security challenges have proliferated.

These trends, exacerbated by the COVID-19 pandemic, collectively point to the need for a nationwide information vision, framework and infrastructure that connect federal, state, territorial, local public health and private sector agencies together and to the patients they serve; and emphasize the need for timely, actionable information across health data systems nationwide.

Within the context of the evolving environment, Section III of the report describes the progress of electronic data and data transmission standards updates, adoption, and implementation together with progress on health information privacy and security, including the issuance of rules and sub-regulatory guidance related to HIPAA implementation during the reporting period. Also during this reporting period, NCVHS issued several recommendations that outline approaches designed to improve the processes for updating, adopting, and using transaction and operating rules standards for administrative health care transactions. Those recommendations reflect industry consensus on a roadmap for advancing standardization in health care transactions to more timely address pressing industry needs. Appendix 3 provides a summary of the complete set of NCVHS letters and recommendations issued during the 2019-2020 reporting period.

Section III also provides an update on proposed changes to the HIPAA Privacy Rule by HHS and an overview of significant HHS activities related to the COVID-19 pandemic specific to the Rule, e.g., issuances of guidance, waivers, and Notices of Enforcement Discretion. It includes an update on trends in reports of breaches of unsecured PHI, with increases in hacking and cyberattack incidents impacting the ability of HIPAA-covered entities to access their EHR systems and deliver patient care without interruption. The Committee also reports updated data from the HHS Office for Civil Rights (OCR) on HIPAA enforcement actions, including an estimate that more than 28,000 HIPAA privacy violation complaints are anticipated to be reported in 2021.

Section IV of the report frames our nation's challenges and opportunities going forward. It outlines the following five areas that continue to challenge all sectors of the nation's health system and for which significant opportunities for improvement remain:

1. Comprehensive, integrated, national health information standards;
2. Greater focus on increased challenges to privacy, confidentiality, and security;
3. Enhanced data sources to support payment reform and price transparency;
4. Equitable information technology access across the "last mile" to reach all end users and thereby help close the health equity gap;
5. A nationwide, digitized infrastructure for pandemic-related information collection and sharing within the federal, non-federal and private federated systems.

Section IV of the report concludes with an outline of the Committee's current areas of focus:

1. Promoting convergence of clinical, administrative, social, and public health data;
2. Improving the health care industry's security posture;
3. Monitoring and advising on ICD-11 readiness; and
4. Identifying new approaches for data collection, sharing, linkages, and analytic methods to address health inequities.

The Committee recognizes the challenges ahead, especially with the addition of new entities (actors) that did not exist in 1996 when HIPAA was enacted, as well as the expanded scope of data sources in the health care information ecosystem. These expanded sources encompass all aspects of health and include social, behavioral and public health information, and will require innovative solutions and strong collaboration across sectors and agencies to be effectively utilized.

The Committee concludes the report by noting that its latest observations reaffirm the importance of health data and information that are available, linkable, private, and secure for optimal management of the nation's health – and it looks forward to undertaking new work to guide development of both near- and long-term recommendations in its role as advisor to HHS.

I. Introduction and Report Overview

The National Committee on Vital and Health Statistics (NCVHS) is charged with assisting and advising the Secretary of the Department of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Department’s strategy to best address these issues.¹ In this capacity, the Committee convenes relevant stakeholders and serves as a forum for interaction with public health, government, private sector, and academic experts on a range of health data issues. The Committee is composed of 18 experts in health care data and information, standards, epidemiology and public health, research, information technology (IT), data privacy and security, law, and related fields.

Congress passed Public Law 104-191, the Health Insurance Portability and Accountability Act (HIPAA) in 1996. One of HIPAA’s main sections, Subtitle F “Administrative Simplification,” mandates that HHS adopt standards for electronic transmission of administrative and financial information throughout the health care system, and for the privacy and security of protected health information (PHI).² These standards and privacy rules apply to covered entities—health plans, health care clearinghouses, and health care providers who exchange electronic health care information—and their business associates (contractors who perform certain functions on their behalf). The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009³ extended HIPAA liability for Security Rule compliance and some Privacy Rule provisions to business associates. HITECH also required covered entities and business associates to report breaches of unsecured PHI to the Secretary.

In addition to the above provisions, HIPAA expanded the responsibilities of NCVHS to include advising the Secretary of HHS on the adoption of the HIPAA Standards and Operating Rules, monitoring their implementation, and reporting on progress (Appendix 1). The present report is the Committee’s 14th report on HIPAA implementation and covers the period January 1, 2019, through December 31, 2020.^{4,5} The report identifies significant trends and changes in the health data ecosystem that have had an impact on the administrative simplification and privacy provisions of HIPAA. It describes the progress of standards adoption, including the issuance of rules and sub-regulatory guidance related to HIPAA implementation. It concludes by first identifying key challenges and opportunities for moving toward a more efficient and effective health system through digitized, secure information exchange across stakeholders, and then outlining the Committee’s specific areas of focus related to HIPAA in the coming period.

¹ National Committee on Vital and Health Statistics, 42 U.S.C. § 242k[k].

² Title II, subtitle F of Pub. L. No. 104-191, adding a new title XI, part C, to the Social Security Act (42 U.S.C. § 1320d et seq.).

³ Pub. L. 111-5, Title XIII, 123 Stat. 115, 226 (Feb. 17, 2009): <https://www.govinfo.gov/content/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf>.

⁴ See Appendix 2 for further information about administrative simplification.

⁵ Previous NCVHS reports to Congress are available on the Committee’s web site: <https://ncvhs.hhs.gov/>.

II. The Evolving Context for Health Information Policy

This section considers significant trends in health care and public health information needs and systems in 2019 and 2020. The trends relate to new technologies and platforms, expanded patient roles with respect to their data, converging clinical and administrative business processes, weaknesses in the public health information infrastructure, and privacy and security challenges. Many of these trends were significantly influenced by the COVID-19 public health emergency.

The reporting period for this report to Congress is unique in that the world experienced a global pandemic that stretched the health care industry and public health systems like no other crisis. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes Coronavirus Disease 2019 (COVID-19), created unparalleled challenges for the health care industry and public health system across the United States throughout 2020 and continuing into 2021.

The COVID-19 public health emergency has heightened awareness of the need for a nationwide, interoperable information infrastructure across federal, state, territorial, and local public health agencies and health care delivery provider settings to enable the nation to rapidly identify and mount an effective, unified response to public health emergencies.⁶

In health care, the COVID pandemic precipitated the widespread use of previously available but infrequently used virtual health care tools and practices. Stay-at-home orders created a pressing need for remote care and diagnostic tools and practices that transformed the physician-patient visit and the hospital experience. The rapid growth of telehealth technology use across the health care spectrum was further enabled by a series of HHS declarations and waivers. While HHS temporarily suspended enforcement of certain HIPAA privacy requirements during the declared public health emergency, the Department encouraged the use of reasonable safeguards to protect the privacy and security of individuals' PHI. Such safeguards include using only the minimum necessary PHI, employing encryption technology, and enabling more extensive privacy settings. These temporary exceptions to the Privacy and Security Rules to enable telehealth have spurred further growth of virtual care practices and technologies to augment or substitute for in-person care, supported by policies to guide how these changes should be implemented.

During the 2019-2020 reporting period, the development of new technologies and platforms also made it easier for patients to access and share their health information and use data to manage their own health, inform conversations with their providers, compare health care prices, engage with condition-specific support groups, and take advantage of third-party health care applications. This has heightened the need for patient education on the benefits and risks

⁶ Interoperability is the ability of different computer systems and software to exchange and make use of information.

of greater data access and data sharing.

This increase in health data availability and sharing has also increased opportunities for bad actors to obtain and misuse personal information. In addition, a significant portion of health data are generated, aggregated, or exchanged outside the scope of HIPAA protections, thus increasing consumer vulnerability. Widespread cybercrime took place across the health care sector throughout 2019 and 2020, in many cases attributed to vulnerabilities exposed by lax security practices during the pandemic.⁷

On a positive note, 2019-20 saw multiple efforts to harmonize standards for the two major types of health care data – clinical and administrative – and improve integration of these data sources across health, wellness and public health data systems. A notable example is the project undertaken by the ONC Integration of Clinical and Administrative Data (ICAD) Task Force, in which NCVHS played a major role, as described below on page 9 and in Appendix 3.H. These efforts generated progress toward a converged information ecosystem that facilitates appropriate information access and exchange for stakeholders across the health care system, including patients, providers, payers, public health and vital records professionals, researchers, and policymakers.

Five Major Trends in Health Information

This report outlines five cross-cutting trends in health care and public health. Based on input gathered from health care providers, hospital systems, health plans, public health, federal and state agencies, and academia, NCVHS finds these interrelated trends particularly relevant to health information policy. The Committee believes continued strong national engagement and leadership are essential to address these developments.

1. New technologies, platforms, and models for managing health information—with varying degrees of maturity and implementation—have emerged to meet pressing business needs.

The pace of change in the health information ecosystem has quickened with the interplay among information needs, technological innovation, and actions designed to promote health system advances, on the one hand, and the need to keep individuals' data secure and respect patient privacy, on the other. Health plans are employing value-based care, a form of reimbursement that compensates providers based on improved health outcomes rather than the quantity of services they provide, to provide incentives for better care coordination and

⁷ "INTERPOL report shows alarming rate of cyberattacks during COVID-19," August 4, 2020: <https://www.interpol.int/en/News-and-Events/News/2020/INTERPOL-report-shows-alarming-rate-of-cyberattacks-during-COVID-19>

information sharing, with greater focus on population health.⁸ In addition to information exchange between care settings, value-based care depends on the collection of demographic, cost, and clinical data, including information on patients' social determinants of health (SDOH).⁹ Providers can then identify at-risk patients (and communities), understand the factors affecting patients' health status and make appropriate referrals for those patients experiencing disparities.

To meet a host of emerging information needs during the reporting period, the health care system saw significant advances in the availability and adoption of new technology for managing and exchanging health information. For example, machine learning and artificial intelligence (AI) technology data systems are now embedded in many health care functions. The use of application programming interfaces (APIs), interactive technologies and communication standards such as Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)¹⁰ has increased exponentially, making exchange of health information faster, more efficient, and more broadly available, though not evenly deployed across the system. These technologies are designed to capture health, wellness and SDOH data more accurately at individual and population levels, and have contributed to efforts to include these data in electronic health records (EHRs) and clinical case reports. New platforms for digital exchange (technology that coordinates health care networks, community-based organizations, and social

⁸ Kindig and Stoddart (2003) define **population health** as an approach that focuses on interrelated conditions and factors that influence the health of populations [i.e., population groups] over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and well-being of those populations. Population health includes both the definition of measurement of health outcomes and the pattern of determinants, which include medical care, public health interventions, genetics, and individual behavior, along with components of the social, e.g., income, education, employment, culture, and physical, urban design, clean air, water, environments (<https://pubmed.ncbi.nlm.nih.gov/12604476/>). In contrast, **public health** can be defined as what “we as a society do collectively to assure the conditions in which people can be healthy.” (Institute of Medicine. 1988. *The Future of Public Health*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/1091>.)

⁹ Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOH have a major impact on people's health, well-being, and quality of life. Examples of SDOH include safe housing, transportation, and neighborhoods; racism, discrimination, and violence; access to nutritious foods and physical activity opportunities; and polluted air and water. SDOH also contribute to wide health disparities and inequities. For example, people who don't have access to grocery stores with healthy foods are less likely to have good nutrition. That raises their risk of health conditions like heart disease, diabetes, and obesity — and even lowers life expectancy relative to people who do have access to healthy foods: <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>

¹⁰ The HL7® FHIR® (Fast Healthcare Interoperability Resources, pronounced “fire”) standard defines how computer systems can exchange health care information regardless of how it is stored in those systems. It allows health care information, including clinical and administrative data, to be available securely to those who have a need to access it, and to those who have the right to do so for the benefit of a patient receiving care. The standards development organization HL7® (Health Level Seven®) uses a collaborative approach to develop and upgrade FHIR. FHIR is based on internet standards widely used by industries outside of health care. FHIR significantly lowers the barriers of entry for new software developers to support health care needs. While the information requirements of health care data are extremely complex, the HL7® FHIR® standard is a landmark step to remove many of the barriers to health care data exchange. <http://hl7.org/fhir/>

service providers),¹¹ also have emerged to share behavioral and social service data among community service and health care providers.

Electronic data exchange outside institutional walls has become commonplace, aided by connections among the health information exchange (HIE) organizations that exist in many regions across the U.S. and ubiquitous health information networks using the internet. In addition, as discussed above, during 2020 an increasing number of non-urgent patient care visits took place using remote and virtual care technologies due in large part to the COVID-19 pandemic.¹² Developers started to create new mobile apps for exposure notification and vaccination tracking in response to COVID-19 (see Appendix 3.G).

A number of public-private collaborations, such as the HL7 DaVinci project,¹³ the Gravity project,¹⁴ and the Argonaut project,¹⁵ are facilitating these developments by working as “accelerators” of new technology for health information exchange among patients, payers, and providers. At the same time, HHS has developed policy guidance and regulations to extend opportunities for patient-directed information exchange while protecting its contents. For example, the May 2020 CMS Interoperability and Patient Access final rule is designed to give patients better access to their health information, improve interoperability, and promote innovation, while also reducing burden on payers and providers.¹⁶ As another example of new cross-institution data sharing, the federal Health Information Technology (HIT) Strategic Plan,¹⁷

¹¹ For example, see “Unite Us” care platform from Center for Health Care Strategies: <https://www.chcs.org/digital-health-products/unite-us-care-platform/>

¹² “The Impact of COVID-19 on Outpatient Visits in 2020,” The Commonwealth Fund, February 22, 2021: <https://www.commonwealthfund.org/publications/2021/feb/impact-covid-19-outpatient-visits-2020-visits-stable-despite-late-surge>

¹³ HL7 Davinci Project stakeholders are industry leaders and health IT technical experts who are working together to accelerate the adoption of HL7 Fast Healthcare Interoperability Resources (HL7® FHIR®) as the standard to support and integrate value-based care (VBC) data exchange across communities. The project was initiated to promote interoperability across stakeholders and to guide the development and deployment of interoperable solutions on a national scale because interoperability challenges have limited many stakeholders in the healthcare community from achieving better care at lower cost: <https://www.hl7.org/about/davinci/>

¹⁴ HL7 Gravity Project is a national public collaborative that develops consensus-based data standards to improve how we use and share information on social determinants of health (SDOH): <https://confluence.hl7.org/display/GRAV/The+Gravity+Project>

¹⁵ HL7 Argonaut Project is a private sector initiative to advance industry adoption of modern, open interoperability standards. The purpose is to rapidly develop a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for electronic health records and other health information technology based on Internet standards and architectural patterns and styles: https://argonautwiki.hl7.org/Main_Page

¹⁶ “Interoperability and Patient Access,” CMS.gov Fact Sheet. (March 9, 2020): <https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet>

¹⁷ Health IT Strategic Plan: <https://www.healthit.gov/topic/about-ohc/health-it-strategic-planning>

ICD-10-CM,¹⁸ ICD-11, SNOMED CT,¹⁹ and USCDI²⁰ all now include data on social factors affecting health.²¹ Collection of SDOH data has become more common within many provider organizations but this captured data has not been exchanged with other institutions nor has it been consistently translated to standardized information due in large part to lack of industry consensus regarding technical specifications.²² A 2014 National Academy of Medicine report suggested that the collection of SDOH data in an EHR is necessary to empower providers to address health disparities and support further research into the health effects of SDOH.

The growth in telemedicine heightened awareness of data exposure risks and challenges, including those related to secure messaging, remote monitoring, and shared data standards. Recent events in the health information ecosystem, e.g., data breaches and ransomware attacks, also present a number of privacy and security challenges that in some circumstances have led to public distrust of the institutions that manage health information. This is further discussed in subsection 5 below (page 10-12).

These factors have spurred significant progress in health information data exchange, though they also have created challenges, especially for public health, small clinics, and rural providers. One challenge is the wide variation in capacities and implementation rates across health care providers and organizations, which make it necessary for payers and policymakers to accommodate widely varied technical and governance practices and capabilities. In addition, significant “last mile” issues exist for small providers, safety net systems, and rural areas, which affect IT support, health record system workflow configuration, workforce training, and affordable and available broadband telecommunications connectivity.²³

¹⁸ International Classification of Diseases, Tenth Revision (ICD-10). In the U.S., the ICD-10 code set has two components: the ICD-10-CM (clinical modification) codes for diagnostic coding, and the ICD-10-PCS (procedure coding system) for inpatient procedures performed in the hospital. For details: “Fundamentals of Medical Billing and Coding”: <https://revcycleintelligence.com/features/exploring-the-fundamentals-of-medical-billing-and-coding>

¹⁹ SNOMED CT is a multi-lingual healthcare terminology that supports the development of comprehensive high-quality clinical content in electronic health records. It provides a standardized way to represent clinical phrases captured by the clinician and enables automatic interpretation of these: <https://www.snomed.org/snomed-ct/five-step-briefing>.

²⁰ United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange: <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

²¹ USCDI (United States Core Data for Interoperability) is a set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

²² Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017. CMS Office of Minority Health *Data Highlight*, No. 18. January 2020: <https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf>.

²³ For purposes of this report, “last mile” issues concern the ability of the telecommunications network chain to physically reach the end-user’s premises and be successfully incorporated into office systems, procedures and workflows.

2. Patients' roles in accessing and using their health data have expanded and evolved.

Patients' right to access their health information is a cornerstone of the HIPAA Privacy Rule. The "Right of Access" HIPAA enforcement initiative of the HHS Office for Civil Rights (OCR), announced in 2019, reinforced the importance of the right of patients' access to their health information.²⁴ During the reporting period (2019-20), new opportunities to exercise this right opened up, with patients assuming a more central and active role in the health information landscape. To date, there have been 18 enforcement actions as part of this initiative. ONC's interoperability and information blocking rule now requires health care providers to give patients access to their electronic protected health information (ePHI) comprising a variety of data elements, including clinical notes.²⁵

As new technologies and policies have grown to enable expanded patient involvement, more patients have used technology to access and share their health information. Particular cohorts and social networks, such as cancer patient communities, are leading the way to expand patient interest and skills in using health information resources and personal health data to manage their health in partnership with their providers.

This trend has led to increased recognition of the need for transparency and attention to patients' needs and preferences when developing information-sharing technologies and policies. With that recognition comes an awareness of the need for robust patient education about the risks and benefits of increased information access and how patients can use the opportunity safely and effectively outside the protections of HIPAA.

3. The convergence of clinical and administrative data standards is gaining recognition and crossing the boundaries of traditional data and program silos.

As noted, there has been progress toward an interoperable, integrated health and wellness data exchange system that minimizes the burdens on all health care stakeholders. In recent years, a number of private and public organizations have been working to improve the automation and interoperability of clinical and administrative data. A notable step in that direction took place in 2020, when NCVHS collaborated with the HHS Office of the National Coordinator for Health IT's (ONC's) advisory committee, the Health Information Technology Advisory Committee (HITAC), to create, lead, and serve on the ICAD Task Force. The ICAD Task Force submitted its report to the HITAC in October 2020, with prior authorization as the primary use case (see Appendix 3.H). Its recommendations will inform future approaches to promoting the convergence of clinical and administrative data and improving interoperability. The ultimate goals of data integration and system interoperability are to support clinical care, reduce burden, and improve efficiency in accordance with the ICAD principle of "record once

²⁴ "OCR Settles First Case in HIPAA Right of Access Initiative," Sept 9, 2019: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/bayfront/index.html>.

²⁵ "New Day for Interoperability—The Information Blocking Regulations Start Now," ONC Health IT Buzz, April 5, 2021: <https://www.healthit.gov/buzz-blog/information-blocking/a-new-day-for-interoperability-the-information-blocking-regulations-start-now>.

and reuse.”²⁶ The closely-related NCVHS project on data convergence²⁷ is described below (pages 30-31) and in the referenced ICAD report (pages 16-17).²⁸

The prior authorization process serves as a useful exemplar of the urgent need for enhanced integration of health care administrative and clinical data.²⁹ Patients must obtain authorization from the relevant payer prior to receiving particular procedures or services to ensure insurance coverage for the service. Evidence and testimony clearly indicate that prior authorization processed can pose significant administrative burdens and delays in care, which can create hardship for patients and clinicians alike and has been shown to have serious impacts on health care quality and outcomes.³⁰ Streamlining and standardizing the prior authorization data exchange across all payers would promote administrative efficiency and improve care delivery.

The expansion of value-based care programs is driving the need for patient-centric data from multiple sources and organizations in order to manage the health of enrolled populations. This type of data integration supports delivery of efficient and lower cost care by coordinating patient care in order to reduce duplication in services, identify at-risk populations, and avoid preventable hospitalizations and emergency department visits.^{31,32}

NCVHS will continue its collaboration with industry stakeholders and the HHS Office of the National Coordinator (ONC) to facilitate data convergence to advance the promise of an integrated, patient-centric health information ecosystem.

4. The COVID-19 pandemic has exposed critical weaknesses in the public health information infrastructure.

The COVID-19 pandemic has shed light on long-existing weaknesses in public health information system data compilation and exchange. The pandemic has clarified the urgent need to modernize the public health information infrastructure and data sources, which too often is

²⁶ ICAD Task Force Report, p.46, as described in Appendix 3.H, which includes a link to the report.

²⁷ NCVHS Standards Subcommittee Project Scope, “Standardization of Information for Burden Reduction and Post-Pandemic America,” June 21, 2021: <https://ncvhs.hhs.gov/wp-content/uploads/2021/07/NCVHS-SS-project-scoping-convergence-2021-06-21-508.pdf>

²⁸ ICAD Task Force Report, as described in Appendix 3.H, which includes a link to the report.

²⁹ Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before the service is rendered to a beneficiary and before a claim is submitted for payment: <https://www.cms.gov/files/document/opd-frequently-asked-questions.pdf>

³⁰ See page 12 of HITAC ICAD Task Force report: https://www.healthit.gov/sites/default/files/page/2021-02/2020-11-17_ICAD_TF_FINAL_Report_HITAC_508_0.pdf and AMA presentation to HITAC ICAD, Heather McComas, PharmD, Director, Administrative Simplification Initiatives, May 12, 2020:

https://www.healthit.gov/sites/default/files/facas/2020-05-12_ICAD_TF_AMA_Presentation_508.pdf

³¹ American Journal of Managed Care, December 2017, Volume 23, Issue 12:

<https://www.ajmc.com/view/edbased-care-coordination-reduces-costs-for-frequent-ed-users>

³² Evaluation of a Multidisciplinary Care Coordination Program for Frequent Users of the Emergency Department, Flowers, Angela DNP, MBA, RN; Shade, Kate PhD, RN Professional Case Management:

https://journals.lww.com/professionalcasemanagementjournal/fulltext/2019/09000/evaluation_of_a_multidisciplinary_care.3.aspx

paper-based and reliant on fax machines for case reporting. Glaring gaps in interoperability and data sharing hamper analysis and leave unanswered major questions such as how specific population groups are faring, what actual outcomes look like, what resources are available, and what the accurate death rate is. The need to track patients' post-vaccination experience for potential complications has been added to the urgent information demands, complicated by the fact that this information is not routinely linked to other patient records.

Furthermore, the pandemic has heightened awareness of the wide disparities and lack of health equity among different U.S. racial, ethnic and other population groups and geographic areas. It has also highlighted stark disparities among the financial, human, and technical resources of different local, tribal and state public health departments. Increased reliance on the use of technology has raised awareness of the inability of some communities to access resources, such as affordable and available broadband telecommunications connectivity. While affordable broadband is available to most of the U.S. population, it is not available to (nor affordable for) many small/rural communities and certain communities within large/urban areas.

Moreover, the pandemic has exposed critical weaknesses in the public health surveillance system that supports population health. As a national system, our public health information infrastructure is too fragmented and under-resourced to supply critical information reliably to health care providers, public health departments, and policymakers.

Federal, state, territorial, tribal, and local governments require timely bidirectional electronic data exchange to monitor population health and manage public health emergencies. However, decades of fragmentation, non-standardized data submission requirements, and inconsistent data reporting formats across jurisdictions have resulted in critical gaps in information availability and comparability. The public health information infrastructure has been stressed to adapt to the volume and varieties of case data and health resources data needed to track and manage the pandemic while facing information gaps, fragmentation, lack of standardization, and human and financial resource scarcities.

In many cases, these issues have made it necessary for hospitals to manually compile, calculate, and submit requested data through web portals. (See sidebar.) Besides being inefficient, the fragmentation of the public health information system also poses burdens on private sector systems. COVID-19 reporting requests and requirements from federal and state agencies have

Fragmentation Is Inefficient

In the absence of an effective hospital reporting system, COVID-19 reporting to local, state and federal governments caused extreme administrative burden to health care providers through unclear, conflicting, and duplicative reporting requirements across agencies. Each reporting stream required separate interpretation, calculation, and manual reporting. The non-standardized approaches added to the reporting burden in the midst of a health care utilization crisis. One regional multi-specialty health system had to compile over 360 different data elements to meet the reporting requirements. Additionally, multiple agencies have requested different data (or the same data but in a different form, format or code set) that often do not match standard code sets and descriptions, or which require manual calculation. The data requests required labor-intensive and error-prone manual submission through direct data input or uploads to websites.

—Oral report to NCVHS Subcommittee on Standards (January 7, 2021)

necessitated a system-wide hospital effort to maintain seven-day-a-week reporting. While the importance of these data requests is unquestionable, complying with the numerous and uniquely customized requests has consumed substantial resources and imposed significant provider burden during the public health emergency.

The public health data now being captured vary in the ways in which demographic information is collected, codified and released, limiting the utility of the data especially in a public health emergency. Suppression of geographic specificity protects privacy but may limit understanding of risks and potential harms at neighborhood, community, or population levels. States have struggled to develop and maintain dashboards providing timely and comprehensive COVID-19 statistics for the public. A lack of uniform public health data standards, compounded by the complexity of some data-sharing agreements and laws, in many cases undermines timeliness of reporting and data quality. Linkages are needed across administrative data, clinical treatment data, public health surveillance data, immunization data, testing data, and lab data to support various business use cases such as patient referrals between providers or hospital diversions due to over-capacity emergency departments and intensive care units.

Finally, leaders responsible for national and community health need access to more complete small-area data to help them understand the health status of specific population groups and localities for priority-setting. In this regard, the release in 2019 of the *WIN Measurement Framework* was a significant and timely development. Leveraging the initial framework developed by NCVHS in 2017,³³ the *Well-being in the Nation Network* developed its Framework in collaboration with NCVHS.^{34,35} The Committee applauded the WIN Framework as a targeted set of indicators on which the federal government could make valuable small-area data available to communities and counties.

5. Health information privacy and security challenges have proliferated.

The health information ecosystem experienced important changes related to the privacy and security of the nation's health information during the reporting period. Many new tools including mobile apps and health devices for managing health information have emerged during the COVID-19 nationwide emergency, including those for exposure notification. A major concern, however, is that much of the health data being generated, aggregated, and shared through new technologies and platforms is not protected by HIPAA. Meanwhile, health data have become an increasingly valuable commodity, and the gaps in protection are exacerbated by a lack of mechanisms for identifying and controlling "bad actors." NCVHS continues to advise

³³ NCVHS Report, "Measuring Health at the Community Level: Data Gaps and Opportunities," p.29. March 1, 2017: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/Measuring-Health-at-the-Community-Level-Data-Gaps-and-Opportunities.pdf>

³⁴ "Well-Being in the Nation: A Living Library of Measures to Drive Multi-Sector Population Health Improvement and Address Social Determinants," S. Saha et al. *The Milbank Quarterly*, Vol. 98, No. 3, 2020 (pp. 641-663). Sept 1, 2020.

³⁵ Well-Being in the Nation measures website: <https://insight.livestories.com/s/v2/win-measures/2fda874f-6683-49bd-adb2-22f6f3c5a718>

the Secretary on the privacy and security issues involving technologies that fall outside the scope of HIPAA.³⁶

The HHS Office for Civil Rights (OCR) works with other federal agencies to enforce HIPAA provisions and promulgate regulations that address the importance of data access and use, along with appropriate privacy and security protections. As described in the Introduction section of this report, during the COVID pandemic HHS used its discretion to temporarily suspend certain specific provisions of the HIPAA Privacy and Security Rules, allowing providers to use telehealth technologies for virtual health care³⁷ and permitting them to share PHI more easily for public health purposes,³⁸ among other permissions. Federal regulations are part of a larger national patchwork of disconnected and sometimes conflicting privacy policies and laws, including some enacted at the state level that set locally higher standards.

Regulations implementing the 21st Century Cures Act's information blocking and interoperability provisions require health care providers and health plans to provide patients quick access to their health information through third-party mobile or internet software applications. Many applications that patients select to access their health information are not subject to HIPAA's privacy and security standards. This rule became effective in May 2021 and requires that health care providers give patients access without charge to all the health information in their EHRs "without delay."³⁹

Most seriously, recent years have seen an unprecedented proliferation of cybersecurity events, malware, ransomware, and data breaches. In 2019, there was a period of widespread cybercrime across the health care sector that increased in frequency and severity in 2020, in part as a result of the COVID-19 pandemic. There have been massive data breaches of personal information and other cybersecurity events in both the public and private sectors, perpetrated by both private and suspected state-sponsored bad actors.⁴⁰ At the same time, the pandemic has forced organizations to operate remotely, increasing reliance on third-party digital infrastructure and exposure to potential cyberthreats. Recognizing the pressure on health care organizations and the new dependence on remote access, cybercriminals saw an opportunity to target organizations that must, by necessity, pay to resolve ransomware events. In some

³⁶ NCVHS has studied and issued recommendations to the Secretary on "Beyond HIPAA" issues, as described in Appendix 1A. [Health Information Privacy Beyond HIPAA: A Framework for Use and Protection](#), issued June 18, 2019.

³⁷ OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Public Health Emergency, March 17, 2020: <https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html>

³⁸ OCR Issues Guidance on HIPAA, Health Information Exchanges, and Disclosures of Protected Health Information for Public Health Purposes, December 18, 2020: <https://www.hhs.gov/about/news/2020/12/18/ocr-issues-guidance-on-hie-and-disclosures-of-protected-health-information-for-public-health-purposes.html>

³⁹ "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," Final Rule issued by ONC on May 1, 2020: <https://www.healthit.gov/curesrule/>

⁴⁰ "Officials Warn of Cyberattacks on Hospitals as Virus Cases Spike," The New York Times, 10/28/2020: <https://www.nytimes.com/2020/10/28/us/hospitals-cyberattacks-coronavirus.html>

Health-Related Cybercrime in 2019-2020

- An attack that shut down the University of Vermont Medical Center’s electronic medical record system for nearly a month forced the hospital to turn away hundreds of cancer patients scheduled to receive chemotherapy.
- A ransomware attack on the cloud service provider Blackbaud Inc. exposed more than one hundred of Blackbaud’s health care clients and more than 10 million records were compromised. Prior to deploying ransomware, the hackers stole the fundraising and donor databases of many of Blackbaud’s clients, which included information such as names, contact information, dates of birth, and some clinical information. Victims included Trinity Health (3.3 million records), Inova Health System (1 million records), and Northern Light Health Foundation (657,392 records).
- The Florida-based business associate MEDNAX Services, Inc., a provider of revenue cycle management and other administrative services to its affiliated physician practice groups, experienced one of the largest phishing attack of 2020. Hackers gained access to its Office 365 environment and potentially obtained the ePHI of 1,670 individuals, including Social Security numbers, driver’s license numbers, and health insurance and financial information.
- Magellan Health’s million-record data breach also started with a phishing email and ended with ransomware being deployed. The breach affected several of its affiliated entities and potentially saw patient information stolen.
- Dental Care Alliance, a dental support organization with more than 320 affiliated dental practices across 20 states, had its systems hacked and the dental records of more than 1 million individuals were potentially stolen.
- First reported in December 2020, SolarWinds, a major U.S. information technology firm, was the subject of a major cyberattack that spread to its clients and went undetected for months. In a coordinated effort backed by the Russian government, hackers penetrated thousands of organizations, including the cybersecurity firm FireEye and health care organizations.

reported cases, these cyberthreats forced health care organizations to suspend patient care and vaccine research, revert to pen and paper, and convert cash to cryptocurrency to pay their attackers.⁴¹ Cyber-attackers were shown to be capable of intentionally invading patient care systems, potentially creating life-threatening risks. One result of these crimes is that, according to surveys conducted by the Pew Research Center, a majority of the U.S. public now distrusts both the private sector and government to manage their personal health information safely.⁴²

⁴¹“Patients of a Vermont Hospital Are Left ‘in the Dark’ After a Cyberattack,” The New York Times, 11/26/2020: <https://www.nytimes.com/2020/11/26/us/hospital-cyber-attack.html>

⁴² Pew Research Center, Trust in Institutions (2019), and Americans’ Complicated Feelings in an Era of Privacy Concerns (2018).

The following examples (see textbox, above) and the data provided in Section III.B (pages 23 - 26) show the need for an improved cybersecurity posture across the health care industry, including enterprise-wide risk analyses and risk management.

Some policymakers have called for comprehensive federal privacy legislation, but to date comprehensive legislation has not been enacted. At the state level, however, momentum has been building to enact increasingly strong data privacy and breach notification laws. For example, California voters passed an initiative in November 2019 to strengthen existing legislation through the California Privacy Rights and Enforcement Act of 2018,⁴³ and several other states have similar bills pending, or recently enacted.⁴⁴ In addition, during the 116th session of Congress,⁴⁵ lawmakers introduced two competing privacy bills aimed at protecting privacy interests related to data collection in connection with the COVID-19 response.^{46, 47}

III. Progress and Status of HIPAA Implementation

The five trends described in Section II have clearly impacted the health care information system in significant ways. To place these developments in the context of HIPAA, this section provides an overview of progress toward implementing HIPAA Administrative Simplification Provisions and Privacy Rules in the 2019-20 reporting period.

A. HIPAA Transaction and Medical Code Set Standards

1. Transactions Background

HIPAA was a visionary 1996 law that put the country on a path toward standardizing electronic health care administrative transactions and protecting patients' health care information. By ensuring consistency throughout the industry, the HIPAA standards make it feasible for health plans, health care clearinghouses, doctors, hospitals, and other health care providers to automate the processing of claims and related transactions, thereby improving the efficiency and effectiveness of the health care system.

Standardization of administrative transactions is carried out in three steps:

1. **Legislation:** HIPAA named the transactions for which covered entities in the health care

⁴³ California Privacy Rights and Enforcement Act of 2018, November 4, 2019: https://oag.ca.gov/system/files/initiatives/pdfs/19-0021A1%20%28Consumer%20Privacy%20-%20Version%203%29_1.pdf

⁴⁴ Colorado and Virginia enacted significant new data privacy laws in 2021: https://leg.colorado.gov/sites/default/files/2021a_190_signed.pdf and <https://law.lis.virginia.gov/vacodepopularnames/personal-information-privacy-act/>

⁴⁵ The 116th Congress began on January 3, 2019, and ended on January 3, 2021.

⁴⁶ COVID-19 Consumer Data Protection Act of 2020, S. 3663, 116th Cong. (2020), available at <https://www.congress.gov/bill/116th-congress/senate-bill/3663/text>.

⁴⁷ Public Health Emergency Privacy Act, S. 3749, 116th Cong. (2020), available at <https://www.congress.gov/bill/116th-congress/senate-bill/3749/text>.

industry must adopt standards. The Affordable Care Act (ACA)⁴⁸ added the mandate to adopt operating rules for each transaction.

2. **Rulemaking:** HIPAA authorized HHS to adopt standards, code sets, and identifiers. Later, the ACA added operating rules.
3. **Implementation by the health care industry:** Covered entities (providers, health plans and clearinghouses) are required to implement and use the standards, a requirement that is extended to their business associates.⁴⁹

NCVHS has been actively involved in advising HHS on the adoption and implementation of standards, identifiers, and code sets since the passage of HIPAA in 1996, issuing periodic reports to Congress on the status of HIPAA implementation in addition to making numerous recommendations to the Secretary developed through extensive consultations with health care industry stakeholders. In 2010, the ACA established a new requirement to name an entity to author operating rules for each of the adopted standard transactions. Based on NCVHS recommendations, HHS designated CAQH CORE (Committee on Operating Rules for Information Exchange) to serve in that capacity.

2. Transactions Status 2020

HHS has adopted standards for eight transactions authorized in the HIPAA legislation: Claims & Encounters, Claims Status, Coordination of Benefits, Eligibility, Enrollment, Claims Payment/Remittance Advice/Electronic Funds Transfer, Prior Authorization/Services Review, and Premium Payment. The Department published a rule to adopt standards for the eight transaction sets in August 2000. The Department made an update to the non-pharmacy rules in January 2009. Table 1 shows CAQH tracking of standards implementation beginning in 2013.

HHS is required to adopt a standard for attachments, which is listed in the Unified Agenda of Regulatory and Deregulatory Actions for consideration. NCVHS first recommended that HHS adopt an Attachment standard in 2016, and the Committee has reiterated that recommendation on two subsequent occasions based on consistent input from stakeholders. There are two major issues with an Attachment rule: 1) the convergence with clinical standards and workflows heavily impacts the various use cases for which an Attachment rule would be promulgated; and 2) the technology shift from older but well-established technologies to the emerging API-based standards such as HL7's FHIR complicates the regulatory picture.

Industry has readily implemented some of the adopted HIPAA transaction standards, but not others. For example, covered entities have widely implemented Claims and Eligibility

⁴⁸ Pub. L. 111-148, 124 Stat. 119 (Mar 13, 2010), available at <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>.

⁴⁹ HIPAA administrative transaction provisions are extended to business associates through their contracts with covered entities. While a business associate must agree to comply with HIPAA Rules and is responsible for ensuring the confidentiality, integrity, and availability of PHI in its possession, it is the responsibility of a covered entity to ensure that all business associates are complying with HIPAA Rules.

transactions, but Prior Authorization and Attachments⁵⁰ show very limited industry implementation. The payment and banking-related transactions show significant but not optimal implementation. These implementation patterns suggest there is still significant work to be done by Standards Development Organizations (SDOs), industry, and regulators. The NCVHS Predictability Roadmap (discussed in the next subsection and in Appendix 3.B) and other recommendations have offered advice to HHS and the industry on addressing many barriers to industry implementation.

Table 1 is a snapshot of the uptake of standards adoption from 2013 to 2020, showing trends in utilization. The CAQH Efficiency Index[®] is an analysis of the utilization of the adopted HIPAA standard transactions, other than pharmacy standards and premium payment. CAQH compiles the data from payers and providers who participate voluntarily each year. CAQH uses the data to estimate industry transaction utilization rates, administrative transaction spending rates, and cost savings opportunities. More detail is available in the CAQH 2020 Index at <https://www.cagh.org/sites/default/files/explorations/index/2020-cagh-index.pdf>.

Percent Industry Implementation of Transaction Standards	2013	2016	2017	2018	2019	2020
Health care claim submission	90%	94%	95%	96%	96%	96%
Eligibility for a health plan	65%	76%	79%	85%	84%	84%
Coordination of benefits	NR	56%	75%	80%	86%	89%
Health care claim status inquiry/response	48%	63%	69%	71%	70%	72%
Claim payment (EFT)	50%	62%	60%	63%	70%	71%
Remittance advice	43%	55%	56%	48%	51%	57%
Prior Authorization	NR	18%	8%	12%	13%	21%
Attachments (no std adopted)		NR	6%	NR	20%	22%

Table 1. CAQH Efficiency Index, 2013-2020, <https://www.cagh.org/sites/default/files/explorations/index/2020-cagh-index.pdf>

⁵⁰ No attachment standard rule has been promulgated under HIPAA, but transmission of attachment information is possible. NCVHS previously recommended that HHS adopt an attachment standard: NCVHS Letter to the HHS Secretary, “Recommendations for the Electronic Health Care Attachment Standard,” (July 5, 2016): <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2016-Ltr-Attachments-July-1-Final-Chair-CLEAN-for-Submission-Publication.pdf>.

3. HIPAA Transactions Initiatives and Actions, 2019-2020

In 2017 and 2018, NCVHS completed development of a Predictability Roadmap after consultation with a broad range of stakeholders, with the goal of improving the processes for updating, adopting, and using transaction and operating rules standards for administrative health care transactions. The Roadmap addresses how to:

- Improve predictability for planning, budgeting, and implementing updated or new standard transactions by HIPAA-covered entities; and
- Facilitate innovation, promote convergence between administrative and clinical information, and enable the health care industry to meet the rapidly changing business and technology changes, e.g., the rise of value-based purchasing in lieu of fee-for-service payment models.

In its workshops and hearings, NCVHS heard loud and clear from a broad range of industry stakeholders a strong consensus regarding the need for much greater responsiveness, timeliness, and transparency from HHS and SDOs.

Based on hearings and work done throughout 2017-2018, NCVHS sent a letter to the Secretary on February 13, 2019, outlining “Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry.” This letter contains five recommendations that outline approaches to improve the adoption of national transaction standards. Subsequent “visioning” meetings in July 2019 focused on the Designated Standards Maintenance Organizations (DSMOs)—with the goal of defining a timeline and approach to standards updates and adoption by the government to promote predictability in the health care industry. NCVHS sent a letter with three follow-on recommendations to the Secretary on December 10, 2019 (see Appendix 3.B).

These NCVHS letters identify areas of industry and regulatory improvement to make implementation of HIPAA standards timelier in responding to changing business needs, more predictable for budgeting and resource planning, and in smaller and more discrete packets to make implementation less burdensome.

In addition to the Predictability Roadmap, NCVHS produced the following recommendations and reports on HIPAA transaction issues:

- NCVHS recommended adoption of updated pharmacy standards (NCPDP version F6, April 22, 2020) (Appendix 3.F).
- NCVHS made specific recommendations, but declined to recommend adoption of additional proposed Operating Rules for certain HIPAA transactions (November 23, 2020) to address key industry issues identified by those proposed Operating Rules (Appendix 3.I).

4. HIPAA Medical Code Sets Plus Related Terminology and Vocabulary Initiatives and Actions, 2019-2020

In 2017, NCVHS undertook a project to advise the HHS Secretary on 1) the changing environment and implications for timing and an approach to terminologies and vocabularies standards adoption; 2) the needs, opportunities, and problems with development, dissemination, maintenance, and adoption of these standards; and 3) actions HHS might take to improve these practices. The National Library of Medicine has been an important partner to NCVHS in this work.

Health terminology and vocabulary standards are foundational to patient care, research, and public health. These standards are a necessary precondition for interoperability. The interoperability goals of the 21st Century Cures Act⁵¹ cannot be realized without terminology and vocabulary curation practices that bridge these environments.

The World Health Organization (WHO) published ICD-11 for review in 2018, and the World Health Assembly formally adopted this version on May 25, 2019, to be effective beginning January 1, 2022. For context, the U.S. implemented ICD-10 for mortality reporting in 1999 and implemented the standard for morbidity in 2015, *25 years after* it was endorsed by the WHO. The ICD-10 code set for morbidity was initially adopted as a required code set for use under HIPAA in 2009, however the mandate was delayed, eventually becoming effective in 2015.

The NCVHS Subcommittee on Standards began studying ICD-11 in 2018 to inform an efficient U.S. strategy for transitioning to this updated version of ICD. Based on its assessment, NCVHS has advised HHS to take a proactive approach toward ICD-11, specifically recommending the following:

- HHS conduct the studies necessary to vet ICD-11 for potential U.S. adoption. This would include ascertaining the “fit” of ICD-11 morbidity for U.S. use as a HIPAA-mandated medical code set, and determining whether or not a U.S. clinical modification to ICD-11 would be necessary. The research outline also addresses digital capabilities of ICD-11, compatibility with other terminologies and vocabularies in use in the U.S., and other technical and legal considerations. Importantly, the NCVHS recommendations seek to provide the type of critical information that was lacking in the U.S. implementation of ICD-10 and ICD-10-CM, which contributed to multiple avoidable delays and unnecessarily high implementation costs. The recommendations include considerations of potential adoption timelines for mortality and morbidity. They also propose an outline for a communication plan intended to help industry avoid many of the pitfalls and costs it experienced in the ICD-10 adoption. (Appendix 3.C)

⁵¹ 21st Century Cures Act: <https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf> and <https://www.healthit.gov/curesrule/overview/about-oncs-cures-act-final-rule>.

- HHS execute significant changes to how ICD is adopted in the U.S. and how the various terminologies, vocabularies, and code sets used in U.S. health care are adopted, implemented, curated, and disseminated (Appendix 3.C).

Taking a proactive approach to the transition to ICD-11 for mortality and morbidity classification in the U.S. through research, communications, and copyright (to ensure that copyright will not be a barrier to U.S. adoption and use of ICD-11) will enable the U.S. to identify the optimal path forward, maximizing benefit, minimizing cost and avoiding a repeat of the protracted and costly transition from ICD-9 to ICD-10.

5. Other HIPAA Administrative Simplification Initiatives and Actions, 2019-2020

As stipulated in the 21st Century Cures Act, NCVHS continued its collaboration with ONC with regard to the standards work of each entity. This effort focused on the Prior Authorization transaction to help with standardization, simplification, and automation. This transaction presents a clear area of opportunity to advance the goals of both administrative simplification and burden reduction. As described above and in Appendix 3.H, NCVHS, through its Subcommittee on Standards, was part of the ICAD Task Force, whose report and recommendations were accepted by the HITAC on November 10, 2020, and forwarded to ONC.

The ICAD project and subsequent recommendations addressed the convergence of administrative and clinical standards, using prior authorization as the exemplar and lens for a more global vision of convergence. The report describes the Task Force's envisioned "Ideal State" and makes fifteen recommendations on approaches necessary to achieve the Ideal State. The recommendations are an aspirational approach to bridging the gaps between HIPAA's 1990s-centric approach to standards and the industry requirements (business and technology) of the 2020s, including appropriate enablement of patient participation in digital transactions.

Future initiatives by NCVHS and others will begin to flesh out the ICAD vision and identify actionable steps to be taken by various stakeholders across the health care and health data ecosystems. The specific steps are still to be defined, but will likely include actions by Congress, federal regulators, federal health care-related programs, SDOs, providers, health plans, and industry action organizations. Included in the concept of provider and health plan are the HIT vendors who support them, including EHR developers, billing and practice management systems developers, clearinghouses, HIEs, and others.

HIPAA Privacy, Security, and Breach Notification

1. Proposed Changes to Privacy Rule

On December 10, 2020, HHS issued a Notice of Proposed Rulemaking (NPRM) to modify the HIPAA Privacy Rule. The public comment period closed on May 6, 2021. Comments are available for public viewing online.⁵² The NPRM requested public comment on proposed changes to the Privacy Rule, including proposals to:

- Strengthen individuals' rights to access their own health information, including electronic information;
- Improve information-sharing for care coordination and case management for individuals;
- Facilitate family and caregiver involvement in the care of individuals experiencing emergencies or health crises;
- Enhance flexibilities for disclosures in emergency or life-threatening circumstances, such as the Opioid and COVID-19 public health emergencies; and
- Reduce administrative burdens on HIPAA-covered health care providers and health plans.

NCVHS continues to monitor HHS work on rulemaking related to the Privacy Rule.

2. Updated Guidance on FERPA and HIPAA

The U.S. Department of Education and HHS released updated joint guidance in December 2019 addressing the application of the Family Educational Rights and Privacy Act (FERPA) and the HIPAA Privacy Rule to records maintained on students.⁵³ The guidance, which the agencies first issued in November 2008, clarifies for school administrators, health care professionals, families, and others how FERPA and HIPAA apply to education and health records maintained about students. The revised guidance includes additional frequently asked questions and answers addressing when a covered school can share a student's health information without the written consent of a parent or eligible student under FERPA, or without written authorization under the HIPAA Privacy Rule. This guidance document supports improved public understanding of how FERPA and HIPAA apply to students' health and educational information and when regulated entities can disclose such information, especially in connection with health and safety emergency situations.

⁵² "Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement," posted January 21, 2021: <https://www.regulations.gov/document/HHS-OCR-2021-0006-0001>

⁵³ "Joint Guidance on the Application of FERPA and HIPAA to Student Health Records," December 2019 update: <https://www.hhs.gov/hipaa/for-professionals/special-topics/ferpa-hipaa/index.html>

3. Guidance on HIPAA, Health Information Exchanges, and Disclosures of PHI for Public Health Purposes

HHS issued guidance in December 2020 on when HIPAA permits covered entities and their business associates to use HIEs to disclose PHI for the public health activities of a public health authority.⁵⁴ The guidance provides examples relevant to the COVID-19 public health emergency and illustrates for the regulated industry how HIPAA supports the use of HIEs in sharing health data to improve the public's health.

4. HIPAA and COVID-19

During the reporting period, HHS issued a number of waivers and Notices of Enforcement Discretion related to the SARS-CoV-2 pandemic that address the HIPAA Privacy Rule, the majority of which have been translated into Spanish:

- February 2020 Bulletin on HIPAA and COVID-19⁵⁵
- Notification of Enforcement Discretion on Telehealth Remote Communications⁵⁶
- Guidance on Telehealth Remote Communications⁵⁷
- Guidance on Disclosures to Law Enforcement, Paramedics, Other First Responders, and Public Health Authorities⁵⁸
- Notification of Enforcement Discretion on Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities⁵⁹

⁵⁴ Guidance on HIPAA, Health Information Exchanges, and Disclosures for Public Health Purposes, HHS Office for Civil Rights, December 18, 2020: <https://www.hhs.gov/sites/default/files/hie-faqs.pdf> - and <https://www.hhs.gov/about/news/2020/12/18/ocr-issues-guidance-on-hie-and-disclosures-of-protected-health-information-for-public-health-purposes.html>

⁵⁵ February 2020 Bulletin on HIPAA Privacy and Novel Coronavirus, HHS Office for Civil Rights: <https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf>

⁵⁶ Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, HHS Office for Civil Rights, March 17, 2020: <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>

⁵⁷ FAQs on Telehealth and HIPAA during the COVID-19 nationwide public health emergency, HHS Office for Civil Rights, March 20, 2020: <https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf>

⁵⁸ COVID-19 and HIPAA: Disclosures to law enforcement, paramedics, other first responders and public health authorities, HHS Office for Civil Rights, March 24, 2020: <https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf>

⁵⁹ Notification of Enforcement Discretion under HIPAA to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID-19, HHS Office for Civil Rights, April 2, 2020: <https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-hipaa.pdf>

- Notification of Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites⁶⁰
- Guidance on Media and Film Crew Access to Protected Health Information⁶¹
- Guidance on HIPAA and Contacting Former COVID-19 Patients about Plasma Donation⁶²
- Notification of Enforcement Discretion for Use of Online or Web-Based Scheduling Applications for the Scheduling of COVID-19 Vaccination Appointments⁶³

HHS developed a HIPAA and COVID-19 resource page at <https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html> that receives close to 500,000 unique visits a month.

5. HIPAA Breach Notification

HHS posts reports of all breaches of unsecured PHI affecting 500 or more individuals, available at https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf. The public can search and sort posted breaches. All of the data shown in the figures below are HHS/OCR data.

During the reporting period, the Department received 511 breach reports affecting 500+ individuals in 2019 and 648 reports affecting 500+ individuals in 2020. OCR has opened investigations into all breaches affecting 500+ individuals, and into a number of smaller breaches.

⁶⁰ Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites (CBTS)

During the COVID-19 Nationwide Public Health Emergency, HHS Office for Civil Rights, April 9, 2020:

<https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-community-based-testing-sites.pdf>

⁶¹ Guidance on Covered Health Care Providers and Restrictions on Media Access to Protected Health Information about Individuals in Their Facilities, HHS Office for Civil Rights, May 5, 2020:

<https://www.hhs.gov/sites/default/files/guidance-on-media-and-film-crews-access-to-phi.pdf>

⁶² Updated Guidance on HIPAA and Contacting Former COVID-19 Patients about Plasma Donation, HHS Office for Civil Rights, July 12, 2020: <https://www.hhs.gov/sites/default/files/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-plasma-donation.pdf>

⁶³ Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID-19 Vaccination during the COVID-19 Nationwide Public Health Emergency, HHS Office for Civil Rights, December 18, 2020: <https://www.hhs.gov/sites/default/files/hipaa-vaccine-ned.pdf>

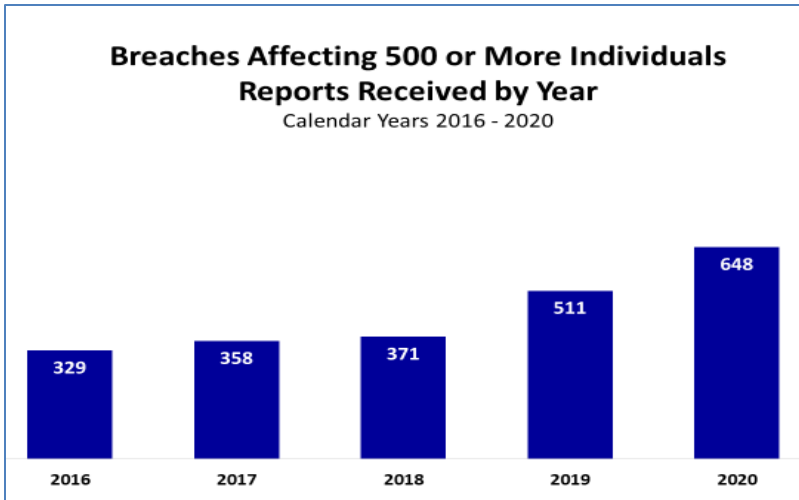


Figure 1. Breaches Affecting 500 or More Individuals, Reports Received by HHS by Year, CY2016-2020, HHS/OCR

Hacking and IT incidents have emerged in recent years as the leading type of breaches affecting HIPAA-covered entities and their business associates. In 2020, hacking and IT incidents reported to HHS accounted for 67 percent of all breaches affecting 500+ individuals.

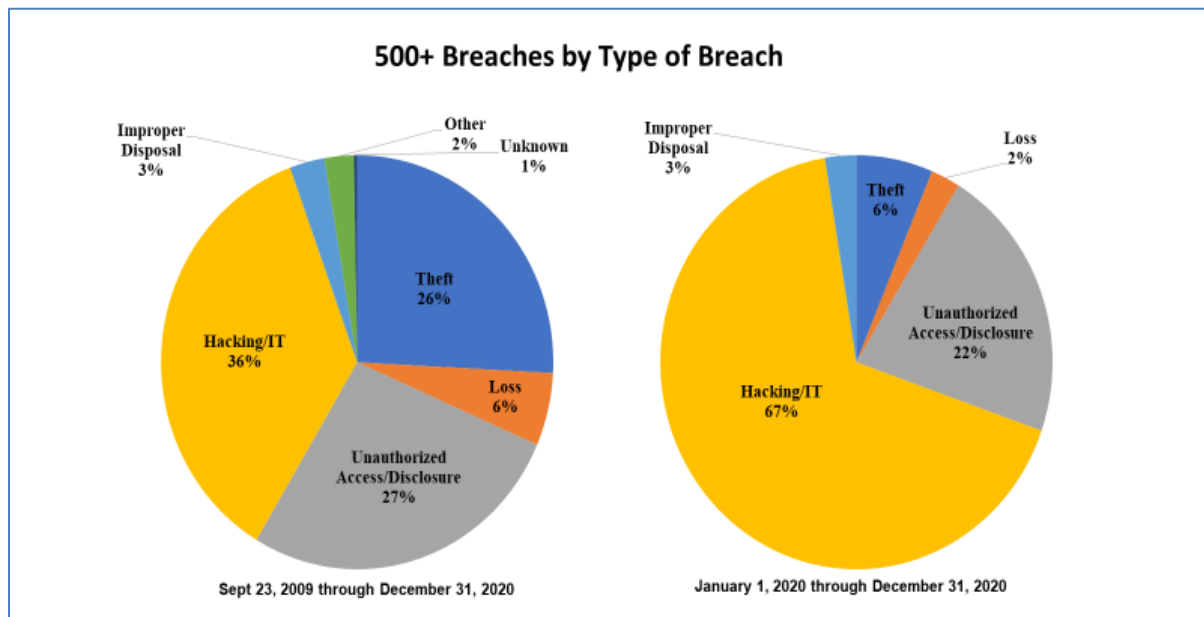


Figure 2. Breaches Affecting 500 or More Individuals by Type, HHS/OCR

Of these breaches, a growing number are located on email and network servers, reflecting the rise in cybercrime affecting the health care industry, such as ransomware.

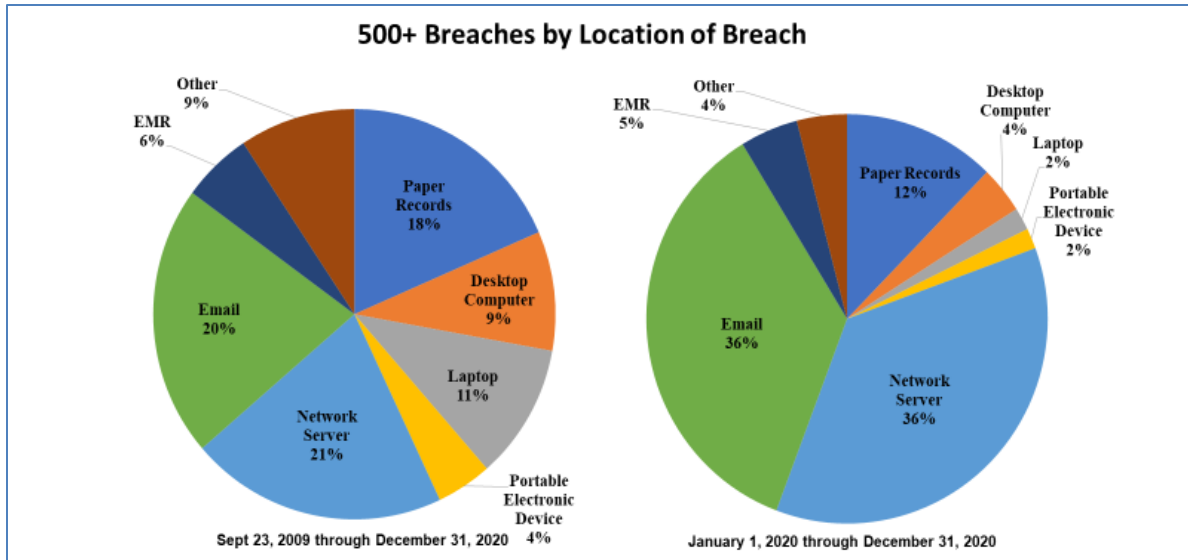


Figure 3. Breaches Affecting 500 or More Individuals by Location of Breach, HHS/OCR

The types of security breaches of health care information have shifted over the years from misplaced laptops to major cyberattacks. In Figure 3 above, the left pie chart reflects the percentage of breaches by location since the beginning of breach reporting as mandated in HITECH on September 23, 2009. The chart on the right shows the percentage by location for calendar year 2020. The types of breaches have shifted over the years from misplaced laptops to hacking/IT incidents.

Lax security practices in health care organizations make valuable health information particularly vulnerable. Growing reports in the media highlight HIPAA-covered entities that have been affected by ransomware attacks and rendered unable to access their EHR systems or deliver care to their patients.

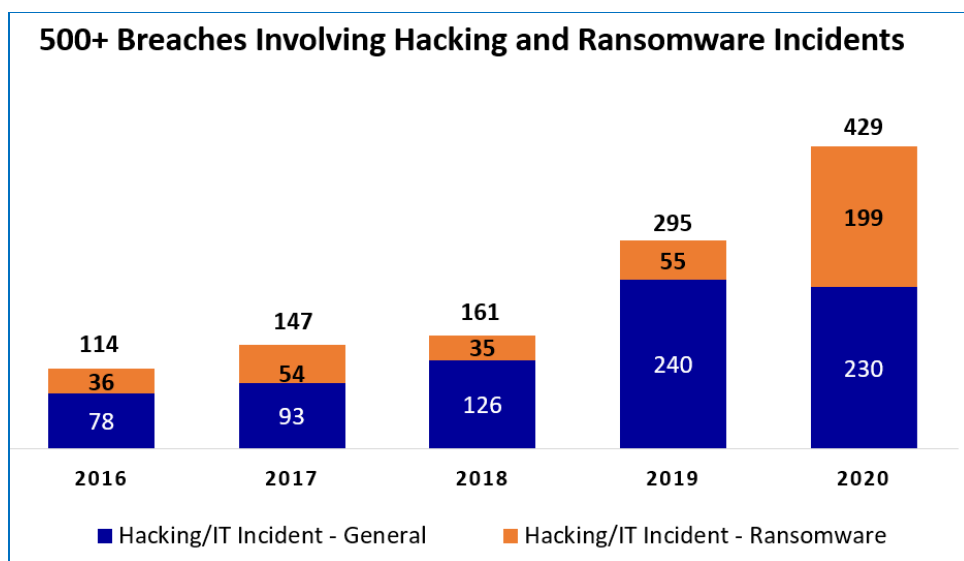


Figure 4. Breaches Affecting 500 or More Individuals, Reports Received Involving Hacking/IT Incidents, HHS/OCR

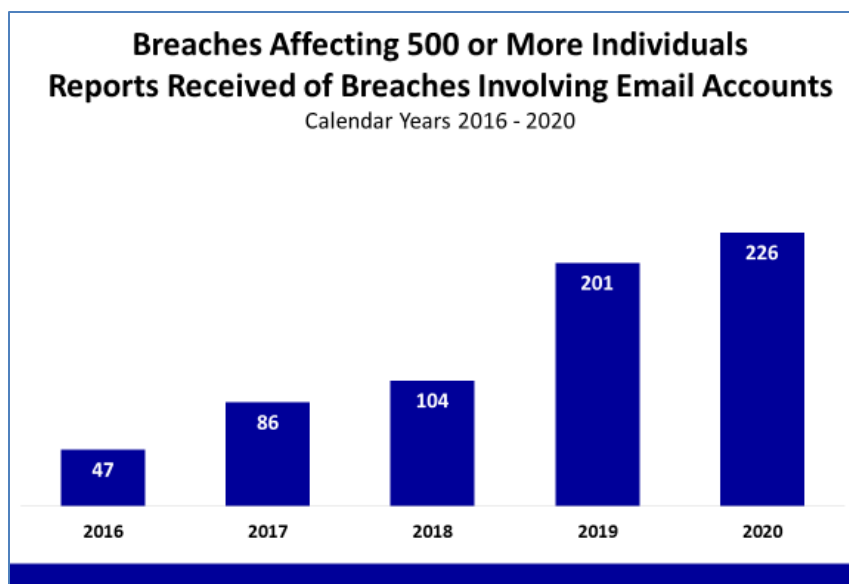


Figure 5. Breaches Affecting 500 or More Individuals, Reports Received Involving Email Accounts, HHS/OCR

6. HIPAA Enforcement

Enforcement of the HIPAA Privacy, Security, and Breach Notification Rules continues. HHS/OCR expects to receive more than 28,000 complaints in 2021. In most cases, entities under investigation are able to demonstrate satisfactory compliance through voluntary cooperation and corrective action. In some cases, the nature or scope of noncompliance warrants additional enforcement action. OCR has settled 89 investigations of violations of the HIPAA Privacy Rules since 2009 in actions that include detailed corrective action plans and monetary settlement amounts. Six cases have resulted in civil money penalties. In 2020, 19 HIPAA privacy investigations resulted in monetary settlements, as shown in Table 2.



2020 OCR HIPAA Enforcement Actions

Feb-20	Steven A. Porter, M.D.	\$100,000
Mar-20	CHSPSC	\$2,300,000
Mar-20	Metropolitan Community Health Services	\$25,000
Mar-20	Premera Blue Cross	\$6,850,000
Jun-20	Housing Works, Inc.	\$38,000
Jun-20	Lifespan	\$1,040,000
Jul-20	All Inclusive Medical Services, Inc.	\$15,000
Jul-20	Athens Orthopedic Clinic PA	\$1,500,000
Aug-20	Beth Israel Lahey Health Behavioral Services	\$70,000
Aug-20	King MD	\$3,500
Aug-20	Wise Psychiatry, PC	\$10,000
Sept-20	St. Joseph's Hospital and Medical Center	\$160,000
Sept-20	NY Spine Medicine	\$100,000
Oct-20	Aetna	\$1,000,000
Oct-20	City of New Haven, CT	\$202,400
Oct-20	Riverside Psychiatric Medical Group	\$25,000
Oct-20	Dr. Rajendra Bhayani	\$15,000
Nov-20	University of Cincinnati Medical Center	\$65,000
Dec-20	Elite Primary Care	\$36,000

Table 2. 2020 HHS Office for Civil Rights HIPAA Enforcement Actions

7. HIPAA Right of Access Enforcement Initiative

In February 2019, OCR announced its HIPAA Right of Access enforcement initiative,⁶⁴ to address the complaints that HHS continues to receive from individuals who are unable to receive a copy of their health records, as required by the HIPAA Privacy Rule. The initiative focuses on ensuring that individuals have a right to timely access to their health records at a reasonable, cost-based fee. OCR launched and settled investigations across the country, including settling fourteen cases during the reporting periods 2019 and 2020. OCR has stated it will continue to enforce this right vigorously,⁶⁵ and it settled eight additional cases through June 2021.

IV. Looking Ahead to 2021-22

This section highlights several key challenges and opportunities affecting the national health information ecosystem and a preview of upcoming NCVHS work. NCVHS will address those issues that align with its mission, building on previous accomplishments and leveraging ongoing partnerships.

A. Near-term National Health Information Challenges and Opportunities

1. Need for Comprehensive, Integrated, National Health Information Standards

The types and volume of health data are proliferating along with demand for these data by the private sector as well as local, state, federal, and international authorities. In addition to traditional health data sources such as administrative data (data collected by governments or other organizations for non-clinical reasons, such as claims payment), clinical data (diagnosis, treatment and related data captured in the patient's health records), and public health surveillance data (vital statistics and infectious disease tracking databases), there are now novel data sources generated by mobile health applications (apps), wearables and devices such as home-based health monitoring systems. These novel data sources suggest a number of future health policy considerations. At present, these data systems are fragmented and data reside in a multitude of silos.

While each individual data source brings inherent value to a program or audience, if data sources were strategically integrated and aggregated, the analytic power of the combined data could provide valuable insights about individual health and the public's health, deepen

⁶⁴ OCR Settles First Case in HIPAA Right of Access Initiative, September 9, 2019: <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/bayfront/index.html>

⁶⁵ "Health care providers have a duty to provide their patients with timely access to their own health records, and OCR will hold providers accountable to this obligation so that patients can exercise their rights and get needed health information to be active participants in their health care," said Acting OCR Director Robinsue Frohboese in announcing its 17th case in the HIPAA Right of Access Initiative on March 24, 2021: <https://www.hhs.gov/about/news/2021/03/24/ocr-settles-seventeenth-investigation-in-hipaa-right-of-access-initiative.html>

understanding of underlying problems, and inform development of priorities and solutions. This additive data richness could enhance the practices of precision medicine, care coordination across settings, population health modeling and planning, community health promotion research, cost-reduction strategies, and much more. Additional operational and data protection improvements also may be realized when diverse data are used together. Such benefits can only be achieved, however, when the meaning of the data from the disparate sources is clear and consistent (i.e., semantic interoperability), and the data sources' information systems are interoperable.

In general, clarity and consistency do not yet exist across health data, but rather are a work in progress. Strides in this direction have been made through HIPAA administrative simplification standardization and EHR development, but more needs to be done to achieve national policy goals of burden reduction, interoperability, health equity, quality, affordability and consumer empowerment.

The following opportunities could build on existing efforts:

- A convergence of clinical and administrative data systems to facilitate improved interoperability between these systems. Current efforts to implement prior authorization and related clinical attachment standards could help advance administrative simplification and potentially improve public health reporting.
- A more widespread, sustainable standardization process, flexible enough to respond to dynamic information needs and emerging technologies. This effort should include a rethinking and rescoping of standardization processes under HIPAA to accommodate new technologies and information needs while also allowing for legacy technologies and practices.

These actions need to incorporate data beyond traditional medical records and administrative transactions to include data about the patient's essential human needs. Data about housing, food security, race, ethnicity, education, and employment are crucial to understanding and improving health – at both the individual level and the population health level. There are unique challenges to capturing these data points. Collecting them at the point of care within a health setting is often a burden to the provider concerned with immediate health issues or crises. Insurers may not have this type of information; and many people are uninsured. The best SDOH information may be obtained by integrating or linking medical data sources with other data sources such as health survey data, vital statistics data, and community/human service data. Thus, the integration of multiple data sources, along with a robust, sustainable standardization infrastructure, are needed to advance knowledge about the health of the nation's population.

To make this kind of convergence possible, decision-makers must implement and fund policies that will build on the existing frameworks for the national standardization processes under HIPAA and other authorizing legislation, and leverage new technologies and data sources to meet information needs. At the same time, modernizing data capture and transmission

requirements must not be implemented in ways that unduly burden health care services. Nor should capture requirements be unreasonably imposed on persons interacting with patients for purposes not directly related to the scope of those requirements; for example, labs should not be tasked with reporting SDOH, nor should the cardiologists and radiologists who read electrocardiograms or MRIs.

National standards matter. As stated earlier, our national data infrastructure is composed of various local, state, federal, and private sector data sets. When there is no clear national standard for a given data need, states, counties, and independent programs tend to adopt inconsistent and oftentimes conflicting data standards that meet only the immediate local and operational information needs. Availability of more comprehensive national standards along with policies to educate local agencies about how use of the standards can meet local needs could reduce burden on those capturing and reporting the data, make the data more interoperable across jurisdictions, and reduce the cost of standards development and maintenance for local authorities.

2. Need to Address Increasing Challenges to Privacy, Confidentiality, and Security

Going forward, “big data” collaborations⁶⁶ and analysis through artificial intelligence (AI) are likely to continue to foster innovation in clinical decision making, care coordination, treatment, and research.^{67, 68} Both the FTC and the White House Office of Science and Technology Policy addressed this advancement in 2016, calling for stronger protections for data use by AI and other technologies, including guardrails on how data is used and shared, consumers’ rights, and lifecycle management.^{69, 70} The National Institute of Standards and Technology (NIST) has conducted a broad interagency program addressing the fairness, privacy, security, transparency and mitigation of harmful bias in AI technologies since 2019 pursuant to Presidential Executive Order 13859 and beyond. NCVHS anticipates that work will move forward to enhance trust in AI and other technologies through measures that promote transparency and accountability and mitigate risks to the privacy and security of individually identifiable information.

NCVHS also anticipates greater movement in 2021 toward standardized adoption of telehealth usage, which has been fueled by the COVID-19 public health emergency. The Department will

⁶⁶ “Big data” is defined by the Oxford Dictionary as “extremely large data sets that may be analyzed computationally to reveal patterns, trends, and associations, especially relating to human behavior and interactions.” <https://www.oxfordlearnersdictionaries.com/us/definition/english/big-data>.

⁶⁷ Big Data in Health Care: Using Analytics To Identify and Manage High-Risk and High-Cost Patients. Health Affairs, Vol 33. No 7. July 2014: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0041>.

⁶⁸ Big Data’s Role in Precision Public Health, Shawn Dolley, Front Public Health. 2018 Mar 7;6:68. doi: 10.3389/fpubh.2018.00068. eCollection 2018.

⁶⁹ Big Data: A Tool for Inclusion or Exclusion? Understanding the Issues, Federal Trade Commission Report January 2016: <https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf>.

⁷⁰ “Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights,” Executive Office of the President, May 2016: https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2016_0504_data_discrimination.pdf.

need to consider privacy and security protections in any long-term adoption of telehealth. Telehealth services have been critical to providing continuity of care. At the same time, there is higher risk with this efficiency to PHI as unauthorized access is a leading cause of data breaches. This is not to say that organizations should not use such efficiencies. They should, however, be aware of the potential risks to these data and the location of where data are stored, and have appropriate security measures in place.

It is also possible that the HHS Secretary will address the calls by some for stronger consumer privacy and security standards, as well as requirements to account for how third-party apps access patients' health information.⁷¹

Finally, at the end of 2020, H.R. 7898⁷² amended the Health Information Technology for Economic and Clinical Health Act (HITECH) Act to require OCR to take into consideration when conducting compliance reviews, regulatory audits, or enforcement actions whether a covered entity or business associate has implemented viable security practices, such as use of the NIST Cybersecurity Framework. HHS rulemaking will be required to implement the legislation that NCVHS expects to change future OCR enforcement and industry's compliance efforts with the HIPAA Security Rule.

NCVHS will continue to monitor legislative and policy developments in the health information privacy and security space.

3. Need for Enhanced Data Sources to Support Payment Reform and Price Transparency

The national trend of moving away from fee-for-service payment in health care necessitates new business information data content and data flows. Value-based care is becoming more prevalent. Medicare and other payers are migrating to payment models that pay a fixed rate (capitation) or provide incentives for reducing over-use (high-volume utilization of health care). While these models of care are intended to emphasize value, they also are data-intensive. For purposes of population health management and risk stratification, data on a targeted population must include longitudinal data on medical utilization as well as patient SDOH, enhanced with clinical data typically contained in the patient's EHR.

Population health retrospective and predictive analytics require accurate reporting and pricing of claims, as well as detailed claims data – which are typically de-identified. Growing opportunities for capturing information for price transparency are found in aggregated data

⁷¹ “Draft Consumer Privacy Framework for Health Data,” eHealth Initiative, August 26, 2020: <https://www.ehidc.org/resources/draft-consumer-privacy-framework-health-data>.

⁷² H.R. 7898: To amend the Health Information Technology for Economic and Clinical Health Act to require the Secretary of Health and Human Services to consider certain recognized security practices of covered entities and business associates when making certain determinations, and for other purposes: <https://www.congress.gov/116/bills/hr7898/BILLS-116hr7898eh.pdf>.

sources such as All-Payer Claims Databases (APCDs)⁷³ and similar data sources that can support price transparency initiatives in addition to their primary purposes for health care quality and utilization policy analysis. Statewide APCDs are emerging across the U.S. and include system-wide data on medical, dental, and pharmaceutical utilization of insured populations to provide consumers and policymakers with accurate, comparable information about the price and utilization of medical procedures and services.⁷⁴ Some opportunities include:

- Linkage of APCDs with other public health and human service databases to gain a broader view of how insured patients access and use health services, and to identify inequities and disparities in costs and outcomes for vulnerable populations;
- Standardization of non-claims transactional data (payments to providers not included in a claim), such as capitated payments, performance or quality incentives, and back-end settlements that are included in the total cost of care but not currently transparent to the public; and,
- Standards-based support for value-based care programs, currently lagging because the adopted HIPAA standards for health IT administrative systems of payers and providers were originally designed for fee-for-service models/systems.

4. Need for Equitable Information Technology Access Across “The Last Mile” to Reach All End Users

Digital health is transforming health and the health care industry. However, the digital divide is real and is creating additional health disparities for disadvantaged populations, rural areas, and small or undercapitalized providers and their patients, who lack “last mile” connectivity.⁷⁵ Last mile policy issues include:

- Available and affordable broadband telecommunications connectivity for patients and providers in rural areas and disadvantaged populations in urban areas;
- Affordable technology and resources to support the software configuration, integration, maintenance, and ongoing network connectivity of certified health IT, along with the

⁷³ Statewide APCDs are “databases, typically created by a state mandate, that generally include data derived from medical claims, pharmacy claims, eligibility files, provider (physician and facility) files, and dental claims from private and public payers.” (Porter, J., Love, D. et al, 2015, “All-Payer Claims Database Development Manual: Establishing a Foundation for Health Care Transparency and Informed Decision Making”: [http://www.westhealth.org/wp\[1\]content/uploads/2015/04/All-Payer-Claims-Database-Development\[1\]Manual_03042015.pdf](http://www.westhealth.org/wp[1]content/uploads/2015/04/All-Payer-Claims-Database-Development[1]Manual_03042015.pdf)).

⁷⁴ APCDs contain data only on insured populations, but the information can and does apply more broadly beyond insured populations. Indirectly the data are used to inform transparency, payment, and policy decisions that may affect the uninsured, for example pricing of non-covered services and out-of-network liabilities through benchmark pricing.

⁷⁵ As noted on page 6, “the last mile” refers to the ability of the telecommunications network chain to physically reach the end-user’s premises and be successfully incorporated into office systems, procedures, and workflows.

professionals needed to facilitate the technical work, who are scarce within the affected communities.

There is an increasingly urgent need to address this set of challenges to nationwide health data sharing, given that interoperability among providers, payers, and government agencies is now essential for treatment, payment, health care operations, and public health purposes.

5. Need for a Nationwide, Digitized Infrastructure for Pandemic Information Collection And Sharing

As discussed above (pages 8-10), the COVID-19 pandemic has underscored the essential role of public health information and revealed multiple obstacles in our ability to share electronically public health data seamlessly at all levels—local, state, federal, and global. The pandemic exposed numerous limitations and failures of our public health data infrastructure that hinder the responses of the health system. The fragmentation of key data systems, uneven technical capacities in public health agencies, chronic underfunding (as previously identified by NCVHS⁷⁶), and prohibitions or lack of clarity related to timely and robust data sharing across the health care ecosystem all converged to create critical information and knowledge gaps and make pandemic management much more difficult than it might have been.

By dramatically raising awareness of the fragmented and overburdened public health information system, the pandemic has exposed the need to invest in modernization to fix some of what is broken. It has underscored the need for a nationwide public health information system capable of providing real-time, consistent data, with appropriate privacy and security protections, on disease prevalence and incidence and on the availability of critical treatment resources.

The need is clear for a nationally interoperable information ecosystem among federal, state, and local public health agencies that serves local needs well and is also able to support a unified response to emerging infectious threats. The systems should ideally connect state and local health department systems with one another bi-directionally and with private providers. This depends upon the participation of providers, labs, and manufacturers to give a complete picture of available resources. Such a nationwide public health digitized infrastructure should leverage existing health IT (standard code sets and interoperability standards, including electronic case reporting [eCR] and syndromic surveillance standards) with a defined standard that allows diverse health systems to create an open dashboard for COVID-19 and future public health emergencies. This should include a series of standardized data extracts and queries that will allow for accurate, near-real-time data to better understand the impacts of a public health emergency and allow for ease of data exchange at federal, state, and local levels. Reporting by providers to authorized agencies regarding resource availability, resource deficiencies,

⁷⁶ NCVHS Letter to the HHS Secretary with Recommendations on the U.S. Vital Registration and Vital Statistics System – Critical Challenges and Opportunities (May 21, 2018): <https://ncvhs.hhs.gov/wp-content/uploads/2018/05/Letter-to-the-Secretary-US-Vital-Registration-and-Vital-Statistics-System-Recommendations.pdf>.

distribution of immunizations, and vaccinations must be supported. In addition, the new system must be designed to compile data to identify vaccine equity for public health purposes, to mitigate any geographic, socioeconomic, racial, or ethnic inequalities.

B. NCVHS Focus Areas in the Period Ahead

The Committee is organizing its work plan for the upcoming period, and anticipates that its work efforts will focus on the following priorities. The Committee believes these efforts, taken together, will help address some of the challenges discussed above and help to advance the administrative simplification and privacy protection goals established by HIPAA.

1. Promoting Convergence of Clinical, Administrative, Social, and Public Health Data

NCVHS intends to undertake a review of the national health data standards landscape to identify approaches that will address industry concerns with the 25-year-old HIPAA standards development and adoption processes. This will include identifying opportunities to promote a health information ecosystem that is more supportive of population health, value-based purchasing, transparency initiatives, and other evolving business and policy information needs.

Building on the Committee's Predictability Roadmap (see Appendix 3.B) and the HITAC ICAD Task Force report (Appendix 3.H), the Committee plans to examine how emerging standards and new technologies, such as FHIR apps, can co-exist with HIPAA standards. In particular, the Committee will explore how health-related data, once captured, could flow bi-directionally across all types of data systems in a way that is semantically interoperable, reduces overall burden, and takes end-users' workflows into consideration.

In contrast to HIPAA's somewhat narrow scope (with applicability limited to covered entities and their business associates—providers, health plans and clearinghouses), NCVHS will take the broader view and examine the entire ecosystem that a patient's needs may touch. Those areas include acute care, long-term post-acute care, behavioral health, social services, patient-generated health data, etc., as well as health-related reporting systems such as statewide All-Payer Claims Databases, registries, vital statistics, public health, population health, and research.

Activities of the Committee will address the many aspects of standardization issues including:

- Standards assessment, including but not limited to functional suitability for purpose, ease of implementation, manageability over the life cycle, and conformity assessment;
- Convergence of data, e.g., interoperability across use cases and across health industry sectors;
- Semantic harmonization among terminologies, vocabularies, and code sets; and
- Privacy, confidentiality, and security.

The Committee will implement this project in phases over a multi-year period. Phase I will include the initial activities that assess the standards landscape and identify potential deliverables. The Committee will base its Phase II activities on the outcome of Phase I.

The intended benefit to patients, providers, payers, and the health care system as a whole includes standardized data capture and improved availability of data to support individual health care and wellness, public health, health policy, price transparency, coordination of care, burden reduction, privacy, and the usability of personal health information.

2. Improving the Health Care Industry's Security Posture

As described in Section III of this report, the health care industry has experienced an unprecedented number of cybersecurity threats over recent years. NCVHS is currently scoping a project for 2021-2022 that will take a comprehensive look at a range of cybersecurity challenges impacting the health care industry and the range of policy options that may be available to the Department and data stewards to better safeguard electronic PHI. Specific goals are as follows:

- Identify and describe the changing cybersecurity landscape and the risks to the privacy and security of ePHI, and highlight promising policies, practices, and technologies;
- Lay out integrative models for how best to secure ePHI while enabling useful uses, services, and technologies; and,
- Formulate and deliver recommendations for the Secretary on actions that HHS might take.

3. Monitoring and Advising on ICD-11 Readiness

NCVHS will continue to monitor and analyze national and international developments related to determining the suitability of ICD-11 for U.S. mortality and morbidity adoption, and advise HHS on this matter as appropriate. (Appendix 3.C provides a summary of the Committee's initial recommendations.) The Committee will draw on research by the National Institutes of Health's National Library of Medicine and on past research, lessons learned, and communication strategies to advise HHS on strategies to effectively transition from ICD-10 to ICD-11. It also will look at the interrelationships of ICD-11 and SNOMED-CT to understand clinical-business integration needs and cross-mapping of the two code systems.

4. Identifying New Approaches for Data Collection, Sharing, Linkages, and Analytic Methods to Address Health Inequities

The COVID-19 pandemic exposed a number of data and information gaps that hindered the nation's ability to respond quickly and efficiently in determining the impact of the pandemic, which affected racial and ethnic minority populations disproportionately. Early on in the pandemic, researchers, advocates, and states called attention to the lack of data identifying race and ethnicity in cases, hospitalizations, and deaths despite the fact that such data are a part of many public health reporting requirements. The lack of race and ethnicity data not only

affects rapid identification and response to health threats; it also impedes future capacity to identify outcomes in research, treatment, and appropriate evidence-based interventions at the sub-population (community and neighborhood) levels.

The pandemic highlighted the need to improve current practices and apply innovations to reduce the variation in reported data. New approaches need to include a framework for the timely and uniform collection of race and ethnicity data and standardized metrics to interpret the data. The improvements needed affect the entire health information spectrum, cutting across all types of data including EHRs, public health surveillance systems, and administrative/claims data systems, and therefore call for national attention and leadership.

The Committee proposes to identify ways in which current practices and gaps in data collection and analytic methods—including strategic data linkage and data exchange—can be improved to better support measurement efforts to understand and reduce health disparities and better achieve health equity.

C. Conclusion

NCVHS is grateful for the opportunity to submit this report to Congress. We believe the Department and the healthcare industry have made significant progress to advance the administrative simplification provisions of HIPAA but also that significant challenges remain to continue its advancement.

At its essence, this report reaffirms the importance of health information that is available, linkable, private, and secure, for optimal management of the nation's health. NCVHS stands ready to assist the Secretary of Health and Human Services in addressing the urgent health information policy priorities highlighted here, while continuing to inform Congress of its progress.

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Appendix 1. NCVHS Statutory Reporting Requirements for HIPAA

The statutory reporting requirements from P.L. 104-191, Sec. 263. Changes in Membership and Duties of National Committee on Vital and Health Statistics stipulate:⁷⁷

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

(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for non-compliance with such standards.

(C) Whether the Federal and State governments are receiving information of sufficient quality to meet their responsibilities under such part.

(D) Any problems that exist with respect to implementation of such part.

(E) The extent to which timetables under such part are being met.”

⁷⁷ <https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996>

Appendix 2. About Administrative Simplification

This appendix begins with an overview in Table A2.1 below of the regulations and related laws published under the HIPAA legislation since its release. It is followed by information on financial and administrative transactions and code sets, unique health identifiers and operating rules.

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 for the administrative simplification provisions of the law. HIPAA added a new Part C – Administrative Simplification to the Social Security Act of 1935.
2000	Aug 17	Reg	Standards and Code Sets for Electronic Transactions and DSMO Process	HHS adopts code sets (ICD-9, CPT-4, National Drug Codes, Code on Dental Procedures and Nomenclature, and HCPCS) and standards for electronic transactions: ASC X12 Version 4010 and NCPDP Version 5.1. HHS publishes a regulation outlining the process for standards development organizations to collaborate on the review of proposed modifications to standards and code sets, including the execution of a Memorandum of Understanding on which HHS is a signatory. The collaboration is called the Designated Standards Maintenance Organization (DSMO). Adoption of the standards and code sets is required by Oct 16, 2002 for all HIPAA-covered entities, except small health plans, which were required to comply on Oct 16, 2003.
2001	Jan 3	Law	ASCA, Administrative Simplification Compliance Act	Congress requires electronic submission of Medicare claims.
2002	May 31	Reg	Employer Identification Number (EIN)	HHS adopts standard for Employer Identifier Standard (EIN) which becomes mandatory for use on July 30, 2002.
2003	Feb 20	Reg	Transaction Standards and Code Sets	HHS modified specifications for 1) transaction standards, and 2) how HIPAA-covered entities use standards, effective Mar 24, 2003.
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 for Medicaid subrogation and required adoption by Jan 1, 2012.
2009	Jan 16	Reg	ICD-10 Final Rule	HHS required HIPAA-covered entities to transition from ICD-9 to ICD-10 codes for medical diagnosis and inpatient hospital procedures on Oct 1, 2013. After two delays, ICD-10 became effective Oct 1, 2015.
2009	Feb 17	Law	HITECH Act and Civil Penalties	Part of the American Reinvestment and Recovery Act, HITECH adjusted civil monetary penalties for HIPAA violations, including Administrative Simplification.
2009	Oct 30	Reg	Enforcement and Civil Penalties	HHS released interim final rule on civil monetary penalties effective Nov 30, 2009.
2010	Mar 23	Law	ACA, Patient Protection and Affordable Care Act ACA Administrative Simplification Provisions	Congress expanded on HIPAA to require operating rules for transactions, standards for electronic funds transfer (EFT) and claims attachments, adoption of the unique health plan identifier (HPID) as required in the 1996 law, health plan certification of compliance, and HHS outreach to advisory bodies for input on potential improvements to Administrative Simplification. ACA also required the ICD-9-CM Coordination and Maintenance Committee to solicit input on and revise ICD-9 to ICD-10 crosswalk posted on CMS website.
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 IFR was final.
2012	Aug 10	Reg	Operating Rules for EFT and ERA	HHS adopted operating rules for EFT/ERA, effective Jan 1, 2014.
2012	Sept 5	Reg	Adopt a final rule for the HPID and OEID	This final rule adopted the standard for a national unique health plan identifier (HPID) and established requirements for the implementation of the HPID. In addition, it adopted a data element that would serve as another entity identifier (OEID), or an identifier for entities that are not health plans, September 5, 2012.
2019	Oct 28	Reg	Rescind the Health Plan Identifier (HPID)	This final rule eliminates the regulatory requirement for health plans to obtain and use an HPID and eliminates the voluntary acquisition and use of the OEID.

2020	Jan 24	Reg	Adopt modification to NCPDP standard	HHS published a final rule adopting a modification to the NCPDP D.0 standard to require covered entities to use a field to distinguish whether a prescription is a partial fill or a full refill for Schedule II drugs.
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Table A2.1: History of HIPAA and ACA Regulations, as of December 31, 2016

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 were implemented. Under the 2010 ACA legislation, Congress required the adoption of new standards and operating rules, increased enforcement authority, and reiterated the requirement to adopt a standard for health care attachments and an identifier for health plans.

As noted, Table 1 (above) provides an overview of the regulations and related laws that have been published pertaining to the HIPAA legislation since 1996.

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 updated versions of the standards and implementation specifications would significantly eliminate the optionality of the previous version, and reduce or in most cases eliminate the need for companion guides. With the transition to Version 5010 (X12) and NCPDP Version D.0 in 2012, this did not occur. In addition, the ACA sought to further address the gaps and optionality issues associated with the implementation of electronic transactions by calling for the adoption of operating rules for each transaction. In the past four years, these rules have also not decreased the use of companion guides by health plans.

Unique Health Identifiers

HIPAA called for four unique health identifiers: Employer, Provider, Patient and Health Plan. Two of the four have been adopted and implemented. HHS is prohibited by law from expending funds on the development of a patient identifier. HHS had not adopted the Health Plan Identifier by the time the Affordable Care Act passed in 2010, and it was included as a mandate for HHS, to be adopted by October 1, 2012. NCVHS held hearings on this subject, and the Workgroup for Electronic Data Interchange (WEDI) held a Policy Advisory Group. 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. A proposed rule to rescind the HPID was published on December 18, 2018. A final rule that rescinded the HPID and OEID was published on October 28, 2019, and went into effect December 27, 2019. NCVHS recommendations to the HHS Secretary provided substantive support for the HHS action.⁷⁸ No further action by HHS has been taken subsequently

Operating Rules

The ACA 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.

⁷⁸ <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/2017-Ltr-HPID-June-21-wws-w-sig.pdf>

Appendix 3. NCVHS Recommendations, Reports & Activities in 2019-2020 to Advance Standardization, Interoperability, and Privacy Protections for Health Data

The National Committee on Vital and Health Statistics (NCVHS) advises HHS on health data, statistics, privacy, national health information policy, and the Department's strategy to best address these issues. As stipulated in its Charter, NCVHS consults with stakeholders and experts and collaborates with HHS agencies and staff, taking their input into account as it develops its reports and recommendations to the Secretary. Many NCVHS recommendations pertain to aspects of national health information policy that have evolved over decades.

In the 2019-2020 reporting period, NCVHS sent the HHS Secretary a report and eight sets of recommendations. These recommendations and the related work of the Committee are summarized below.

A. Recommendations on Health Terminology and Vocabulary Standards

NCVHS Letter to the HHS Secretary with 2 Recommendations

- [*Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards \(February 13, 2019\)*](#)

In 2017, NCVHS undertook a project to advise the HHS Secretary on actions HHS could take to improve the development, dissemination, maintenance, and adoption of health terminology and vocabulary standards in a changing environment. The National Institutes of Health/National Library of Medicine served as a key partner in this work. Over a two-year period, the Committee conducted an extensive environmental scan and convened experts, including an Expert Roundtable in September 2018. The environmental scan and roundtable highlighted the need for greater coordination to ensure that redundant terminology and vocabulary concepts are purposeful and useful and that gaps are addressed. A key finding was that a deliberate pathway toward convergence of clinical and administrative data domains will be essential to realizing health transformation goals and administrative simplification.

In February 2019, the Committee issued a letter to the Secretary conveying two sets of recommendations to HHS based on the findings of the environmental scan and input from experts. The letter included two attachments: 1) a set of revised criteria for adoption and implementation of health terminology and vocabulary standards⁷⁹ and 2) new guidelines for curation and update of already adopted standards. The Committee recommended that HHS use

⁷⁹ The revised criteria for adoption and implementation in these recommendations replace “Guiding Principles for Selecting PMRI Standards,” which NCVHS submitted to the Secretary in July 2000.

both to guide health terminology and vocabulary initiatives. The letter also conveyed the Committee’s environmental scan report results and a summary of what was learned from the Expert Roundtable meeting.

These recommendations are intended to guide evaluation of new standards and version updates for existing named standards (of which there were ten at the time), and also to serve as a reference to raise the bar for development, curation, and implementation of health terminology and vocabulary systems that are not named standards. Adoption of the guidelines is expected to advance transparency and support migration to better approaches.

In its letter, NCVHS stated that it would continue to develop recommendations regarding health terminology and vocabulary policy and science, to advance the accurate capture of medical and health information and more fully support health and health care transformation.

B. Recommendations on Transaction Standards and Operating Rules

NCVHS Letters to the HHS Secretary with 8 Recommendations

- [*Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry \(February 13, 2019\)*](#)
- [*Additional recommendations for HHS actions to improve the adoption of standards under the Health Insurance Portability and Accountability Act \(HIPAA\) of 1996 \(December 10, 2019\)*](#)

In 2019, NCVHS sent two letters to the HHS Secretary conveying a total of eight recommendations, which were the result of NCVHS’ “Predictability Roadmap” initiative. The purpose of this initiative was to more effectively realize the potential of standards to increase efficiency and reduce burden for the health care industry, as Congress intended for HIPAA. The Committee noted the greater need to address process barriers, inefficiencies, and lack of transparency in a system under HIPAA that, it pointed out, was designed in 1996 under very different conditions.

In the Committee’s judgment, HHS is at a pivotal juncture in protecting the basic and critical value of standardization while also enabling innovation. Starting in 1996, clearly defined parameters were deemed essential to the success of industry migration into a standards-based mindset. However, now that a standards mindset has been widely demonstrated and embedded in health care technology, NCVHS believes that relaxing that rigidity and promoting the evaluation process will go a long way to supporting innovation and reducing the time-to-market for standards development, adoption, and updating.

Stakeholders in the health care industry have stressed to NCVHS in recent years that policy changes have not kept up with technology and that the constraints and complexities of the HIPAA regulatory process for financial and administrative standards have become an

impediment to progress. Industry stakeholders have emphatically asked the Committee to “*do something and do something now*” to speed the availability of updated standards for their use. In addition, certain regulations and federal processes governing industry standards impose barriers to the convergence of administrative and clinical data exchange, without which interoperability is impossible. In short, the evidence shows that neither interoperability between administrative and clinical standards nor the appropriate pace of adoption for useful transaction standards can be achieved by following current processes. Further, the current processes for modifications do not accommodate the pace at which the health care industry needs to address changes in technology, payment models, and patient care delivery strategies.

In the Committee’s February 2019 letter, the first three recommendations address the predictability and pace of the standards adoption process, and the last two propose ways to optimize the standards environment to set the stage for the harmonization of administrative and clinical data exchange. A key recommendation was that HHS handle updates to HIPAA and ACA transaction standard and operating rules in the same way it allows for code set updates (apart from ICD updates): That is, instead of requiring rulemaking, periodic and routine updates for code sets released by the responsible organization are automatically implemented.

In its second, December 2019 letter to the Secretary, NCVHS reiterated its findings that the current pathway for HIPAA-related rulemaking should be procedurally optimized because it is meeting neither the needs of the U.S. health care industry nor federal policy objectives.

The letter conveyed three NCVHS recommendations for HHS action to fix systemic deficiencies and modernize the processes by which electronic standard administrative and financial transactions are adopted under HIPAA. In essence, NCVHS recommended that the adoption of updated HIPAA standards come more frequently, more predictably, more reliably, and in smaller and more easily assimilated sets. Further, end-users of all sizes and types, including small health care providers and plans and state and local public health agencies, should participate in the standards- and rule- development processes of SDOs and Operating Rule Authoring Entities (ORAEs). NCVHS stressed that HHS action on these recommendations would significantly improve the standards development process and result in a less time- and resource-intensive HHS process to publish regulations. This, it noted, would benefit the health care industry by enabling greater innovation through availability of updated standards on a timelier, more predictable basis.

The Committee advised that, taken together, the strategies put forward in the Predictability Roadmap will not only enable greater efficiencies and lower costs for the health care industry, but also improve efficiency for HHS and reduce regulatory burden overall. The Predictability Roadmap has generated considerable support within the health care industry, and several NCVHS members gave presentations to stakeholder groups in 2019 and 2020 regarding the Committee’s recommendations.

C. Health Terminology and Vocabulary Standards—Transition to ICD-11

NCVHS Letters to the HHS Secretary with 6 Recommendations

- [*Recommendations on Regulatory Simplification of the International Classification of Diseases \(ICD\) \(February 21, 2019\)*](#)
- [*Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard \(November 25, 2019\)*](#)

As the international standard for reporting diseases and health conditions, the ICD, which is developed and promulgated by the World Health Organization (WHO), serves as the foundation for identifying health trends and statistics worldwide. The WHO formally adopted ICD version 11 (ICD-11) in May 2019, to be effective as of January 1, 2022.⁸⁰

As an advisor to HHS on the previous transition from ICD-9 to ICD-10, NCVHS is concerned that the U.S. avoid a repeat of that protracted and costly transition. The U.S. faces critical decisions about such matters as whether ICD-11 includes enough detail to meet U.S. needs for morbidity classification without a clinical modification, the cost-benefit of a version update, and the optimal timing with respect to other standards updates.

Adoption by the U.S. involves two dimensions: mortality (cause of death reporting), and morbidity (diseases, disorders, injuries and other health conditions). The WHO requires the use of ICD for all Underlying Cause of Death coding. As a HIPAA-designated code-set, the use of ICD for morbidity is mandatory for all health care providers and health care service settings in the U.S.

In 2019, NCVHS studied the issues associated with the impending transition to ICD-11 and consulted a wide range of stakeholders and experts. In August 2019, it convened a Roundtable meeting of experts representing government, academia, health industry associations, health care providers, and other stakeholders.^{81,82} The objectives of the Roundtable were to clarify the lessons learned from the transition from ICD-9 to ICD-10, to identify the differences between ICD-10 and ICD-11 for morbidity and mortality, to reach consensus on the research questions that need to be answered, and to identify key messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

Informed by those inputs, NCVHS submitted two sets of recommendations in 2019: the first on regulatory simplification of ICD, and the second on preparing for the transition. The February 2019 letter recommended that HHS use sub-regulatory processes to make version updates to

⁸⁰ World Health Organization (WHO) ICD-11 website site: <https://icd.who.int/en>

⁸¹ NCVHS ICD-11 Expert Roundtable meeting, August 6-7, 2019: <https://ncvhs.hhs.gov/meetings/subcommittee-on-standards-icd-11-evaluation-expert-roundtable-meeting/>

⁸² NCVHS ICD-11 Expert Roundtable Meeting Summary: <https://ncvhs.hhs.gov/wp-content/uploads/2020/02/Final-Meeting-Summary-Standards-Subcommittee-ICD-11-Meeting.pdf>

the ICD, in the same way it handles updates to all other named HIPAA code set standards. The Committee also recommended investing in a project to evaluate ICD-11 and developing a transition plan. An ICD-11 evaluation project would be an ideal test for the criteria the Committee put forward in its February 2019 recommendations on health terminology and vocabulary standards.

After convening another meeting to obtain input from experts in August 2019, NCVHS submitted a second letter to the Secretary (dated November 25, 2019) on preparing for the transition. It outlined why ICD-11 is a major advance over ICD-10, described the need for research and evaluation, and reiterated the important leadership role of HHS to take a proactive approach to research, communications, and copyright to avoid the lengthy and costly delays that encumbered the previous ICD transition. With the letter, the Committee submitted detailed recommendations for research questions and a strategic communications plan that delineated stakeholder audiences and proposed specific key messages.

The Committee's main message to HHS was, and still is, that taking a proactive approach to research, communications, and copyright for the transition to ICD-11 in the U.S. will enable stakeholders in healthcare, led by HHS, to identify the optimal path forward, thereby maximizing benefit and minimizing cost. NCVHS urged the Department to provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11.

In February 2020, the WEDI Board of Directors sent a letter to the HHS Secretary in response to these NCVHS recommendations. It applauded the Committee's work and offered its assistance on several recommendations and next steps on preparing for ICD-11. WEDI may be able to help identify use cases for ICD-11 and evaluate how well ICD-11 will meet these needs; evaluate the impact of the ICD-11 code structure changes in different environments and on other health information standards adopted under HIPAA; and identify the potential of ICD-11 to support greater convergence of clinical and administrative standards.

D. Recommendations and a Report on Health Information Privacy Beyond HIPAA

[NCVHS Report & Letter to the HHS Secretary with 6 Recommendations](#)

- ***[Health Information Privacy Beyond HIPAA: A Framework for Use and Protection. A Report for Policy Makers \(June 18, 2019\)](#)***
- ***[Recommendations for HHS Actions to Improve Privacy Protection for Health Information not Subject to HIPAA Regulations \(June 18, 2019\)](#)***

NCVHS began its *Beyond HIPAA* initiative in 2018 to examine emerging health information privacy and security challenges that are beyond the scope of the HIPAA law and its regulations to explore a health data privacy and security framework for the 21st century. Informed by hearings and development of an extensive environmental scan, the Committee produced a

letter with six recommendations and a report for policymakers, “Health Information Privacy Beyond HIPAA: A Framework for Use and Protection.” The report focused on the dynamic and largely unregulated world of health and health-related information not covered by the HIPAA Privacy and Security Rules and related implications.

In the Committee’s assessment, the nation must adopt enhanced privacy protections for health information beyond HIPAA, a concern that continues to be a national priority. Failing to take steps to protect health information beyond HIPAA could be harmful to individuals, to public health, and to health care innovation.

The Privacy Framework is intended to advance understanding of the issues, provide advice for HHS and other federal agencies as they consider the levers they have under current laws to improve protections, and promote greater public and private collaboration. It presumes that the federal floor secured by the HIPAA Privacy and Security Rules is in place, and it calls on covered entities, business associates, and non-HIPAA-covered entities to take the initiative where expanded care and vigilance in disclosure practices will enhance protections for individuals. It has the potential to complement HIPAA and does not propose changes to HIPAA, though the recommendations identify a few areas where HIPAA protections could be better leveraged. Improving protections for health information uses beyond HIPAA need not be highly regulated and prescriptive. Rather, as the Framework indicates, key levers can provide targeted protections, serving as rules of the road and guardrails. The adoption of laws and practices based on Framework elements can advance the interests of individuals and those of a responsible health data industry.

The *Beyond HIPAA* report concludes by suggesting a set of short- and long-term actions for data holders that build on a foundation of the law and the guiding principles and protective best practices outlined in the report.

In its June 2019 letter to HHS, NCVHS urged HHS to take action on six recommendations. They are intended to reduce risks when data move between regulated and unregulated entities and to set the stage for a more comprehensive set of solutions, while also permitting use of health information “Beyond HIPAA.” The first four recommendations target areas of particular vulnerability at the intersection of the regulated HIPAA health information world and the unregulated world. The final two propose two longer term efforts that NCVHS urged HHS to advance as part of its strategic leadership plan.

NCVHS suggests that HHS is in the best position to lead the initiative to improve the protection of currently unregulated health information, drawing on its decades of experience regulating and enforcing HIPAA’s Privacy and Security Rules. In the Committee’s assessment, improving privacy protections beyond HIPAA presents challenges that require a level of collaborative leadership by HHS similar to its successful role in moving the health industry to EHRs.

E. NCVHS Comments on the Federal Data Strategy

NCVHS Letter on Draft 2019-2020 Federal Data Strategy Action Plan

- [*Response to Request for Public Comment on the Draft 2019-2020 Federal Data Strategy Action Plan \(July 8, 2019\)*](#)

The Federal Data Strategy (FDS) provides a common set of data principles and best practices for implementing data innovations that result in greater value for the public. Annual action plans identify and prioritize practice-related steps for a given year, with targeted timeframes and responsible entities. The FDS Action Plan was last updated in May 2020.⁸³

NCVHS submitted comments on the FDS in July 2019. After expressing appreciation, in particular, for the aim of assembling federal data assets to increase access to linkable data, the Committee emphasized that communities need access to information specific to their geographic areas, and called attention to the then-recent loss of several federal data resources. These losses make it increasingly difficult for states, counties, and communities to get the information they need to assess and improve local health.⁸⁴ The Committee noted that the chief purpose of its comment was to convey that it is vitally important that the FDS prioritize the development of a process for making publicly consumable health information readily available and accessible from federal health data assets.

In its comment and an attachment, NCVHS described its partnership with 100 Million Healthier Lives (convened by the Institute for Healthcare Improvement) to develop and release a community health measurement framework. The Framework is based on the 2018 NCVHS report, “Measuring Health at the Community Level: Data Gaps and Opportunities.” The result of this evidence-based and broadly participatory effort, which was based on the initial NCVHS measurement framework, was “Well-Being in the Nation (WIN) Measurement Framework: Measures for Improving Health, Well-Being and Equity Across Sectors,” released on June 3, 2019. NCVHS emphasized that *Well-Being in the Nation (WIN)* offers a vetted framework to the FDS for policy-relevant data products to be produced out of the Federal Statistical Research Data Centers by federal agencies or contracted partners. Offering the analytic outputs publicly and equitably would revolutionize policymaking for local governments across the country, facilitating achievement of the goals of the Evidence-Based Policymaking Act.

⁸³ <https://strategy.data.gov/action-plan/>

⁸⁴ The examples cited include the Health Indicators Warehouse and the Behavioral Risk Factor Surveillance System county-level estimates, as well as the withdrawal of other previously public data sets into Federal Statistical Research Data Centers.

F. Recommendations on a HIPAA Pharmacy Standard

[NCVHS Letter to the HHS Secretary with 3 Recommendations](#)

- [*Recommendations for Adoption of New Pharmacy Standard Under HIPAA \(April 22, 2020\)*](#)

In its purview, NCVHS is charged with advising HHS on proposed and modified transaction standards and operating rules. It engaged in two such activities during this reporting period.

In January 2020, the Designated Standards Maintenance Organization (DSMO) asked NCVHS to consider recommending the adoption of an updated version of the pharmacy standard that applies to retail pharmacy transactions. The Committee issued a request for public comment, which provided constructive insight about the benefits and costs of changing to the new version. On the basis of that input, the Committee recommended that the HHS Secretary adopt as a HIPAA standard Telecommunications Standard Implementation Guide version F6, developed by the National Council for Prescription Drug Programs. In its letter, the Committee also included a recommendation on the timing of the adoption of the new standard to give adequate time for planning and completion of budget cycles, especially for the Medicare and Medicaid programs. The Committee's proposed timeframe would also allow and encourage thorough end-to-end testing.

To the best of the Committee's knowledge, HHS is working on a proposed rule to adopt NCPDP Version F6 for publication in 2021.

G. Virtual Hearing on Privacy, Confidentiality, and Security Considerations for Data Collection and Use during a Public Health Emergency

[Best Practices for Data Collection and Use During PHEs](#)

- [*Summary of Hearing on Privacy, Confidentiality and Security Considerations for Data Collection and Use during a Public Health Emergency \(September 14, 2020\)*](#)

On September 14, 2020, the Subcommittee on Privacy, Confidentiality and Security convened a meeting to hear testimony from public health practitioners and other experts from multiple fields about privacy, confidentiality, and security considerations for data collection and use during a Public Health Emergency (PHE), such as the COVID-19 PHE. The meeting was structured to achieve three broad objectives:

- Understand current policies and practices involving data collection and use with respect to privacy and security during the COVID-19 PHE;

- Understand challenges and potential areas in need of clarification in light of these practices, new and emerging technology developments, and new and evolving policy directions; and
- Identify best practices and areas where additional technical assistance or guidance may be useful.

State and local entities need data stewardship principles designed to guide the privacy and security of individually identifiable health information as they consider deploying new technologies for public health surveillance, including new uses of medical data, social media, geolocation data, proximity or adjacency data, and contact tracing applications. Guardrails are essential for responsible use of data when creating and employing new tools, including the consideration of future use and lifecycle management of individually identifiable health data. Privacy, civil rights, and public interest advocates have raised concerns over the potential for discrimination and harm based on the use of information intended to protect the public if the information is repurposed for unrelated uses such as law enforcement, immigration, or even unrelated research or commercial enterprise.

The Subcommittee is working to translate the knowledge gained during this hearing into recommendations regarding best practices for data collection and use during PHEs, including methods and approaches to responsibly collect, use, protect, store, and share data during a pandemic or long-term nationwide PHE.

H. Final Report from the Task Force on the Intersection of Clinical and Administrative Data (ICAD)

The report described in this section was produced as a joint effort of ONC, the Health Information Technology Advisory Committee (HITAC), and NCVHS.

A Path Toward Further Clinical and Administrative Data Integration

- [***Final Report of the Health Information Technology Advisory Committee's Intersection of Clinical and Administrative Data Task Force to the National Coordinator for Health Information Technology \(November 17, 2020\)***](#)

The 21st Century CURES Act includes this language: “The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.” It catalyzed discussions between ONC and NCVHS regarding the most useful approach to accomplish this.

In March 2019, ONC invited the NCVHS Chair and members of the Subcommittee on Standards to its HITAC meeting, which focused primarily on the burdens on patients, providers, and

payers related to prior authorization. Continuing from there, ONC leadership met with NCVHS at its 2019 meetings to further strategize on next steps.

The vision driving the work was to support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency—furthering implementation of “record once and reuse” wherever possible and clinically appropriate.

ONC asked HITAC to stand up a new Task Force on the Intersection of Clinical and Administrative Data (ICAD). To promote alignment of the work, the co-chair of NCVHS’ Subcommittee on Standards served as a co-chair of the ICAD Task Force, and three additional NCVHS members served as at-large members.

The charge to the Task Force was to make recommendations to support the convergence of clinical and administrative data and improve data interoperability across the ecosystem, to enhance patient access and improve health care efficiency. Use of the prior authorization process was strongly encouraged as the exemplar for a convergence use case. The Task Force further sought to enable innovation and continuous improvement, minimizing the need for special effort on the part of ecosystem participants. The Task Force met weekly for most of 2020 and invited substantial industry input to inform its deliberations. The result was a report that outlined a consensus vision and recommendations toward that vision designed to:

- Create patient-centered design approaches to enhance patient experience, safety, and health outcomes;
- Ensure that patient consent, privacy, and security are established and maintained throughout interoperable processes;
- Use digital capabilities to automate manual, time-consuming activities;
- Optimize approaches to achieve “record once and reuse” whenever clinically appropriate;
- Address key barriers to effective information exchange;
- Improve the transparency and timeliness of the prior authorization and decision-making processes for all stakeholders;
- Build and extend current standards to enable maturity and evolving processes, and resolve conflicting standards which inhibit innovation and adoption;
- Provide a path forward to harmonize today’s national health care policies, vocabularies, and transport standards; and
- Create an ecosystem that enables patients and caregivers to focus on their well-being rather than devoting resources to navigating administrative process complexities.

HITAC plans to use the report to advance its efforts related to 21st Century Cures Act responsibilities to further interoperability and burden reduction, while NCVHS plans to use the

report to inform its HIPAA responsibilities, the Committee's project on data convergence, and ongoing coordination with ONC.

I. Recommendations on Operating Rules for HIPAA Transactions

NCVHS Letter to the HHS Secretary with 4 Recommendations

- [Recommendations on Three Operating Rules for Prior Authorization and Connectivity for HIPAA Transactions \(November 23, 2020\)](#)

In February 2020, NCVHS received a request from CAQH CORE (the ORAE) to consider three new operating rules proposed for federal adoption:

1. Prior Authorization Data Content Rule (v5.0.0);
2. Prior Authorization Infrastructure Rule (v4.1.0); and
3. Connectivity Rule (v4.0.0).

Two of the proposed operating rules address data content and infrastructure and apply to the HIPAA prior authorization transaction. The third addresses connectivity and applies to prior authorization as well as certain other adopted transactions.

In response to this request, the NCVHS Subcommittee on Standards issued a request for public comment and held a two-day virtual hearing in August 2020 to obtain industry input on the three proposed operating rules. It received testimony from 37 organizations and individuals as well as additional written input regarding the anticipated benefits, costs, and possible downsides of each rule. NCVHS analyzed the testimony and deliberated the proposed operating rules in light of current use of the prior authorization standard transaction, the rapid evolution of interoperability innovation and burden reduction, and the principles of HIPAA.

On the basis of the public input and their evaluation, the Subcommittee submitted four recommendations: 1) to adopt an attachment standard; 2) to support and encourage voluntary use of the two proposed operating rules for prior authorization prior to an action for adoption; 3) not to adopt the proposed operating rule for connectivity and to encourage CAQH CORE to complete its new version of the connectivity rule, and 4) to increase visibility of enforcement information related to operating rules. The recommendations reflect the Committee's analysis of industry input as well as recognition of other federal policy initiatives underway to evaluate opportunities to improve electronic prior authorizations through the use of the HL7 FHIR standard and APIs.

Appendix 4. Acronyms Used in This Report

ACA – Affordable Care Act

APCD – All-Payer Claims Database

API – Application programming interface

CAQH CORE — Committee on Operating Rules for Information Exchange

CMS — Centers for Medicare & Medicaid Services

COVID – Coronavirus Disease

CPT – Current Procedural Terminology

DSMO – Designated Standards Maintenance Organization

eCR – Electronic case reporting

EDI – Electronic data exchange

FDS – Federal Data Strategy

FERPA – Family Educational Rights and Privacy Act

FHIR – Fast Healthcare Interoperability Resources

HL7 – Health Level 7

HCPCS — Healthcare Common Procedure Coding System

HHS — Department of Health and Human Services

HIE – Health information exchange

HIT – Health information technology

HIPAA -Health Insurance Portability and Accountability Act

HITAC – Health Information Technology Advisory Committee

HITECH – Health Technology for Economic and Clinical Health Act

ICAD – Integration of Clinical and Administrative Data

ICD – International Classification of Diseases

IT – Information technology

LOINC – Logical Observation Identifiers Names and Codes

MRI – Magnetic resonance imaging

NCPDP – National Committee for *Prescription Drug Programs*

NCVHS -National Committee on Vital and Health Statistics

NIST -National Institute of Standards and Technology

NPRM – Notice of Proposed Rulemaking

OCR – HHS Office for Civil Rights

ONC – HHS Office of the National Coordinator for Health Information Technology

ORAE – Operating Rule Authoring Entity

PHE – Public health emergency

PHI – Protected health information

SDO – Standards Development Organization

SNOMED-CT – Systematized Nomenclature of Medicine -- Clinical Terms

USCDI – United States Core Data for Interoperability

WEDI – Workgroup for Electronic Data Interchange

WHO – World Health Organization

WIN – Well-being in the Nation

Appendix 5. NCVHS Membership Roster

For biographical information of Committee members, please visit the NCVHS website:
<https://ncvhs.hhs.gov/membership/full-committee/>.

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