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Improving Health Care System Efficiency by Accelerating the Update, Adoption, and Use of Administrative Standards and Operating Rules:

A Brief History and Draft Recommendations

Paving the Way to a Predictability Roadmap

September 2018

Subcommittee on Standards

National Committee on Vital and Health Statistics

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVIC

DRAFT REPORT

This is a draft report. This document will be revised based on public input received through December 2018. Send written comments to NCVHS at NCVHSmail@cdc.gov with the subject line "Predictability Roadmap Recommendations." Please include your name, email address, and organization with your comments.

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The National Committee on Vital and Health Statistics

The National Committee on Vital and Health Statistics (NCVHS) serves as the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42U.S.C.242k[k]). NCVHS serves as a forum for interaction with interested private sector and industry groups on important health data issues. Its membership includes experts in health policy, health statistics, electronic data interchange (EDI) of healthcare information, electronic health records (EHRs), privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing healthcare services, healthcare delivery systems, integrated computerized health information systems, health services research, quality measurement, patient safety, consumer interests in health information, health data standards, epidemiology, and the provision of health services. The HHS Secretary to terms of four years each appoints sixteen of the 18 members. Congress selects two additional members. The NCVHS website provides additional information: **www.ncvhs.hhs.gov**

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<u>Executive Summary</u>

Standards development, adoption, and implementation are not predictable and are not keeping pace with business and technology innovations.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that electronic standards be adopted to improve the efficiency and effectiveness of the health care system. The intent of exchanging information electronically was to simplify certain key processes in health care, such as billing or eligibility for health care benefits. The adoption and use of the electronic transactions has resulted in significant efficiencies over the past 15-20 years as both standardization and automation have replaced manual/paper based interactions

However, two main challenges have become apparent, as NCVHS has listened to the marketplace:

1. The enhancements to the standards and operating rules are not happening at a pace to keep up with accelerating business and technology innovation

2. the changes aren't predictable enough to allow for effective planning, resource allocation and rational implementation by all effected parties

For the past eighteen months, NCVHS has been soliciting feedback from industry regarding the update and adoption process for standards and operating rules. The dialog has been robust, and has provided an opportunity for the Subcommittee to identify positive opportunities for change that, if embraced by all parties, can lead to a successful transformation. The current draft recommendations included in this report incorporate these opportunities.

1. Introduction and Background

Purpose

This document addresses long-standing industry concerns regarding the predictability of updates, adoption, and enforcement of the administrative and financial standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Affordable Care Act of 2010 (ACA). For more than a decade, stakeholders have wanted to know:

- When will updated standards and operating rules be available to be recommended to HHS;
- When will HHS adopt updated standards or operating rules;
- When can covered entities legally use updated standards and operating rules;
- How do covered entities most effectively leverage the newest technologies and be innovative without updated standards;
- How do organizations predict what technology to use and plan in this environment, and;
- Will a new version of an adopted standard/operating rule provide a return on investment?

In other words, how do health care managers effectively plan for the future of their organizations?

Today more than ever, health plans, covered health care providers, clearinghouses, and business associates must be strategic in addressing fiscal practicalities, technological innovations, member satisfaction, and high quality patient care. Apropos of standards and operating rules, health care organizations need and expect regular updates, and want a predictable schedule for their adoption. Predictability is an asset in health care operations because it enables more effective planning for the

necessary transitions in workflows, business process changes and system updates. Organizations need sufficient time and information to make the right calculations for scope and resources.

Over the past eighteen months, the NCVHS Subcommittee on Standards has been collecting input about the issues pertaining to the lack of predictability in the processes surrounding the update, adoption, and use of standards and operating rules. The goals of this project were to identify opportunities for change and develop recommendations for improvement – the resulting information was intended to be used to form a Predictability Roadmap for the industry. The Subcommittee will gather additional input through the end of 2018.

Context

For two decades, providers and payers have shared a vision to improve the exchange of health information in a secure, simple manner to manage the administrative and billing processes of health care better. Historically the exchange of information had been paper based and manual. This changed in 1996 when Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Act had four primary objectives: 1) assuring health insurance portability by eliminating job-lock due to pre-existing medical conditions (Title I); 2) protecting the security and privacy of personal health information (Title II); 3) preventing fraud and abuse (Title II); and 4) establishing and enforcing standards for the exchange of electronic health information (Title II). In Subtitle F – Administrative Simplification, sections 261 through 264, the purpose was to improve the Medicare program, the Medicaid program, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information. The Centers for Medicare & Medicaid Services (CMS) regulates and enforces the provisions for the HIPAA standards under the authority of the Secretary of the Department of Health and Human Services. The provisions of HIPAA have been implemented through the regulatory process (rulemaking), and Table 1 provides a list with links to existing regulations published since 2000.

There have been other legislative initiatives that support the growth of health IT, and which affect the exchange of health information for NCVHS stakeholders. In 2009, the Health Information Technology for Economic and Clinical Health Act (HITECH) was enacted, which granted HHS the authority to establish programs to improve health care quality, safety and efficiency by promoting health IT including electronic health records (EHRs). Though not directed at administrative standards, the

Subcommittee on Standards understood the implied potential for convergence of all data, systems, and standards which HITECH foretold.

In March 2010, Congress passed the Patient Protection and Affordable Care Act (ACA). This legislation included a number of provisions for administrative simplification: a reiteration that standards must be adopted for health care attachments, a new requirement to adopt a standard for electronic funds transfer (EFT), requirements to adopt operating rules to support each of the adopted HIPAA standard transactions, and enhanced compliance review activities to support enforcement. In 2015, Congress subsequently passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which included the use of incentives for using EHRs and submitting quality data through technology. The most recent legislation, passed unanimously by Congress, was the 21st Century Cures Act of 2016. This legislation was enacted to improve the flow and exchange of information across the health care system by focusing on the interoperability gains that have accelerated in recent years.

Since 1996, momentum has been building to enable systems, and most importantly, health care stakeholders, to exchange information seamlessly in support of the delivery and reimbursement of health care. In 1996, most data processing was paper or magnetic tape based. Today, most processing is electronic and telecommunications-based and, largely driven by HITECH. The prevalence of electronic health record systems among hospitals, physician practices and dental practices has risen from under 25% to well over 85% (https://dashboard.healthit.gov/quickstats/quickstats.php).   As experience in use of health, IT grows, and the convergence of the systems for administrative and clinical data evolves, the need for predictability and the ability to innovate has increased.

Table 1: Timeline of HIPAA related Statutes and Regulations

Year	Date	Law or Regulation
1996	Aug 21	HIPAA, Health Insurance Portability and Accountability Act
2000	Aug 17	Standards and Code Sets for Electronic Transactions and DSMO Process
2001	Jan 3	ASCA, Administrative Simplification Compliance Act
2002	May 31	Employer Identification Number (EIN)
2003	Feb 20	Transaction Standards and Code Sets

Year	Date	Law or Regulation
2003	Aug 15	Electronic Submission of Medicare Claims
2004	Jan 23	National Provider Identifier (NPI)
2006	Feb 16	Enforcement of Administrative Simplification
2009	Jan 16	Version 5010/D.0 Final Rule
2009	Jan 16	ICD-10 Final Rule
2009	Feb 17	HITECH Act and Civil Penalties
2009	Oct 30	Enforcement and Civil Penalties
2010	Mar 23	ACA, Patient Protection and Affordable Care Act; ACA Administrative Simplification Provisions
2011	July 8	Operating Rules for Eligibility for a Health Plan and Claim Status
2011	Dec 7	ICD-10 Medical Loss Ratio Update
2012	Jan 10	Standards for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA)
2012	Aug 10	Operating Rules for EFT and ERA
2012	Sept 5	HPID Standard and ICD-10 Compliance Delay to 2014
2013	Mar 26	Administrative Simplification Regulations Consolidated (Unofficial)
2014	Jan 2	Certification of Compliance for Health Plans
2014	Apr 1	PAMA, Protecting Access to Medicare Act
2014	Aug 4	ICD-10 Compliance Delay to 2015
2014	Oct 31	HPID Enforcement Discretion Period
2017	Oct 4	Certification of Compliance Withdrawal Notice

Standards Development Process and Statutory Roles (in alphabetical order)

A list of relevant terms and organizations is provided below with a brief explanation for each. This list provides a common context for each of the terms, and in some cases a citation is included if appropriate.

The American National Standards Institute (ANSI) – ANSI facilitates the development of American National Standards (ANS) by accrediting the procedures of independent standards developing organizations (SDOs). Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of American National Standards meet ANSI's requirements for openness, balance, consensus, and due process.

Designated Standards Maintenance Organization (DSMO) – The concept of the DSMO process and the DSMOs were created in the August 17, 2000 Transactions and Code Sets Rule. Section §162.910 established criteria for the standards maintenance and update process and identifies the *organizations* designated by the Secretary of HHS to be responsible. Detailed information is available at http://www.hipaa-dsmo.org/Overview.asp.

Operating Rules – Operating Rules were introduced to the Administrative Simplification provisions of HIPAA under section 1104 of the Affordable Care Act of 2010 (ACA). Operating rules are defined as the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications (also defined at 45 CFR 162.103). Operating rules set certain requirements for transactions for which standards have been adopted under HIPAA. Operating rules specify the information that must be included when conducting the standard transactions, making use of the transactions more consistent between health plans and providers.

Operating Rule Authoring Entity (ORAE) – This is an organization that meets the criteria specified in section 1104 of the Affordable Care Act, is selected by NCVHS and recommended to HHS to develop the operating rules for the HIPAA standards and approved by the HHS Secretary. An organization may be selected and approved as an operating rule authoring entity by going through a review process and meeting specific criteria defined in the law. The criteria include, for example: a) mission focus on administrative simplification; b) multi-stakeholder and consensus based process; c) workgroup representation by health plans, health care providers, vendors, relevant Federal agencies and other standard development organizations; d) a public set of guiding principles that ensure the process is open and transparent; e) public review and updates of the operating rules.

Standards – Standards are an agreed upon format and established content for exchanging information between two parties. In the case of HIPAA, the Secretary has identified and adopted administrative transaction standards for administrative and retail pharmacy transactions.

Standards Development Organization (SDO) - is an organization whose primary activities are developing, coordinating, maintaining and producing technical standards intended to address the needs of a group of affected adopters. SDOs are defined at 45 CFR 160.103 in the Transaction and Code Sets (TCS) rule as "an organization accredited by ANSI that develop and maintain standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of this part" (i.e., meaning the regulation).

Designated Participants in HIPAA Standards Development and Maintenance (alphabetical order)

ASC X12 – ASC X12 develops and maintains administrative transaction standards for many industries, including the insurance industry. Several of the ASC X12 transactions are in use today under HIPAA, including claims, eligibility for benefits, enrollment/disenrollment etc. The full set of transactions can be found in Table 1 at the end of this document. ASC X12 is a DSMO in the Transactions and Code Sets (TCS) rule.

CAQH CORE - The Council for Affordable Quality Health Care created the Committee on Operating Rules for Information Exchange (CORE). CORE's mission is to develop business rules, or the Operating Rules to promote the interaction of exchange of health information between health care organizations in a consistent, standardized manner, in compliance with applicable laws and regulations, with the goal of increasing efficiency and reducing administrative costs.

CMS - Centers for Medicare & Medicaid Services, Division of National Standards (DNS). This is the agency and division under Health and Human Services to which authority has been delegated by the Secretary for preparation of regulations and enforcement of HIPAA and the administrative simplification provisions of ACA. CMS also houses the Medicare and Medicaid programs, which are covered entities under HIPAA.

DCC - Dental Content Committee – The American Dental Association hosts this committee, which represents the dental community. It is responsible for the maintenance of the data specifications for dental billing. The DCC is one of the Designated Standards Maintenance Organizations (DSMO) in the Transactions and Code Sets (TCS) rule.

HHS – The U.S. Department of Health and Human Services is the federal department responsible for promulgating final regulations for HIPAA – privacy, security and standards. NCVHS submits its recommendations regarding HIPAA administrative standards and privacy considerations to the Secretary of HHS, based on the consultative role for the Committee stipulated in the legislation.

HL7 – Health Level 7 International develops and maintains clinical standards used internationally. HL7 standards support information exchange within and between Electronic Health Records. HL7 is a DSMO in the Transactions and Code Sets (TCS) rule.

NACHA – Electronic Payments Association. NACHA administers the Automated Clearinghouse (ACH) Network for payments and is a non-profit association that supports the payment industry. NACHA is the maintainer of the standard for Electronic Funds Transfer (EFT) and supports the associated operating rules for this standard.

NUBC – National Uniform Billing Committee. This organization is chaired and hosted by the American Hospital Association (AHA) and is responsible for the maintenance of institutional claims and formats. NUBC has a formal consultative role under HIPAA for transactions affecting institutional health care services and is a DSMO in the Transactions and Code Sets (TCS) rule.

NUCC - National Uniform Claims Committee. This organization is chaired and hosted by the American Medical Association (AMA) and is responsible for the maintenance of the professional CMS-1500 uniform claim form and the X12 standard health care claim (837). The NUCC also maintains the Provider Taxonomy Codes and has a formal consultative role under HIPAA for transactions affecting non-dental and non- institutional health care services such as physician and nurses. The NUCC is a DSMO in the Transactions and Code Sets (TCS) rule.

NCPDP – National Council for Prescription Drug Programs is ANSI-accredited and maintains standard formats for use by the retail pharmacy industry, some of which is adopted under HIPAA, and is included in Table 1 at the end of this document. Several of the NCPDP transactions are in use today under HIPAA. NCPDP is a DSMO in the Transactions and Code Sets (TCS) rule.

WEDI – Workgroup for Electronic Data Interchange. Dr. Louis Sullivan, Secretary of HHS in 1991, created WEDI to develop the process for health care information exchange. The 1996 HIPAA legislation included a role for WEDI as an advisor to the Secretary, representing all sectors of the health care industry.

Adoption of Standards, Codes, and Operating Rules

HIPAA requires the adoption of standards, code sets, and identifiers for certain electronic transactions. These transactions include health care claims, health care payment and remittance advice, health claim status, eligibility for a health plan, enrollment, and disenrollment in a health plan, health plan premium payments, health care attachments, referral certification and authorizations, Electronic Funds Transfer, and first report of injury. HIPAA also requires the adoption of medical code sets to be used with the transactions, for procedures and diagnoses, including dental and pharmacy codes, as well as identifiers for employers, providers, health plans and individuals[1]. The Affordable Care Act of 2010 required HHS to adopt a standard for Electronic Funds Transfer (EFT), and individual operating rules for each of the transactions. Appendix B includes a table of all adopted HIPAA standard transactions and operating rules, and their implementation dates.

How are standards and operating rules recommended for adoption? The DSMO and NCVHS Process.

The Transactions and Code Sets rule (TCS), published on August 17, 2000 (65 FR 50368) established the process for both the maintenance of standards as well as the adoption of modifications to standards (§162.910). These provisions have been the foundation of the standards update process for nearly twenty years.

The TCS rule named the participating standards development organizations and code content committees responsible for maintaining and updating the standards to be adopted under HIPAA. Those are listed in the section above. Each organization is responsible for maintaining its own standards, and for receiving and processing requests for modifying an adopted standard. The TCS rule also created the Designated Standards Maintenance Organization (DSMO) in which each SDO and code content committee participates under a self-renewing Memorandum of Understanding (MOU). The DSMO is responsible for reviewing updated standards and submitting its consensus recommendation to NCVHS.

The DSMO process envisioned in this Final Rules was important, because it was the first step towards moving a new or updated standard forward in the adoption process. The rule required the Secretary to consider a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if "the recommendation was developed through a process that provided

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[1] Since 2000, Congress has prohibited HHS from spending funds on the development of an identifier for individuals/patients.

for: open public access, coordination with other DSMOs, an appeals process, an expedited process to address content needs identified with the industry, and submission of the recommendation to NCVHS."

This foundation from the TCS rule resulted in the initial process for addressing change requests to the standards. As described above, the DSMO, comprised of representatives from each of the SDOs, Data Content Committees and HHS is responsible for reviewing and approving requests to change a standard. In the first few years after HIPAA was implemented, industry representatives submitted their change requests for the standards (one implementation specification or transaction) directly to the DSMO[2]. The DSMO initiated its review process between all of the SDOs. Each of the organizations that made up the DSMO had 90 days to review the change request and vote on their response to it. The 90-day timeframe for this step is specified in the DSMO MOU. This 90-day period was to allow further industry approval to move forward with the request for adoption of a modification. During this process, there is also the possibility of a onetime 45 day extension should one SDO need request more time for review. After the individual reviews, the SDOs submit their responses to the change request to the DSMO Steering Committee. The Steering Committee reviewed all of the responses, and formulated a recommendation for a letter to NCVHS. The letter, once delivered to the Chair of NCVHS, was a signal to initiate an industry hearing. At the hearing, stakeholders would opine on the readiness of the standard and its costs and benefits.

Beginning in 2005, the DSMO noticed that change requests were being submitted directly to the maintainer of the standard and documented this trend in their annual reports to NCVHS. These annual reports add insight about the evolution of the change request process. The reports can be found here: http://www.hipaa-dsmo.org/Reports.asp. The history of change requests since 2001 are located here: www.hipaa-dsmo.org/overview.asp.

New and modified operating rules developed and maintained by CAQH CORE do not go through the DSMO process. When a new or updated operating rule has been approved by the consensus based work groups at CAQH CORE, the organization must submit a letter to NCVHS with a copy of the new or updated rule, information about the process, and a request for review. NCVHS will conduct a public hearing in the same way it does for updated standards or code sets. A hearing on operating rules is

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[2] In 2001, the DSMO received more than 140 change requests; by 2005, the number decreased below 20. Read the DSMO annual reports for more information about the shift of requests from the DSMO to the SDOs.

identical to a hearing on an updated standard. Stakeholders testify on the readiness of the rule(s) and provide input on costs and benefits.

The NACHA operating rules for the Electronic Funds Transaction (EFT) transaction are specific to the ACH File Exchange portion of the transaction, and are developed and maintained by the National Automated Clearing House Association (NACHA). The NACHA operating rules were adopted in the Interim Final Rule to adopt the standard for EFT (77 FR 1590), where the detailed specifications can be found. These operating rules, for ACH File Exchanges and Record Format Exchanges, are updated in accordance with the NACHA guidelines. The guidelines can be found on the NACHA website at www.nacha.org. Because these operating rules are specific to the ACH portion of the transaction, they are not part of the DSMO or NCVHS review and approval process.
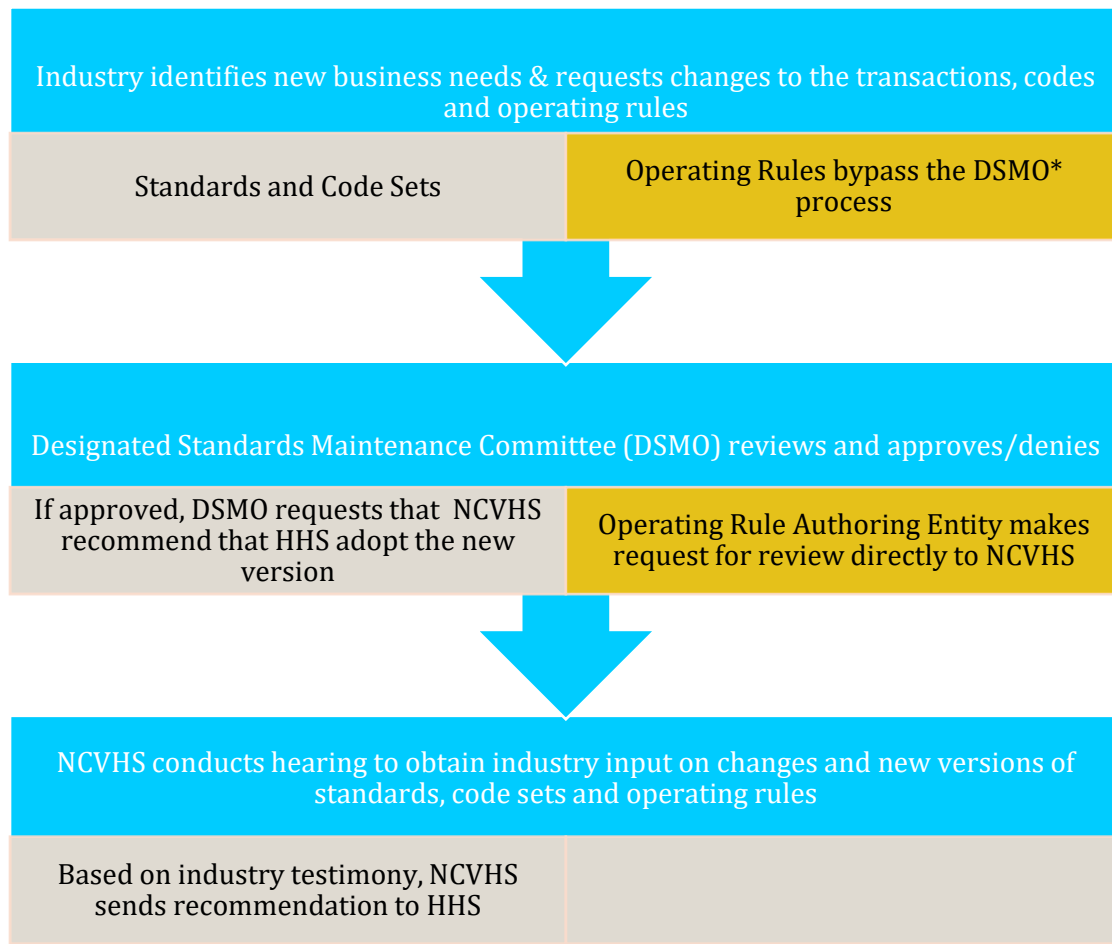
 The graphic below is a simplified view of the movement of a request for updated or new standards or operating rules from the standards organizations to NCVHS. As discussed above, today most, if not all requests for changes to the individual transactions are made directly to each SDO. The SDOs reach out to the DSMO when the ballot process for an updated version of a standard is complete, and they are ready to request a recommendation to NCVHS. Industry makes change requests for the operating rules directly to the authoring entity only.

In either scenario – whether from a DSMO request, or operating rule authoring entity request, NCVHS conducts a hearing with industry representatives to obtain input on the cost/benefit and readiness of the standard or operating rule. Following the hearing, NCVHS makes a recommendation to HHS. If HHS concurs with the recommendation, the Secretary authorizes staff to begin the rulemaking process[3] (i.e., Notice of Proposed Rule Making, or NPRM) to notify industry that it intends to adopt the new or updated standard or operating rule. After consideration of public comments on the NPRM, HHS issues a Final Rule, which becomes the official regulation and includes guidance for implementation and notice that enforcement will begin on a certain date. Under current law, HHS can also publish sub-regulatory guidance that can be useful to help clarify the regulation but cannot change the policy, for example a list of Frequently Asked Questions (FAQs).

Throughout the remainder of this document, the DSMO members, SDOs, CAQH CORE and NACHA will all be referred to as standards organizations or SDOs to simplify the discussion.

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[3] In accordance with the Federal Rulemaking schedule and Unified Agenda

Current process for NCVHS to receive and transmit recommendations about updated standards

Industry identifies new business needs & requests changes to the transactions, codes and operating rules	
Standards and Code Sets	Operating Rules bypass the DSMO* process

Designated Standards Maintenance Committee (DSMO) reviews and approves/denies	
If approved, DSMO requests that NCVHS recommend that HHS adopt the new version	Operating Rule Authoring Entity makes request for review directly to NCVHS

NCVHS conducts hearing to obtain industry input on changes and new versions of standards, code sets and operating rules	
Based on industry testimony, NCVHS sends recommendation to HHS	

2. Purpose of the Predictability Roadmap

Business innovation, technical innovation, and industry transformation are accelerating. The current standards development and Federal regulatory adoption processes are not sufficient to meet industry business needs effectively. The industry has identified the challenges, and there is agreement about the lack of predictability about:

- the process and schedule of *updating* standards,

- the timing of adopting updated standards *through regulation*

- how *use* of standards by trading partners (work-arounds)

- the *enforcement* of regulations when there are inappropriate or inconsistent uses by covered entities and third parties.

This lack of predictability and reliability has locked industry into a rigidity that both stifles innovation and prevents organizations from embracing evolutionary changes to business practices, e.g., the introduction of value-based purchasing and accountable care organizations. The Predictability Roadmap is an attempt to create the environment for effective planning and budgeting for system and operating resources and a well-structured system of effective standards maintenance and adoption.

The Predictability Roadmap aims to provide reasonable solutions, each of which can be acted on over time, and which will have specific and incremental impacts for the benefit of health plans, providers, and clearinghouses. Though efforts to address this topic have been attempted over the years, the Subcommittee on Standards has more recently participated in targeted discussions with industry and the SDOs to understand the issues, identify opportunities for change, and prepare recommendations. The intent was to enable covered entities and their business associates to share:

- information about the impact of current processes and the unmet business needs as the input for updates to standards, and

- opportunities for certain process changes.

The tasks below, from the Subcommittee on Standards' 2017 project planning document, have been accomplished, and are now incorporated in the first stage of the Roadmap:

- Develop implementable ideas for process improvements for each SDO and ORAE, both short term (within 12 months) and longer term;

- Conduct an analysis of alternative opportunities to adopt standards and operating rules for HHS under current and future administrations;

- Create a summary report of a conference call (with the SDOs) and a workshop to be publicly available and used to solicit feedback from other stakeholders;

- Develop actionable recommendations for the Secretary of HHS.

The discussions and meetings with stakeholders over the past eighteen months have focused on understanding how the standards development and adoption processes work today, and what practices will need to change to support a rapidly evolving health care industry. NCVHS is exploring options for providing the needed degrees of certainty for industry. These options may be in the timing and sequence of the development or adoption of standards and operating rules, or, in other aspects of existing regulatory or legislative policies.

Based on the information gathered and synthesized to date, the Committee developed a vision for this Predictability Roadmap. That vision is for covered entities and business associates to be able to use up-to-date HIPAA standards consistently, garnering increased value from the standards by avoiding "one-off" work-arounds, and to reliably know when updated versions will be adopted in time to prepare systems, resources, and business processes.

3. Early History – 2006- 2009

In early 2006, NCVHS published its biennial Report to Congress, which marked a decade since the enactment of HIPAA. In that report, the Committee chair put forth NCVHS' reflections on the HIPAA experience and the lessons learned, drawing on testimony the Committee had solicited over a period of several years. In its June 22, 2006 letter to the HHS Secretary, NCVHS offered 10 recommendations aimed at improving HIPAA updates, adoption rates and return on investment. The letter is available at https://ncvhs.hhs.gov/rrp/letter-to-secretary-levitt-hipaa-lessons-learned/. In the summer of 2006, NCVHS began to focus on solutions to streamlining the updating and promulgation of HIPAA standards, and engaged with industry and SDOs to evaluate how the modification process could be simplified.

On July 7, 2009, representatives from the standards development organizations (SDOs) published an update to an earlier white paper titled, "*Proposal for the Modification of the HIPAA Transaction Implementation Specifications Adoption Process*." This paper explained why improvements were needed in the adoption process for HIPAA standards, and what needs were not being met in the health care industry under the current processes. The authors wrote, "health care industry stakeholders have struggled to understand the impact of HIPAA since its inception, stating that the legislation is complex and is hampered by its own rigid processes. SDOs, with voluntary industry participants, try to address these challenges by actively engaging in the development of implementation specifications. These specifications represent the knowledge, consensus, and approval of the industry members. However, the ability of the SDOs to be responsive to industry needs is greatly impaired by the regulatory process and

its subsequent impact on standards adoption." The authors provided a list of reasons for the inefficiencies in the standards adoption process, primarily:

- Constraints from the regulatory and Administrative Procedures Act (APA) processes
- Length of time from industry approval to implementation of new versions
- Modifications being made to approved implementation specifications
- Lack of predictability in the process
- Pilot testing as a possible requirement step
- Lack of industry understanding of the cyclical process at the SDO
- Not enough industry input at the time of SDO standards development (it's too late once an NPRM is published), and
- Lack of agreement on how often the industry wants to move to a new version versus the market need for making that change.

There are a mix of issues in the list, however, several items point directly and indirectly to the lack of predictability. The 2009 report pointed to the downstream impacts of the inefficiencies in the standards update process, which included inconsistent use of the transactions to accommodate different vendor installations. The report also highlighted difficulties prioritizing staffing allocations and the timing of system installations. As the authors observed, the use of outdated standards hampered progress with newer technologies and which then required more contracts with third party business associates.

In the 2009 paper, the authors also noted that the HHS enforcement protocols were not effective in ensuring the consistent use of the standards across all covered entities, their trading partners, and business associates. Many organizations complained that providers and their vendors are required to implement so many work-arounds to ensure the exchange of information because organizations do not use the transactions in a standard way; the purpose behind standardization has been lost in many installations. Because standards were not updated reliably, or not adopted regularly, the authors wrote: "the net impact to the health care industry of an unpredictable schedule for both the update and adoption of standards negates the ability to conduct effective strategic planning and budgeting for staffing, new technology, or innovation."

NCVHS Review Committee Findings (2016)

The Patient Protection and Affordable Care Act (ACA) {§1104 (i)}, enacted on March 23, 2010, authorized the Secretary to establish a Review Committee responsible for conducting hearings to

evaluate and review the adopted standards and operating rules. Specifically, the Review Committee is to: 1) Conduct hearings not less than biennially to evaluate and review the adopted standards and operating rules, 2) Provide recommendations to the Secretary not less than biennially for updating and improving such standards and operating rules, 3) Recommend a single set of operating rules per transaction standard and maintain the goal of creating as much uniformity as possible in the implementation of the electronic standards, and 4) Ensure coordination, as appropriate in developing recommendations, with the standards that support the certified electronic health record technology approved by the Office of the National Coordinator for Health Information Technology.

In 2014, the Secretary designated NCVHS to act as the Review Committee. NCVHS held its first Review Committee hearing in June 2015. The purpose of the hearing was to gather feedback from the industry regarding the state of implementation of all the HIPAA named transactions. More than 77 testifiers, representing health care organizations, and including the Designated Standards Maintenance Organizations (DSMO), SDOs, and ORAE were invited to testify and address the questions listed below related to the HIPAA standard transactions and operating rules:

- The status of implementation of all HIPAA-named transactions and their corresponding standards and operating rules.
- The degree to which current standards, code sets, identifiers, and operating rules continue to fulfill the business needs of the health care industry.
- The degree to which the use of the standard or operating rule results in discrepancies, ineffectiveness or inefficiencies in the implementation of a transaction, which causes conflicting or unanticipated negative impact to transaction implementers and the industry as a whole.
- Any inability or limitation of the standard or operating rule to meet new and emerging business needs of the industry.
- Whether changes in current standards and operating rules for any particular transaction are needed.

Many stakeholders reported their belief that the adoption and implementation of all HIPAA named transaction standards and operating rules across the industry are viewed as significant steps forward towards achieving greater administrative efficiencies. However, further work is needed to refine and continuously update the adopted transaction standards and operating rules and increase their level of implementation and the consistency in the way in which they are implemented and used. Health care industry representatives indicated that not all adopted transaction standards and

operating rules show consistent and sustained adoption for a number of reasons including advances in information technology, changes in health care delivery models, changes in reimbursement models, and availability of simpler or less costly alternatives.

One of the most significant findings from the June 2015 hearing was the variation in the level of implementation of various transaction standards and operating rules. Another significant and related finding was the degree of inconsistency that still exists within the industry in the way transaction standards and operating rules are being implemented. Even when the transactions are implemented electronically using the adopted standards and operating rules, inconsistencies in the implementation rules that define the data content, coding, and processing are creating barriers that require workarounds or manual interventions to achieve the expected efficiencies and effectiveness. Following the June 2015 hearing, NCVHS sent a [letter] to HHS with a set of recommendations directed at HHS, SDOs, the operating rule authoring entity and the health care industry in general. In general, the recommendations addressed these items:

- Explore the feasibility of expanding the definition of HIPAA covered entities
- Broaden education
- Ensure consistency
- Enforce compliance
- Adopt the acknowledgment transaction
- Provide predictability in the adoption of standards, code sets, identifiers and operating rules
- Ensure responsiveness to evolving changes in health care.

The input from the 2015 hearings closely mirror the input the Subcommittee on Standards received in 2017 and 2018; the draft recommendations provided later in this document are also consistent with the 2015 report.

4. Recent Stakeholder Engagement (2017-2018)

Information gathering. In May 2017, the Subcommittee on Standards met individually with leaders from each of the standards development organizations and the operating rule authoring entity to gather information regarding their ANSI accreditation status, if applicable, their standards update and balloting processes, their publication schedules and the structure of their workgroups. The Subcommittee independently compiled supporting documentation for each organization as well, and populated the information into a comprehensive grid for comparison purposes. The resulting

document demonstrates the similarities and differences between all of the SDOs. To review this grid, visit the NCVHS web site at https://ncvhs.hhs.gov/subcommittees-work-groups/subcommittee-on-standards/. This exercise was instructive regarding the different procedures used by the SDOs and ORAE for updating their products to make them available for adoption on a routine schedule. The Subcommittee on Standards learned that there are several factors affecting a standards organizations' ability to meet publication deadlines. One factor that stood out is access to a sufficient body of resources to do the work – paid or volunteer. The Subcommittee on Standards confirmed that the standards organizations are highly dependent on volunteers and that some SDOs struggle to get sufficient and consistent industry involvement in the workgroups, especially from the provider and state Medicaid communities.

Visioning Exercise. On August 21, 2017, the Subcommittee on Standards invited leaders from each of the standards development organizations and WEDI to participate in a visioning exercise to discuss opportunities for change in the standards development processes. The moderator used Appreciative Inquiry (AI), with the intent to engage the participants in envisioning the potential for change, building on the current strengths of each organization. Appreciative Inquiry is an established change management technique that builds on the positive attributes of each organization, exploring possibilities from respective organizations' perspectives, rather than from negative attributes or perceptions. The foundation of the AI methodology for change is to encourage participants to look positively at the past and collaboratively develop actions that will be meaningful and sustainable for the future. The SDOs and interested industry participants spent the day working through the AI exercises of Discovery (Appreciating), Dream (Envisioning Results), Design (Co-constructing the future), and Destiny (Delivering a collective vision of the future). At the end of this visioning session/AI workshop, the participants discussed shared strengths and opportunities, and identified topics on which they could collaborate. It was through this exercise that the five themes that are the foundation of this Roadmap emerged:

- Governance
- Updates to Standards
- Regulatory Processes
- Data Harmonization and;
- Third Parties as Covered Entities.

The summary report can be found on the NCVHS website at www.ncvhs.hhs.gov or

https://ncvhs.hhs.gov/wp-content/uploads/2018/06/Summary-Report-of-Predictability-Roadmap-Workshop-FINAL-Nov-17-2017.pdf . A broader description of the themes and a chart describing the status quo is available in Appendix A.

HHS Regulatory Process. In March 2018, the Subcommittee on Standards met with the Deputy Director of CMS' Division of National Standards to learn about the Federal regulatory process. The Deputy Director provided a concise description of the internal decision-making process for publishing regulations, how determinations are made to post a regulation on the Federal Unified Agenda, and a discussion of the requirements in the Administrative Procedures Act (APA), foremost of which is the need for notice to the public, and an opportunity for comment. Most rules require a notice of proposed rulemaking (NPRM), on which the public can submit comments. After HHS (CMS) reconciles the comments, it will publish a final rule. The internal clearance process for a final rule is the same as for a proposed rule. Chart 2 shows an abbreviated view of the regulatory process for standards adoption.

The CMS representative explained that the decision to develop regulations is based on several factors, primarily statutory, such as HIPAA and ACA. However, while an Executive Order or a statute may direct that a regulation be published, there are examples of those requirements not being acted on by the statutory dates, such as the ACA requirement to adopt standards for health care attachments by 2014. Regulations are also published based on a recommendation from an advisory committee, e.g., NCVHS. However, lack of action on a recommendation (from NCVHS) may be an issue of administrative priorities.

Chart 2: Current Regulatory Process

1 Initiating Event: Request for Rule Making to adopt a new standard, updated standard or operating rule	**2** HHS Determines if a rule is needed	**3** HHS Prepares a Proposed Rule (NPRM) or Interim Final Rule (IFC) May take 1 – 2 years
4 Regulation goes through the clearance process at CMS and HHS	**5** The Office of Management and Budget reviews the rule (90 days allowed)	**6** HHS Publishes the Proposed Rule for a public comment period (60 days)
7 HHS reviews and reconciles the public comments	**8** HHS Prepares a Final Rule based on the public comments	**9** The Final Rule goes through the internal clearance process at CMS and HHS
10 OMB reviews the Final Rule (90 days)	**11** The Final Rule is published in the Federal Register with an effective date and a compliance date	**12** Typically, the mandatory compliance date for standards and operating rules is 2 years for all covered entities; 3 years for small health plans

CIO Forum. On May 17, 2018, the NCVHS Subcommittee on Standards held a Forum with 21 invited technology experts and senior corporate officers representing a cross-section of organizations that were end-users of the HIPAA and ACA administrative standards. The goal of this Forum was to elicit ideas for improving the standards development, update and adoption process in the context of the five themes. The information has been used to identify actionable steps to include in the Predictability Roadmap, and to inform the recommendations in this document, as well as those that will be sent do the Secretary of HHS. At the Forum, the Subcommittee wanted to get a sense of how standards and operating rules needed to evolve to support business requirements for the health care industry in the

future. Forum participants' agreed that the themes identified at the August 2016 Appreciative Inquiry visioning session represented significant challenges for the industry and merited being addressed. Speaking as end-users of the standards and operating rules, albeit from unique perspectives, they found broad agreement about the ways in which the reality of administrative standards today falls short of their potential, and about the types and urgency of improvements needed. Forum participants agreed that the HIPAA and ACA administrative standards have already enabled significant efficiencies with respect to pre-HIPAA paper processing and direct data entry and positioned the industry for even more innovations for which a robust standards base is necessary. Participants stressed that in their current state, and with current processes, standards do not support enough of their business needs or enable innovation. In fact, this group suggested that the current standards adoption process actually stifles innovation. The pace of standards development and updates lags far behind the pace of technology and business change, still necessitating many manual processes and leading to what one participant called "technical debt" and another called "throwaway work." As one part of the solution, the group urged that the input of end-user organizations be better leveraged in the standards development and adoption processes. The major themes from the CIO Forum that have informed the recommendations for the NCVHS Predictability Roadmap include these concepts:

- The rulemaking process for the HIPAA/ACA administrative transactions, code sets, and operating rules is not functioning adequately to meet industry's business needs. The current process is too lengthy, unpredictable, unaccountable, inconsistent, and constraining. It stifles innovation, cannot keep up with changing business requirements or changing technology, and is not aligned with standards development on the clinical side of the business.

- Because of the mismatches between business needs and the pace of technology development, on the one hand, and standards development, updates, uptake and regulation, on the other, the health care industry's strategic needs are not being met.

- Standards development and governance should involve end-users, organizations of different sizes and content experts.

- Consideration should be given to making funding available for the standards development process instead of continuing to conduct it on a voluntary basis.

- The standards development/update process should involve smaller iterations, have a predictable cadence (i.e., a regular and reliable cycle schedule), and include reasonable backward compatibility.

- More iterative and agile models, based on ample planning, are needed for governance, standards adoption/updates and regulation. Standards should set a floor but not a ceiling (i.e., allow extensibility within clear guidelines), be based on versioning, and include a sunset.

- The standards development process should become more evidence-based. That is, it should incorporate empirical testing and pilots that generate learning, minimize glitches in newly deployed standards, squarely address industry pain points, and demonstrate ROI. Achievement of those objectives would thereby encouraging adoption.

- The types of entities that handle patient information subject to HIPAA transaction, code sets, operating rules, privacy, and security requirements should be expanded. Some Forum participants favored a significant expansion of organizations to be considered as covered entities. Others preferred the creation of some equivalent process to bring other industry actors under the standards use umbrella and data protection obligations.

- Participants were nearly unanimous that there is no longer any meaningful differentiation between administrative and clinical data, so the standards development processes for both HIPAA and HITECH/Meaningful Use appear ready to be aligned. This will have significant impact on both HITAC/ONC and NCVHS/CMS in their respective recommendations and rule making.

A summary of the meeting was published after the Forum and is available on the NCVHS website https://ncvhs.hhs.gov/wp-content/uploads/2018/07/May-2018-CIO-Forum-Final-Summary-for-Exec-Subcmte-Review.pdf

Summary

The NCVHS Subcommittee on Standards' has drafted a Predictability Roadmap by identifying the barriers to the reliable update, adoption, and use of the HIPAA standards and operating rules. Through its processes, the Subcommittee has validated the challenges identified by the health care industry for well over a decade. The consistency, clarity, and consensus discovered during the Subcommittee on Standards' information gathering and engagement process over the past eighteen months have resulted in the draft recommendations in this document.

DRAFT REPORT

This Roadmap now includes an overarching vision, desired outcomes, actionable recommendations, and calls to action to achieve the aim of leading industry to more effective and efficient exchange of health care information. It is clear from all of the hearings and interactions with industry for more than 15 years, that there is a collective call for change and action. This call is particularly urgent given the technology evolution, today's electronic norms compared to the world when HIPAA legislation passed in 1996, and the shift away from fee-for-service payments toward value-based purchasing arrangements.

5. Lessons Learned: Outcome of stakeholder input and recommendations

As stated above, after the August 2017 visioning session, five themes emerged that were consistently regarded as affecting the development, update, adoption, and use of standards and operating rules. Appendix A provides a description of the themes from the Visioning Session. Appendix A also includes Table 1, which provides scenarios of what could happen if the status quo remains in place.

After the CIO Forum, the Subcommittee consolidated its findings, creating a set of three overarching outcomes, a composite of recommendations, calls to action, and measurement suggestions. Together these comprise the next phase of the Roadmap development.

Proposed Recommendations

Each of the recommendations and calls for action addresses one or more of the themes identified through the Subcommittee's stakeholder engagement efforts.

 The overarching vision is to enable covered entities and business associates to know when new standards will be available for adoption and use; to know when they need to update systems and business processes to accommodate new standards, operating rules or codes, or when they can anticipate being able to implement innovations in their systems and processes.

The recommendations focus on improvement opportunities identified from the themes addressed in the Appreciative Inquiry visioning session, and the CIO Forum. These are:

- **Improvements for the federal processes**
    - o Enforcement of existing regulations
    - o Guidance, outreach and education
    - o Responsiveness to recommendations
- **Improvements for SDO processes to ensure productivity and responsiveness**

- o Diversity of industry participation in standards development

- o Ability of standards to support innovation and evolving business and technology

- o Timeliness and reliability of updates

- **Governance and oversight**

  - o Transparency of processes (Federal and SDO)

  - o Responsiveness to industry needs

The outcome goals have been grouped in three non-exclusive areas of focus listed below. These are supported by 23 recommendations and calls to action in the table below which respond to the input provided most recently as well as over the past decade.

- Improved education, outreach and enforcement will promote efficient planning and use of the adopted HIPAA standards and operating rules—by all covered entities and business associates.

- Policy levers will successfully support industry process improvement changes.

- Regulatory levers will enable timely adoption, testing, and implementation of updated or new standards and operating rules.

Draft Recommendations for the Predictability Roadmap

Category	2019 – 2020 Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.	2020 – 2021 Policy levers will successfully support industry process improvement changes.	2021 – 2024 Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules
Recommendations	**1.** HHS should increase transparency of their complaint driven enforcement program by publicizing de-identified information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry. **2.** HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law. *enforcement includes complaints, audits and compliance reviews as defined in statutory language	**3.** HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition. **4.** HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities. **5.** HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.	**6.** SDOs and ORAE should publish updates to their standards and operating rules and make them available for recommendation to NCVHS on a schedule that is not greater than 2 years. Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCVHS. NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months. HHS should adopt the NCVHS recommendations on a regular schedule.
	7. HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.	**8.** HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with	**10.** HHS should adopt incremental updates to standards and operating rules. In accordance with Sec 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCHVS, and if updates are available.

Category	2019 – 2020 **Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.**	2020 – 2021 **Policy levers will successfully support industry process improvement changes.**	2021 – 2024 **Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules**
		what is permitted in §1174 of the Act). **9.** HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.	**11.** HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation. **12.** HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.
Calls to Action	**A.** Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases. **B.** The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.	**C.** HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3rd parties to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.	**D.** HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.
	E. SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.	**G.** Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance	**H.** HHS should continue to publish a universal dictionary of clinical, administrative, and financial standards that are or will be available

Category	2019 – 2020 **Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.**	2020 – 2021 **Policy levers will successfully support industry process improvement changes.**	2021 – 2024 **Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules**
	F. Leadership from the public and private sector should commit to membership in Standards Development Organizations; assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs	should include detailed and enforceable policies regarding business practices, including policies for identifying and implementing best practices in such an organization.	for use, e.g. the ONC Interoperability Standards Advisory (ISA).
Measurement	**M1**. HHS should disseminate results of its enforcement program regularly and publicly, to promote transparency, opportunities for education, and benchmarking.	**M2.** HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance. **M3.** NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.	

6. Metrics and Milestones

The NCVHS Subcommittee on Standards will vet the recommendations across industry and develop metrics and milestones based on the input. The first milestone will be to collect the responses from HHS, the SDOs, Congress, and other industry organizations who choose to respond to the recommendations after the first quarter of 2019.

Once the Subcommittee on Standards has received feedback from HHS and other stakeholders, the Subcommittee on Standards will determine what work is necessary to develop specific metrics, and where responsibility rests for that work.

7. Monitoring

NCVHS is required to report regularly to Congress on the status of HIPAA implementation. Information about the Predictability Roadmap will be included in the 13th Report to Congress in the First Quarter of 2019. Through hearings, informal communication and participation in industry meetings, NCVHS will be able to ascertain information about the industry's progress on the recommendations and on-going barriers. To read previous Reports to Congress, visit the NCVHS website at www.ncvhs.hhs.gov/reports. For the 12th Report to Congress, click here.

8. Next steps

The publication of this document is one-step in our documentation of the Predictability Roadmap, as it contains the draft recommendations. The next step is to obtain feedback on the recommendations.
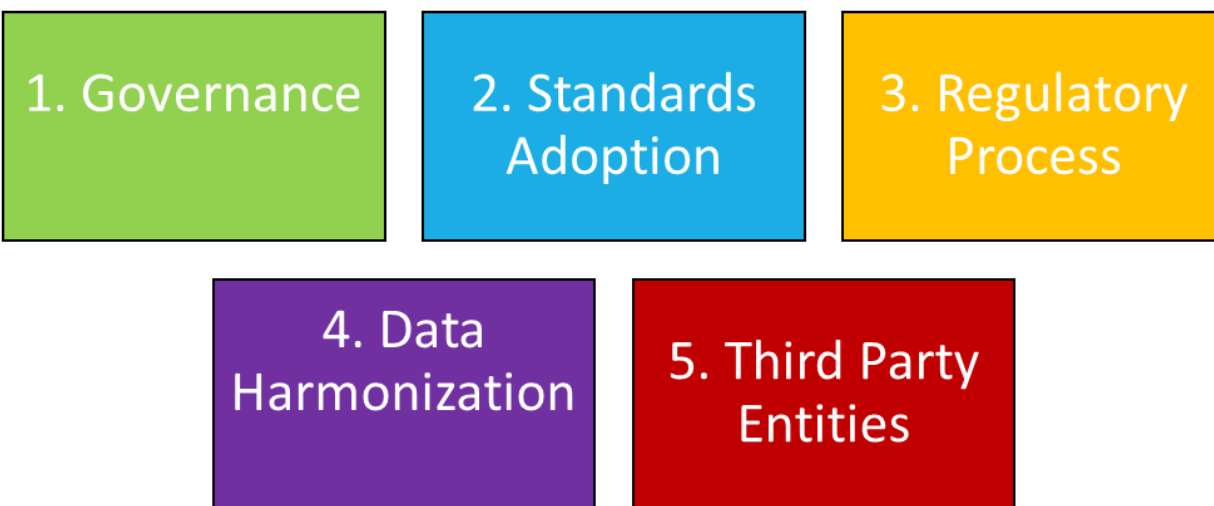
The reader of this report is a valuable asset. Please send your comments on the recommendations to the NCVHS mailbox at NCVHSmail@cdc.gov with the subject line: Predictability Roadmap and include your name, email, and organization.

APPENDICES

Appendix A: Appreciative Inquiry Visioning Exercise:

Summary of the Five Themes

This section summarizes the five themes that drove the thinking of the Subcommittee on Standards as they developed the draft recommendations and the outcome goals for the Predictability Roadmap. The table at the end of this section provides some examples of possible implications if the recommendations are not carried out.

1. Governance	2. Standards Adoption	3. Regulatory Process
4. Data Harmonization	5. Third Party Entities	

Governance for HIPAA Standards and Operating Rules.

The Designated Standards Maintenance Organization (DSMO) process was created through regulation, under the Transactions and Code Sets rule published on August 17, 2000 (65 FR 50312). Section §162.910, identifies each of the members of the Designated Standards Maintenance Organization (DSMO), and specifies their responsibilities for developing and maintaining the standards. The DSMO member organizations included SDOs as well as Data Content Committees (DCCs). The named organizations all signed a Memorandum of Understanding (MOU), whose initial term was three years and subsequently renewed automatically thereafter. Changes to the MOU, including additional signatories, must be approved by a three-fourths majority of the Steering Committee and by HHS. Modifications may be made to the MOU to keep the HIPAA Standard Change Request management system aligned with industry and regulatory needs. To date, no changes have been made to the MOU or

the change request process. The DSMO slide presentation was updated in 2011 to include information about the process for operating rules, to reflect the fact that change requests go directly to the ORAE, and the request for review and approval are submitted to NCVHS rather than through the DSMO review process. CAQH CORE is not a member of the DSMO.

The DSMO used to submit an annual report of change requests to NCVHS, but has not needed to do so in the past few years, because most change requests go directly to each SDO. However, the DSMO does bring requests for any standards update to NCVHS, with a request that NCVHS conduct a public hearing. The most recent request to the DSMO was from NCPDP to adopt an updated version of the pharmacy standard, version F2 and Medicaid subrogation version 10. On March 26, 2018, the Subcommittee on Standards held a virtual public hearing and sent its letter of recommendation to adopt these standards to the Secretary of HHS on May 17, 2018.

Updates to Standards and Operating Rules

To date, HHS has named two versions of the ASC X12 and NCPDP standards, and adopted a standard from NACHA for the Electronic Funds Transfer (EFT). HHS has also adopted three identifiers – for employers, providers and health plans. As of this writing, the Health Plan Identifier (HPID) is under enforcement discretion, which means that if a complaint is filed against a covered entity that does not use the HPID; no civil money penalty will be imposed against that organization. HHS has also adopted code sets for diagnoses, procedures, and drugs for use in the adopted standard transactions (i.e., HCPCS, CPT, CDT, ICD-10 CM and ICD-10 PCS, NDC).

The two standards development organizations responsible for maintaining and updating currently adopted standards are ASC X12 for the administrative standards, and NCPDP for the retail pharmacy standards. Each SDO has its own ANSI-approved maintenance processes, methods for dissemination and approaches to supporting those who must use the standards. Stakeholders seeking additions, changes, clarifications, or answers to questions work through the channels defined by the respective SDOs. Technology companies and end users of each set of standards must understand and accommodate all approaches. NACHA is the standards development organization for the EFT standard and operating rules. HL7 is also a named standards development organization although HHS has not yet adopted any HL7 standards under HIPAA or ACA. Note, however, that NCVHS has recommended that HHS adopt the HL7 standard for health care attachments.

Many of the individuals participating in discussions about the update process described very different procedures at each SDO, some that enable an available version update on an annual basis, and others, which do not. There was extensive discussion about the desirability to make available small, incremental updates.

As described earlier in this document, the Subcommittee on Standards documented the SDO approaches to maintenance and updates, which is available on the NCVHS website at https://www.hhs.gov/reports. The SDOs are accredited by ANSI indicating that they meet requirements for consensus and transparency. The Affordable Care Act did not require that ANSI accredit the operating rule authoring entity. However, there are other performance, transparency, and service level requirements that the ORAE must meet in order to be selected and retain its status, in accordance with section 1104 of the ACA.

Though the SDOs are ANSI accredited, and CAQH CORE was named as the operating rule authoring entity, stakeholder testimony regarding transparency, reliability of updates, and the consensus process may indicate that some of the participating organizations have some process improvement opportunities in the workflows.

Participants noted that the cost of an organization supporting an employee's direct participation in one SDO is prohibitive[4] to all but the largest or most directly impacted organizations, e.g., very large provider systems, large insurers, large chain pharmacies, clearinghouses and processing system vendors. They raised the question of whether there might be a way for small entities to engage virtually in the initial input ('these are my pain points') for standards updating and in the early review of potential solutions proposed by the SDO.

Federal Processes - Regulatory and other

The Subcommittee on Standards heard from stakeholders that the regulatory process for standards adoption takes several years longer than for other federal regulations with which they are involved. Stakeholders at public meetings have said that that HHS does not provide sufficient public information on a timely basis about the status of recommendations made by NCVHS to adopt an update to a standard or new version of a standard, or on the status of a regulation. There was consistent commentary with respect to enforcement of the HIPAA administrative standards, that federal

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[4] Though NCVHS is inclined to provide guidance on what might be cost prohibitive, as an advisory organization to a federal department, the Committee, cannot do so. However, each organization may be able to do some "back of the envelope" calculations by estimating travel, hotel/airbnb and meal costs for attendance at 3+ meetings per year, and adding in lost work hours for time away.

enforcement is practically non-existent, particularly in contrast to enforcement of the privacy and security rules.

The first HIPAA transaction and code set rule was published in 2000. A regulation to address technical corrections for the standards was published in 2003. The next update to the standards (ASC X12 and NCPDP) was published in 2009, with a 2012 compliance date. The requirement to adopt the ICD-10 code set was also published in 2009, but the implementation of the ICD-10 code was subsequently postponed until October 2015. HHS adopted a standard for the Health Plan Identifier in 2012, which has been under enforcement discretion since 2014, as previously stated. HHS adopted a new standard for Electronic Funds Transfer and associated operating rules in 2011, and operating rules for eligibility and claim status in 2012. A table of all adopted standards and operating rules and their compliance dates is available in Appendix B.

Since 2014, NCVHS has submitted a number of recommendations to HHS, including a recommendation to adopt a new standard, and several to adopt updates to standards. These recommendations were made following hearings in which stakeholders and the standards development organizations testified orally and in writing to support the proposed. However, to date, HHS has not taken any action on the recommendations, nor provided communication to NCVHS or to industry as to why no action has been taken. In November 2017, NCVHS received a recommendation from the DSMO and NCPDP to adopt an updated version of the NCPDP standard

The input from stakeholders is that some parts of HHS are not responsive to NCVHS recommendations, specifically the administrative standards, and that 9 or 10 years between version updates is too long. The pace of technology and business change is much faster than that, with industry views appearing to indicate that a five-year life cycle is preferable. Further, industry consensus seems to be that smaller, more digestible and sometime industry segment-specific (i.e., as opposed to industry-wide) modifications are critical, with major revisions on a longer cycle.

Historically, HHS rule making and implementation of a new standard or a new version of an existing standard can take more than four years following the recommendation from NCVHS. The impact of long and unpredictable Federal adoption processes is straightforward: industry cannot effectively plan or budget its resources for staff or system upgrades in addition to missing operational improvements – the objective of administrative simplification. When HHS delays reaction to NCVHS recommendations, all other actions are delayed. Industry's business processes and opportunities for cost savings and innovation are impacted by five years or more.

Finally, once the standards are adopted, stakeholders want HHS to ensure that their education and enforcement efforts are effective. Industry expects a more visible demonstration of HHS' actions in managing complaints and using the data to inform and educate.

Third Parties as Covered Entities

Covered entities include health plans, health care clearinghouses, and certain health care providers that exchange the adopted transactions electronically. Non-covered entities include *some* of the business associates that support health plans and providers, such as practice management vendors, billing companies, and other third party entities that provide value added services. Other non-covered entities include worker's compensation insurers and Property & Casualty Insurance. Employers are not covered entities, but their health plans are. Stakeholders were mixed in their views of how to resolve issues pertaining to non-covered business associates – some wanted to include them as covered entities, while others were non-committal. Some states have chosen to resolve the conflict by creating a broad definition of covered entity, and every organization involved in the transaction is included under the definition. This action has eliminated the debate. Enforcement and guidance from HHS may help mitigate some of the implementation and compliance barriers described by providers.

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The table below provides further definition for each of the themes and summarizes the problem statement and challenges identified by the stakeholders. The last column of the table shows what the situation would be if no actions were taken to address the challenges and barriers that have been identified in this document.

Table 1: Roadmap themes identified in during the Appreciative Inquiry Visioning Workshop:

Current Challenges and Impact of Status Quo

THEME & EXPLANATION	*PROBLEM STATEMENT*	*CHALLENGES*	*IMPACT OF STATUS QUO*
Governance: The Designated Standards Maintenance Organization (DSMO) was created by regulation in August 2000. A self-renewing Memorandum of Understanding (MOU) was signed between all of the participating parties that year. The DSMO	*The current coordinating body (i.e., the DSMO) is charged with oversight of standards revision priorities but may be operating with too narrow a charter or lacking the authority and resources to be effective.*	1. DSMO process is cumbersome because it requires pro forma review by the participating entities; 2. The 2003 mandated process for review of standards update requests (the Designated Standard Maintenance Organization or DSMO) is a throughput	1. DSMO process leads to potential delay of recommendations to NCVHS and/or HHS. 2. New or updated versions of standards could be inappropriate or unnecessary if not appropriately tested/vetted through value added testing 3. Further process improvement efforts will be qualitative,

THEME & EXPLANATION	PROBLEM STATEMENT	CHALLENGES	IMPACT OF STATUS QUO
process is required to ensure open public access; coordination amount DSMOs; an appeals process; and bringing recommendations to NCVHS. The DSMO established a process to handle change requests, review the requests, vote, and make recommendations (90-day process).		{need word} process that is no longer considered useful 3. Industry bypasses the DSMO processes and goes directly to individual SDOs to make change requests. 4. DSMO does not have any formal evaluation methodology to review updates to standards 5. DSMO and individual SDOs do not have funding to test new versions of standards	lacking rigor of quantitative evaluation
Updates to Standards Each SDO has its own ANSI approved processes and procedures for reviewing and updating the standards for which it has responsibility for maintenance and modification. All SDOs are ANSI accredited except for CAQH CORE and NACHA.	*Frequency of updates to standards and operating rules is not aligned with industry business and technical changes and does not enable covered entities, trading partners, or business associates to take advantage of technology developments.*	1. SDO schedules for updating standards are inconsistent 2. Work products developed by some SDOs may not be created on a timely basis or does not include content or functionality that meets upcoming business needs of stakeholders 3. Some SDOs do not have agile work flows or technology to enable workgroups or committees to develop and implement products based on needs of industry 4. SDOs do not necessarily work on the standards that the industry, HHS or other federal agencies believe are necessary to support burden reduction or the new emphasis on the convergence of the administrative and clinical systems 5. Standards development organizations lack sufficiently diverse industry engagement in standards update workgroups and committees. The right type of subject matter experts are not represented on the workgroups and votes do not represent all entity types.	1. Inconsistent schedules do not allow covered entities to meet strategic and financial planning goals; 2. covered entities cannot effectively plan to meet regulatory mandates, make financial plans for new technology, system upgrades, staffing changes or innovation 3. New versions of standards are not available for adoption as expected 4. Requirements development, priority setting (meaning what standards to focus on), implementation oversight, accepting feedback and enforcing correct implementations of the standards are not necessarily aligned with new priorities of health information exchange 5. Development of standards will not be representative of full spectrum of industry stakeholders, or innovative ideas necessary to move new methods of health care operations and interoperability forward

THEME & EXPLANATION	PROBLEM STATEMENT	CHALLENGES	IMPACT OF STATUS QUO
Federal Regulatory Process This process is the development of the proposed and final rules to adopt standards and operating rules (including code sets and identifiers).	*The Federal process for adoption of standards and operating rules is lengthy, of unpredictable duration, and contains numerous checks and balances that duplicate similar processes within the standards development organizations. Time between a recommendation from NCVHS and publication of a final rule can be from 2 to 10 years.*	1. Certain language in the existing HIPAA (administrative simplification portion) of the statute limits the ability to adopt newer versions of updated standards or new types of standards through an expedited regulatory process. Limitations of HIPAA prevent covered entities from using newer versions of standards or new standards that enable them to keep pace with technology or business needs. A specific barrier is the requirement that a modification to a standard necessitate notice of proposed rulemaking, which is a minimum two to four year process. Covered entities must wait another two years before using the updated standard. This could equate to a six-year delay in use of a desired standard. 2. Current regulations require the adoption of a specific version of a transaction vs. a standard. 3. Current regulations set a ceiling rather than a floor	1. The inability to use updated versions of standards for four years after they are available hampers the ability of covered entities to take advantage of improvements to the transactions that were deemed necessary for business process or technical changes based on identified innovations, cost savings, interoperability opportunities or reduction in burden.
Data Harmonization Ensuring that all standards organizations and users define data elements consistently.	*The lack of data cohesion jeopardizes interoperability due to inconsistencies in data dictionaries and data elements across SDOs.*	1. Lack of consistent data exchange between health plans and providers is a key source of frustration. Being able to address a concept and have a definition from one system, mean the same thing in another system, is imperative because it is a patient safety issue. 2. There are differences between the same "concepts" represented in SNOMED versus LOINC.	1. Inconsistent information can be the cause of incorrect payments and medical errors.

THEME & EXPLANATION	*PROBLEM STATEMENT*	*CHALLENGES*	*IMPACT OF STATUS QUO*
Third Parties as covered entities Vendors and practice management vendors are not covered entities under HIPAA and do not have to comply with the regulations to the same level of stringency as covered entities.	*Covered entities are defined as health care providers, health plans, and health care clearinghouses. Vendors and other business associates are not covered entities despite a role in the conduct of the adopted standards. The Federal Government is limited in its authority over non-covered entities. This affects the use of standards in a variety of ways, from costs to actual utilization.*	1. Business associates often do not use the standards consistently. 2. Some health plans, vendors and their business associates use portals as a solution to conducting transactions (individual vendors on behalf of their covered entity business partners). This may undermine the use of the standards, and hinder widespread efficiency. In some cases, portals require that a provider use one form of technology with certain trading partners, and another form of technology with other trading partners.	1. Creates workarounds by providers, adding to burden and manual effort 2. Some entities will continue to be unable to use the standard transactions in a compliant fashion, and may be missing certain data elements that would make business processes more efficient. The portals should be providing the compliant data content of the standard, which should enable the provider to be efficient in providing services to patients.

Appendix B: Adopted HIPAA Standard Transactions and Operating Rules

As of July 2018

Adopted Standards

Transaction	Standard	Final Rule Publication date	Compliance Date
Health care claims or equivalent encounter information – Dental.	X12 Version 5010	January 2009	January 2012
Health care claims or equivalent encounter information – Professional.	X12 Version 5010	January 2009	January 2012
Health care claims or equivalent encounter information – Institutional.	X12 Version 5010	January 2009	January 2012
Retail Pharmacy claims or equivalent encounter information.	NCPDP Version D.0 and equivalent Batch Standard Version 1.2	January 2009	January 2012
Retail pharmacy Health care claims or equivalent encounter information – Retail pharmacy supplies and professional services.	NCPDP Version 5.1, Version D.0 and equivalent Batch Standard Version 1.2 and X12 Version 5010	January 2009	January 2012
Coordination of Benefits – Retail pharmacy drugs.	NCPDP Version D.0 and equivalent Batch Standard Version 1.2	January 2009	January 2012
Coordination of Benefits – Dental.	X12 + errata Version 5010	January 2009	January 2012
Coordination of Benefits – Professional.	X12 Version 5010	January 2009	January 2012
Coordination of Benefits – Institutional.	X12 + errata Version 5010	January 2009	January 2012
Eligibility for a health plan (request and response) – Dental, professional, and institutional.	X12 Version 5010	January 2009	January 2012

Transaction	Standard	Final Rule Publication date	Compliance Date
Eligibility for a health plan (request and response) – Retail pharmacy drugs.	NCPDP Version D.0 and equivalent Batch Standard Version 1.2	January 2009	January 2012
Health care claim status (request and response).	X12 + Errata Version 5010	January 2009	January 2012
Enrollment and disenrollment in a health plan.	X12 Version 5010	January 2009	January 2012
Health care payment and remittance advice.	X12 Version 5010	January 2009	January 2012
Health plan premium payments.	X12 Version 5010	January 2009	January 2012
Referral certification and authorization (request and response) – Dental, professional, and institutional.	X12 + Errata Version 5010	January 2009	January 2012
Referral certification and authorization (request and response) – Retail pharmacy drugs.	NCPDP Version D.0 and Batch Standard Version 1.2	January 2009	January 2012
Medicaid pharmacy subrogation.	NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0	January 2009	January 2012

Transaction	Standard	Final Rule Publication date	Compliance Date
Health Care Electronic Funds Transfer Includes Data content in CCD Addenda Record: X12 Standards for Electronic Data Interchange Technical Report Type 3, "Health Care Claim Payment/Advice (835), Section 2.4: 835 Segment Detail: "TRN Reassociation Trace Number	Stage 1 Payment Initiation: The National Automated Clearing House Association (NACHA) Corporate Credit or Deposit Entry with Addenda Record (CCD+) implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines: NACHA Operating Rules, Appendix One: ACH File Exchange Specifications; and NACHA Operating Rules, Appendix Three: ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries.	January 2012	July 2014

Adopted Operating Rules for the Transactions

TRANSACTION & STANDARD	OPERATING RULES	ADOPTION & COMPLIANCE DATES
Eligibility for a Health Plan (request and response) – Dental, professional, and institutional. Using X12 TR3—Health Care Eligibility Benefit Inquiry and Response (270/271), Version 5010	The following CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction (excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification): (1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in § 162.920). (2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). (3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). (4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). (5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). (6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920). (7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920). (8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920). (9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920). (10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).(b)	July 2011/January 2013 followed by 90 day enforcement discretion

TRANSACTION & STANDARD	OPERATING RULES	ADOPTION & COMPLIANCE DATES
Health Claim Status Using X12 TR3 Health Care Claim Status Inquiry & Response 276/277 Version 5010	The following CAQH CORE Phase II operating rules (updated for Version 5010) -excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification: (1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920). (2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).(b)	July 2011/January 2013 followed by 90 day enforcement discretion
Health Care Electronic Funds Transfer (EFT) and Remittance Advice based on the EFT standard and the X12 TR3 Electronic Remittance Advice 835 Version 5010.	Phase III CORE EFT & ERA Operating Rule Set, Approved June 2012, except Requirement 4.2, Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0 titled "Health Care Claim Payment/Advice Batch Acknowledgement Requirements. Includes Use of CARCs and RARCs, code combinations for CORE business scenarios, EFT & ERA Reassociation, EFT Enrollment Data and ERA Enrollment Data. Not all of the CORE Phase III rules are listed here. Visit the CAQH CORE website for the full set (www.caqh.org)	April 2013/January 2014