

February 29, 2016

Honorable Sylvia M. Burwell  
Secretary, Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

**Re: Findings from Administrative Simplification Hearing**

Dear Madam Secretary,

The National Committee on Vital and Health Statistics (NCVHS) is the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary of the Department of Health and Human Services (HHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS advises the Secretary on the adoption of standards, implementation specifications, code sets and identifiers for the HIPAA-named transactions.

In this letter, we are providing recommendations for action by HHS to address a significant opportunity to advance Administrative Simplification by focusing on the need for increased coordination, education and enforcement. In summary, we recommend that the Department consider the following actions. Background and detailed descriptions of the following recommendations are provided in this letter:

- Expanding the definition of covered entities under HIPAA
- Broadening HIPAA-related education activities
- Ensuring consistency in the interpretation and implementation of administrative transactions, code sets, identifiers and operating rules requirements
- Enforcing compliance
- Adopting standards for the Acknowledgment transaction
- Defining a roadmap to provide predictability in adoption of standards, code sets, identifiers and operating rules
- Increasing utilization of the Enrollment/Disenrollment and Premium Payment standards
- Evaluating the use of the prior authorization transaction.

NCVHS will also be developing a separate report that will include observations, themes, issues and NCVHS recommendations for the entire health care industry.

## **BACKGROUND**

Health care costs continue to rise. Studies support that administrative costs contribute to the cost of health care and that these costs can be reduced through greater standardization. In fact, the overarching goal of the administrative simplification provisions of HIPAA is to improve the efficiency and effectiveness of the health care system through the establishment of uniform standards and requirements for the electronic transmission of certain health information to reduce the clerical burden on patients, health care providers, and health plans. Simplification occurs through adoption of standards via the federal rule making process, followed by implementation of the adopted standards by those entities participating in each of the transactions. Testifiers at the Review Committee hearing acknowledged that there is evidence of savings through the adoption and implementation of standards for the HIPAA named transactions, however, achieving the potential savings have been limited by a number of factors, including variability in the level of implementation and inconsistency in the method of implementation of the transaction standards and operating rules.

In addition to the statutory requirements under HIPAA, the Patient Protection and Affordable Care Act (ACA) Sec. 1104 (b) enacted on March 23, 2010, also calls for NCVHS to further assist in the achievement of administrative simplification to “reduce the clerical burden on patients, health care providers, and health plans.” ACA also requires the Secretary to adopt standard operating rules for the implementation of each of the HIPAA-named transactions. Section 1104(i) of ACA authorizes the Secretary to establish a Review Committee responsible for conducting hearings to evaluate and review the adopted standards and operating rules. The Secretary last year designated NCVHS as the Review Committee.

NCVHS, acting as the Review Committee, held its first Review Committee hearing on June 16 and 17, 2015. The purpose of this hearing was to address all HIPAA-named transactions and their corresponding adopted standards (including code sets and identifiers) and operating rules (referred to in this letter as “standards and operating rules”) currently being implemented by the healthcare industry. The HIPAA-named transactions covered during the hearing included: 1) health plan enrollment and disenrollment; 2) premium payment; 3) health plan eligibility benefits inquiry and response; 4) prior authorization; 5) health care claim or equivalent encounter information; 6) electronic fund transfer and electronic remittance advice; and 7) coordination of benefits. Over the two-day hearing, NCVHS received seventy-seven oral testimonies and reviewed over 100 additional written testimonies from the health care industry representing providers, health plans, vendors, clearinghouses, associations, public programs (Medicare, Medicaid), federal agencies, standard development organizations, operating rules authoring entity and consultants.

## **General Findings and Recommendations**

Consistent and comprehensive adoption and implementation of the HIPAA-named transaction standards and operating rules across the industry is viewed by many stakeholders as a significant step forward towards achieving administrative efficiencies. The health care industry, Standards Development Organizations, Operating Rule Authoring Entity and DHHS have led the way in moving the entire ecosystem towards administrative simplification. However, further work is needed to continuously improve the adopted transaction standards and operating rules and increase their level of implementation and the consistency in the way they are implemented and used.

One of the most significant findings from the hearing was the variation in the *level* of implementation of various transaction standards and operating rules. While six transactions (eligibility, claim, claim status, electronic funds transfer, remittance advice and coordination of benefits) have been widely implemented, others (benefit enrollment/disrollment, premium payment, and prior authorization) are not yet widely implemented. Industry representatives agree that for greatest impact at this time, focus should be on the five adopted standard transactions and operating rules that are most widely implemented. Future focus should be on adopted transaction standards and operating rules that have low implementation.

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 data content, coding, and processing are creating barriers to achieving the expected efficiencies and effectiveness. Such is the case, as noted by testifiers, with some of the submissions and responses of each of the five widely implemented transactions (eligibility, claims, claims status, remittance advice, and coordination of benefits). Reasons for these two issues identified by testifiers included:

- Level of complexity of the adopted standards
- Concerns that adopted standards are not meeting the business needs
- Use of HIPAA-compliant alternative technologies to conduct the transactions in a more efficient and effective manner
- Not all entities engaged in conducting the HIPAA-named transactions are subject to HIPAA as covered entities.

At the same time, rapid advances in health information technology (HIT) and the transformative changes in health care delivery and payment models currently underway are creating the need for transitioning existing models into new paradigms for how administrative and billing processes in health care will be done in the future. NCVHS views these challenges as strategic opportunities to refine and align the goal of administrative simplification with the changes in technology and healthcare delivery models.

NCVHS reviewed testimony and formulated its recommendations utilizing the criteria that formed the basis of the questions testifiers were asked to address in their testimony. The

criteria, centered on identifying if the adopted standards (including code sets and identifiers) and operating rules (where adopted):

- meet the industry's business need/use/problem resolution
- decrease cost and/or administrative processes
- are flexible/agile to meet changes in technology and/or healthcare delivery systems
- can be operationalized
- can be enforced.

In addition to these criteria, NCVHS looked at other factors to evaluate the degree to which the adopted standards and operating rules were meeting the overall goal of administrative simplification. These included:

- **Completeness:** Does the standard or operating rule provide the complete information necessary to execute the transaction and achieve the business purpose?
- **Efficiency:** Does the standard or operating rule decrease resource utilization and the time to perform the transaction function?
- **Complexity:** Do the standard or operating rule requirements exceed the healthcare industry's cost and resource capacity resulting in limited or non-implementation?
- **Flexibility:** Does the standard or operating rule allow for interim updates and can it adapt to changes in technology and health delivery models?
- **Consistency:** Is the standard or operating rule able to be implemented in the same manner across all healthcare entities?
- **Effectiveness:** Does the standard and operating rule solve the business need?
- **Ambiguity:** Does the standard or operating rule result in differences in interpretation and in implementation?

The following recommendations provide specific ways in which DHHS can further advance administrative simplification. Some of the issues identified and the subsequent recommendations are common to all transactions while others are unique to specific transactions.

**Recommendation # 1: Expanding the definition of covered entities under HIPAA.**

Consistent and broad implementation is at times challenged by the current definition of HIPAA covered entity. Various organizations actively engaged in exchanging administrative and financial data such as employers, workers' compensation plans, property and casualty industry, and other health care related organizations are not HIPAA **covered entities**. This results in a lack of use of electronic transaction standards and increased costs attributed to customization and maintenance associated with using proprietary methods to capture necessary data and information.

For example, health plans, as covered entities, are required to be capable of conducting the enrollment/disenrollment and premium payment transactions electronically. However, employers, who are the other end of these two transactions, are not covered under HIPAA,

thus, are not required to conduct these transactions electronically using the adopted standards. Similarly, in the workers' compensation area, providers that submit claims to workers' compensation plans cannot always use the same electronic claim transaction standards adopted for all other health care claims because the workers' compensation plans are not covered entities, and they can and often use a different standard to receive and process these types of claims. *HHS* should:

- 1.1 Explore the feasibility of requesting that Congress amend the definition of a covered entity to include all entities that perform HIPAA-named transactions. As covered entities, they would then be required to comply with the adopted standards and operating rules. This would include but not be limited to employers, workers' compensation, property and casualty industry, practice management systems (PMS), and other vendors of relevant solutions.
- 1.2 In the absence of a statutory amendment to the definition of a covered entity, explore other regulatory and non-regulatory mechanisms (including federal procurement and contractual requirements) to require that any entity that performs a HIPAA-named transaction specified in §1104(h)(B)(3) of ACA comply with the standards (including code sets, identifiers) and operating rules adopted for these transactions.

**Recommendation # 2: Broadening education.**

All testifiers agreed that increased education and knowledge on the use of standards (including code sets and identifiers) and operating rules is needed. As this is an industry-wide, multi-stakeholder need, NCVHS recommends a broad **education** effort. The *healthcare industry, Standards Development Organizations, and Operating Rules Authoring Entity and HHS* should work together to ensure that:

- 2.1 Stakeholders have access to and are educated on the standards and operating rules. This would include intended benefits and other considerations to support greater implementation and standardization of use.
- 2.2 Instructional materials are prepared with multi-stakeholder involvement, address currently adopted standards (including code sets and identifiers) and operating rule requirements, and are clear, concise, consistent and relevant.
- 2.3 Stakeholders are educated on the already demonstrated benefits of administrative simplification transactions, such as:
  - front-end edits by clearinghouses and payers have quickly identified and reported back to providers claim errors or deficiencies so they can be promptly addressed and the claim submitted correctly improving processing timeliness

- automated edits helped speed development and review of claims as fewer claims must be manually inspected and checked
- allowed providers to capture more information needed for payment
- provided the ability to send secondary and tertiary claims electronically
- helped reduce claim adjudication issues and denials
- accelerated turnaround times resulting in better use of staff and resources.

**Recommendation # 3: Ensure consistency.**

Testifiers discussed the multiplicity of requirements and instructions addressed in the standards, operating rules, and proprietary policies. Some testifiers indicated that the standards and their accompanying operating rules are developed in isolation rather than as a system with a number of processes or workflows that need to be **integrated**. As this is an industry-wide issue, NCVHS sees the need to promote consistency as an industry-wide endeavor. The *healthcare industry, Standards Development Organizations, Operating Rule Authoring Entity and HHS* should work together to ensure that standards, code sets, identifiers and operating rules are simplified, unambiguous, able to be operationalized, and adaptable to current and future needs. Specifically, HHS should:

- 3.1 Respond to the ASC X12 request to validate the use of the ASC X12 TR3 Schema thus mitigating inconsistent XML based solutions.
- 3.2 Consider requiring operating rules (e.g., acknowledgement, response time) be consolidated across transactions including combining all phases in a single document to alleviate the need for the industry to support different versions of a similar rule for different transactions.
- 3.3 Begin discussions with the *Standards Development Organizations and the healthcare industry* to measure the degree to which each of the transaction standards and operating rules are being implemented in an inconsistent manner, the reasons for the inconsistent implementation, and explore requirements to reduce or eliminate the causes of these inconsistencies.

**Recommendation # 4: Enforce compliance.**

A common theme by testifiers was the inconsistent level of implementation and compliance with the adopted standards and operating rules and the lack of **enforcement** by HHS. The level and inconsistency in the implementation are for the most part transaction-specific issues and generally associated with two factors:

- Whether the two ends of the transaction are required to conduct the transaction electronically using the adopted standards and operating rules. This is the case for transactions such as enrollment/disenrollment and premium payment, and the issue is covered under Recommendation 1.

- The complexity of the adopted standards and/or operating rules for the transaction. This issue is covered under Recommendation 3 and the “Specific Transaction Recommendations” section below.

Testifiers affirmed that enforcement would serve as an incentive for compliance especially with the possibility of being assessed a considerable penalty fee. However, because of the range of inconsistencies identified, NCVHS recommends that *HHS* should:

- 4.1 Sequence enforcement initially focusing on the five widely implemented transaction standards and operating rules (eligibility, claim, claim status, remittance advice and coordination of benefits).
- 4.2 Educate the industry on compliance and penalties, including communicating compliance, audit, and enforcement requirements to ensure that there is consistency in compliance with all the transaction requirements.
- 4.3 Consider publicizing best practices and educational resource tools to support compliance efforts, consistent with Recommendation 2.
- 4.4 Initiate development of a tool that could be used by stakeholders and by HHS for use in assessing compliance that can evaluate and measure compliance with each standard and operating rule.
- 4.5 Review existing mechanisms designed to enforce compliance with adopted standards and operating rules including the assessment of penalties and fines for non-compliance.
- 4.6 Consider enforcing compliance with the adopted standards and operating rules with the same level of engagement seen in the OCR HIPAA Privacy and Security Compliance Program.
- 4.7 Consider publicizing enforcement details to include but not be limited to:
  - Number of complaints that were penalized
  - Consequences of non-compliance
  - Enforcement process
  - How to file complaints while mitigating damage with the payer relationships.
- 4.8 Working with the industry to consider establishing a certification process for practice management systems and other vendors that can validate adherence to the adopted standards and of operating rules.

**Recommendation # 5: Adopt acknowledgment transaction.**

One transaction that is not currently mandated or used consistently by the healthcare industry yet has great potential value is **Acknowledgments**.

The acknowledgment transaction is widely seen by the industry as a critical element in the end-to-end health care administrative transactions lifecycle. The transaction, which is used to quickly return valuable information about the receipt of an inbound transaction (for example, a claim submitted by a provider to a health plan), helps inform the submitter of the inbound transaction (the provider, in the example) about the need to correct certain elements of the submitted transaction before it can begin to be processed, or confirm that the transaction was appropriately received and no corrections are needed before processing begins.

Acknowledgments are currently voluntarily being used by many in the healthcare industry. For example, Medicare uses claim acknowledgment 277CA transaction to report acceptance or rejection of claims, which many payers have followed. However, others continue to generate proprietary reports which are dynamic and require constant support to maintain the integrity of the data extracted and lack details to show that a payer has moved the submitted claims into its adjudication system. Acknowledgments also provide a way to the submitter, a receipt of a transaction, thus avoiding costly and lengthy details to validate receipt of transactions.

NCVHS has in the past recommended that HHS adopt a national standard for the Acknowledgement transaction<sup>1</sup>. Testifiers have indicated that there is wide industry consensus in support of adopting this transaction.

- 5.0 As previously recommended by NCVHS, HHS should pursue adoption of the standards and operating rules for the acknowledgment transaction, and specify which acknowledgments are to be used in conjunction with which transaction.

**Recommendation # 6: Provide predictability in adoption of standards, code sets, identifiers and operating rules.**

Industry representatives expressed concerns regarding the lack of predictability in the adoption of standards, code sets, identifiers and operating rules and the associated implementation timetables and processes. This applies to initial adoption and version updates. Further, timetables appear to be set without consideration of the range of mandated requirements. The availability and adoption of standards; implementation process for standards, code sets, identifiers, and operating rules; the lag time between standard versions; and the adoption of standards and operating rules often coincide with the need to implement other mandated requirements. NCVHS recognizes that recommendations to resolve these issues require a **long term approach** that would not be achieved within the next year. HHS working with the

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<sup>1</sup> September 22, 2011, September 21, 2012 and September 20, 2013, letters to Kathleen Sebelius, Secretary, Department of Health and Human Services, from the National Committee on Vital and Health Statistics (NCVHS).



*Standards Development Organizations, Operating Rule Authoring Entity and the healthcare industry* should consider developing in 2016:

- 6.1 A roadmap for the adoption and implementation of the next version of standards and operating rules, including a more predictable and efficient cycle from industry recommendation to upgrade of standards and operating rules, to the regulatory levers to mandate scope and timing of the upgrade. This helps ensure an orchestrated glide path for adoption and implementation while reducing the current state of competing priorities. There should be an opportunity for broad industry review and comment on the roadmap. The roadmap development will greatly benefit from coordination among applicable HHS agencies around a consolidated strategic plan, interoperability of the roadmap, and the approach to achieving enhanced processes for the implementation of revised and/or new mandated standard transactions and operating rules. The roadmap and enhanced processes should also be flexible to accommodate the need to adopt standards in between cycles, if required for healthcare industry business needs.
- 6.2 A proposed mechanism for monitoring progress in the implementation of transaction standards and operating rules. This could entail working with other organizations on standardized metrics and data sets to monitor industry usage of the HIPAA required transactions and their respective adopted standards and operating rules.

### **Transaction-Specific Findings and Recommendations**

As noted earlier in this letter, testifiers indicated that there are varying degrees of implementation of specific HIPAA-named transactions due to multiple reasons. Testifiers provided examples of barriers to implementation and specific recommendations to resolve the issues. Some of these barriers have been addressed in the General Recommendations above. NCVHS also found that most of the concerns, barriers and recommendations for specific transactions pertained to the Standards Development Organizations, Operating Rule Authoring Entity and the industry. However, there were two transactions that NCVHS felt important to highlight in this letter with recommendations.

#### ***Health Plan Enrollment/Disenrollment and Health Plan Premium Payment***

**Recommendation # 7: Increase utilization of the Enrollment/Disenrollment and Premium Payment standards.**

Testifiers indicated that there has been low implementation of the health plan enrollment/disenrollment transaction standard (known as the 834 transaction) and the health plan premium payment transaction standard (known as the 820 transaction) citing various reasons including the fact that employers (one of the end-points of these transactions) are not

designated as a covered entity under HIPAA and therefore are not required to implement the standard. In addition, Health Plans participating in the insurance marketplaces (HIX) are having to accept both the 834 standard adopted for HIPAA covered entities, and the 834 HIX standard, mandated for use in the enrollment of individuals participating in the insurance marketplaces.

Therefore, NCVHS recommends that:

- 7.1 The *healthcare industry and HHS* examine approaches that would increase implementation of the 834 and the 820 standards, avoiding maintenance of multiple channels of data input that results in increased customization of vendor tools increasing costs and labor, into enrollment systems.
- 7.2 HHS explore ways to bring to full convergence the 834 HIX (used by the insurance marketplaces) and the current 834 used by HIPAA-covered entities for all other enrollment transactions, so they become one and the same. This would simplify and reduce administrative burden on health plans.

### ***Prior Authorization***

#### **Recommendation #8: Evaluate the use of the prior authorization transaction.**

The complexity of the prior authorization transaction standard (known as the 278 transaction) is reported as not helping the industry achieve its intended purpose and benefits. Testifiers indicated that because of the variation in medical and pharmacy benefits, there are different prior-authorization rules that result in cumbersome and inconsistent workflow processes and the need to provide additional requested information through manual processes. Additionally, health plans' web portals have become predominant venues for providing greater level of functionality and information exchange to achieve prior-authorizations. Therefore, NCVHS recommends that:

- 8.1 The *Standards Development Organization, Operating Rules Authoring Entity, healthcare industry and HHS* should evaluate the value of the current prior authorization transaction and the adopted standard. This includes (1) identifying why web portals and other HIPAA-compliant alternative technology data exchange means are more effective and provide all the necessary and useful information, compared to the adopted transaction standard, and, (2) consider appropriate changes to future versions of the standard, including potentially leveraging the attachments transaction standards and operating rules to enhance the usefulness and effectiveness of the 278 transaction.
- 8.2 *HHS* respond to the NCPDP's request and NCVHS recommendation (in NCVHS May 15, 2014 letter to the Secretary) that HHS should name the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transaction as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit.

In summary, the healthcare industry's adoption and implementation of administrative simplification standards and operating rules has presented many challenges. The first Review Committee hearing provided an opportunity for NCVHS to learn about the successes as well as the barriers to successful implementation. Thank you for consideration of the recommendations in this letter. NCVHS remains available to answer any questions and will continue to support your efforts in the promotion and expansion of administrative simplification.

Sincerely,

/s/

Walter G. Suarez, M.D., M.P.H., Chairperson,  
National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs