July 6, 2016

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

Re: Recommendations for the Proposed Phase IV Operating Rules

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 (DHHS). 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. Provisions in the Patient Protection and Affordable Care Act of 2014 (ACA) also called for the adoption of a set of Operating Rules for each of the HIPAA-named transactions.

Over the past five years, NCVHS has recommended the adoption of Operating Rules for the following transactions: 1) Eligibility; 2) Claim Status; 3) Electronic Remittance Advice; and 4) Electronic Fund Transfer. DHHS has issued regulations adopting these recommended operating rules, and they are now in effect and being implemented by the industry.

On February 26, 2015 and more recently on February 16, 2016, NCVHS held hearings on the next set of proposed operating rules, the Phase IV operating rules. These Phase IV rules were developed specifically for the following four HIPAA-named transactions: 1) Health Plan Enrollment and Disenrollment; 2) Health Plan Premium Payment; 3) Prior Authorization; and 4) Health Care Claim or Equivalent Encounter Information. This letter provides background information about the proposed operating rules, a summary of findings from the hearing, and a series of recommendations.

In summary, we recommend that the Secretary consider the following actions:

- Strongly support the voluntary adoption and use of the Phase IV operating rules by the industry.
- Do not adopt the Phase IV operating rules via federal regulations at this time.

NCVHS commends CAQH CORE for its work in developing the proposed Phase IV operating rules. NCVHS recognizes CAQH CORE's efforts to provide a transparent, collaborative and criteria-driven process in the operating rules' development and vetting process. NCVHS also appreciates and recognizes the importance of security infrastructure called out in the proposed operating rules.

CAQH CORE has indicated that the proposed operating rules are an initial step that standardizes selected infrastructure elements involved in the execution of the four transactions to which the operating rules apply. However, NCVHS does not believe that the proposed operating rules provide sufficient benefits and value to the health care industry to be adopted and mandated for implementation by all HIPAA covered entities.

NCVHS believes there are three main issues associated with the proposed operating rules.

- First, the proposed operating rules call for the adoption and use of electronic transaction **standards** not yet named or defined by the Secretary in federal regulations. Specifically, the operating rules requires the use of Acknowledgments, as well as the X.509 digital certificate for submitter authentication.

    - With respect to Acknowledgments, NCVHS has already submitted detailed recommendations to the Secretary for the adoption of this transaction and applicable standards. Without having those federal regulations in place first, NCVHS believes that it would be inappropriate to require its adoption and use of the acknowledgment standard through operating rules, but strongly support its voluntary promotion by CAQH CORE and adoption by the industry.

    - With respect to use of X.509 digital certification, NCVHS believes that adopting such a standard requires the existence of an entire Public Key Infrastructure (PKI) ecosystem with trusted cross-certification issuers and certificate chains not yet available or in use for the exchange of health care administrative transactions. NCVHS does recognize, however, that the use of digital certificates in the industry is becoming a best practice and understands digital certificates are already included in existing HHS regulations pertaining to mandated Phase II-III operating rules, Meaningful Use Stage 2: ONC Health IT Certification Criteria (which references Federal Information Processing Standard Publication 140-2), and Electronic Prescriptions for Controlled Substances. This said, NCVHS believes that consideration for establishing a federally mandated requirement to implement digital certificates for the exchange of health care information should be a much broader question, and one not just limited to the four administrative transactions to

which Phase IV rules apply. NCVHS also believes adopting such technical standards should not be done through these operating rules.

- Second, the Committee believes, based on the testimony received during the two hearings it held on the subject, that the remaining Phase IV operating rules (those not related to acknowledgments and digital certificates) offer limited administrative simplification and efficiency benefits to the industry to warrant the cost and resources necessary for its adoption and implementation. These remaining Phase IV operating rules define specific requirements that HIPAA-covered entities must satisfy related to infrastructure aspects of the electronic exchange of the transaction, such as processing mode, system availability, and response times.

- Third, three of the four transactions for which the proposed Phase IV Operating Rules apply have been implemented in a very limited basis across the industry.

    - NCVHS heard testimony both during the February 2016 hearing, as well as at previous hearings (including the Review Committee hearing in June 2015) noting that the level of implementation of Prior Authorization across the industry is extremely low (less than 5% of all prior authorizations being done across the board). The benefit of adopting the proposed Phase IV Operating Rules for Prior Authorization is not clear when there is such low use. And there might be the risk of creating additional barriers to its adoption.

    - Similarly, NCVHS heard testimony in the past that the Enrollment and Premium Payment transactions have also limited use across the industry. This is mainly due to the fact that employers, one of the two participants in the execution of these two transactions, are not covered entities and thus, not subject to complying with the HIPAA mandated transaction standards.

NCVHS is also concerned about the level of maturity and extent to which these operating rules have been tested in operational environments by the Industry before recommending them for adoption through regulations.

Given these issues, NCVHS strongly supports the voluntary adoption of the Phase IV operating rules and recommends that the Secretary consider not adopting these operating rules in federal regulations at this time. This will provide CAQH CORE and the industry an opportunity to test, assess, evaluate and improve the scalability, cost, benefit and value to the industry before recommending national adoption through regulations.

NCVHS also believes that the observations from the hearing and the recommendations specified below could assist CAQH CORE in enhancing the operating rules that would support recommending national adoption.

Part 1 - 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 and operating rules via the federal rule-making process, followed by implementation of the adopted standards by those entities participating in each of the transactions.

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.

NCVHS held a hearing on February 16, 2016. The purpose of this hearing was to gather industry input regarding the proposed Phase IV Operating Rules for selected HIPAA Transactions. Specifically, the objectives of the hearing were to:

- Understand the business needs for each of the operating rules being presented for recommendation for adoption.
- Review the process for developing the proposed operating rules.
- Consider the effect that the proposed operating rules will have on standards and operating rules already adopted and implemented.
- Identify the benefits and efficiencies gained by the health care industry through the adoption and implementation of the proposed operating rules.
- Consider possible risks, concerns, costs, or issues that the adoption of the proposed operating rules may create.

The HIPAA-named transactions covered during the hearing included: 1) health plan enrollment and disenrollment; 2) premium payment; 3) prior authorization; and 4) health care claim or equivalent encounter information. NCVHS received presentations by CAQH CORE, the Operating Rules Authoring Entity (ORAE). In addition, 24 oral testimonies were provided and over 30 written testimonies were submitted from the health care industry representing providers, health plans, vendors, clearinghouses, associations, public programs (Medicare, Medicaid), federal agencies, standards development organizations, operating rules authoring entity and consultants.

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 whether the proposed operating rules:

- 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, and
- Can be enforced.

NCVHS also looked at other factors to evaluate the degree to which the adopted 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?

In addition to these criteria, specific questions were posed to the Operating Rule Authoring Entity and stakeholders to determine for the proposed operating rules and attachment standard:

- The degree of industry input into the development,
- If concerns raised during the February 2016 NCVHS Review Committee hearing were incorporated,
- Relationship to existing operating rules and standards,
- Impact of adoption,
- Benefits of their adoption, and
- Their recommendation for adoption.

Part 2: General Findings and Recommendations

Adoption and Implementation of Phase IV Operating Rules

One of the most significant findings of the February 2016 hearing was that stakeholders were not in agreement on the adoption of the proposed Phase IV operating rules. Some testifiers supported the adoption of the operating rules rather than waiting for an updated standard. While many indicated that the Phase IV operating rules focused on infrastructure requirements, many expressed concerns regarding the potential administrative cost and business impact of

the new infrastructure (connectivity) specifications that differ from Phase I through Phase III operating rules. Many testifiers questioned the inclusion of industry privacy, security and confidentiality specifications that are required by existing specifications specified in HIPAA regulations. Most testifiers agreed that data content should not be part of the proposed operating rules. However, some questioned the absence of data content. Most of the testifiers rejected the required use of the X.509 Digital Certification as the *sole* authentication source stating that its implementation would result in significant and costly system changes as many providers currently utilize the login/password option. Many testifiers also stated the lack of universal implementation of currently adopted operating rules and thus questioned the need to adopt the proposed operating rules.

Recommendation #1: Voluntary Adoption of the Phase IV Operating Rules

As noted above, NCVHS recommends that the proposed Phase IV Operating Rules for Claims, Prior Authorization, Enrollment and Premium Payment not be adopted in regulations and mandated for implementation at this time. NCVHS *strongly* supports the voluntary adoption of the Phase IV operating rules, to allow the industry to test, assess and evaluate the scalability, cost, benefit, and value of these operating rules before recommending them for national adoption through regulations.

Connectivity Requirements

Most testifiers expressed the need for operating rules to serve as a supplement to the standard, clarifying and enhancing the transaction, but expressed concerns with the restrictive Safe Harbor connectivity requirements in the proposed Phase IV operating rules that are different from currently adopted operating rules. Some testifiers stated the need for flexibility of requirements based on stakeholder need and the level of technology while others stated too much discretion is allowed. Some cited the length of time for modifying or creating new standards. However, many believed that the connectivity rules are a good starting point.

Testifiers who agreed with the operating rules not containing data content indicated that specific data content was costly to interpret and implement. Other testifiers stated that business functions could not be realized without addressing data content, which would need to be required to achieve efficiencies in the future. Testifiers did acknowledge that the safe harbor options on connectivity and security allow entities to utilize methods currently in place with their trading partners.

Recommendation #2: Address the Inconsistencies in the Connectivity Requirements

CAQH CORE should address inconsistencies in direction and interpretation found in the Connectivity requirements of the Phase IV operating rules including the rationale for a compatible change in the safe harbor; a safe harbor already allows for other connectivity methods.

Acknowledgment Standard

NCVHS understands the inclusion of acknowledgment requirements in the proposed operating rules as HHS has not adopted the acknowledgment standard. However, NCVHS believes that standards should not be part of operating rules and operating rules should not mandate standards.

While many testifiers support the voluntary use of the ASC X12 999 and/or 277CA, they did not support the mandated use of standards that have not been formally adopted through rulemaking. CAQH CORE has included acknowledgements as part of the infrastructure requirements in the proposed operating rules, and in all CAQH CORE rules since CAQH CORE's inception. NCVHS recognizes that CAQH CORE has attempted to incorporate the need for acknowledgments within the operating rules in the absence of HHS adoption of the acknowledgment standard. NCVHS does not believe that a standard not already adopted by federal regulation should be included within operating rules.

NCVHS has in the past recommended that HHS adopt a national standard for the Acknowledgement Transaction[1]. At the 2015 NCVHS Review Committee Hearing, stakeholders were unanimous in recommending that the one transaction that is not currently mandated or used consistently by the healthcare industry, yet has great potential, value is Acknowledgments**.** Testifiers indicated that acknowledgments should be adopted as a separate transaction and should not be included within the operating rule. This recommendation was reiterated at the February 2016 Phase IV Operating Rules and Attachment Standard hearing. Stakeholders continue to view the Acknowledgment Transaction 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 this example) about the need to correct certain elements of the submitted transaction before it can begin to be processed, or to confirm that the transaction was appropriately received and no corrections are needed before processing begins. Medicare uses claim acknowledgment 277CA transaction to report acceptance or rejection of claims, which many payers have followed. Consequently, NCVHS strongly recommends that HHS respond to the need for the acknowledgments and promptly adopt the acknowledgment standard.

Recommendation #3: Adoption of the Acknowledgment Standard

3.1: HHS should adopt the Acknowledgment Standard, consistent with previous recommendations made by the Committee on the subject.

3.2: At such time when the Acknowledgement standard(s) are mandated through regulation, the Operating Rule Authoring Entity should immediately determine how all existing operating rules be adjusted. In the interim, NCVHS supports the

[1] 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).

ongoing voluntary implementation of Acknowledgements by CAQH CORE in the absence of a regulation.

Authentication

The Phase II Connectivity Rule 270 permitted HIPAA covered entity submitters to use either an X.509 Digital Certificate or Username and Password as authentication methods. Many used the Username and Password as it did not require additional investments. The proposed Phase IV Connectivity Rule 470 requires a single submitter method using the X.509 Digital Certificate for claims, prior authorization, premium payment and enrollment transactions.

Testifiers disagreed with the requirement for a single submitter authentication requirement of the X.509 Digital Certificate proposed in the 470 Connectivity Rule. Many expressed that it would be a burden on covered entities and that the requirement differed from the optional choice requirement in the previous operating rules which allow for the use of Username + Password for authentication. Some opined concern over existing security and suggested enhancing security requirements of the existing authentication method. Others stated that it is premature to select a single authentication standard requirement. Non-covered entities who are trading partners are not required to utilize the digital authentication. Most testifiers recommended that consistency be maintained across all transactions by applying the Phase II Connectivity Rule 270 for the remaining transactions. NCVHS understands that CAQH CORE has indicated in its proposed operating rules that the Connectivity Rule Safe Harbor would apply and that the X.509 digital certificate must be offered and used if requested by a trading partner. However, requiring the need to offer a specific form of authentication means that the HIPAA-covered entity would be required to employ the X.509 authentication, if requested, which NCVHS heard would be a burden by requiring the provision of a specific authentication method at a time when the technology is evolving and which is different from the authentication requirements of previous operating rules.

Recommendation #4: For Authentication:

4.1: Establishing a requirement to implement digital certificates for the exchange of health care information should be considered in a much broader context, and not just to apply to four selective administrative transactions.

Part 3: Transaction-Specific Findings and Recommendations

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.

The following sections summarize the *findings and recommendations for each of the four proposed Phase IV operating rules*. As noted above, these recommendations are intended to guide the voluntary implementation of the operating rules.

Proposed Health Care Claims Operating Rule

Testifiers indicated that the health care claim or equivalent encounter transaction (837) is being widely used by the healthcare industry. The 2014 CAQH Index reported 92 percent adoption by the health care industry. The pharmacy industry uses the ASC X12 Standards for Electronic Data Interchange Technical Report 3 (TR3) – Health Claim: Professional (837) known as the X12N 837 to bill medications and supplies under Medicare Part B program and for professional pharmacy services covered under a medical plan. While many testifiers believed the operating rule meets the business needs, a few stated that the business needs are met within the ASC X12 Technical Reports (TR3) and concurred with the exclusion of any data content in the proposed operating rule.

The proposed Health Care Claim Operating Rule requires that payer system availability must be no less than 86 percent per calendar week for real time and batch processing. Some testifiers believed that this requirement is too lenient and is less than the requirements that exist in current business agreements.

The proposed infrastructure operating rule addresses certain requirements for submitting the 837 in real time, however, it does not address the requirements for real-time adjudication. It also imposes requirements for the acknowledgment standards (999 and 277CA) that have not been adopted. As discussed in Recommendation #4, many testifiers were in support of the adoption of the acknowledgment standard.

Testifiers were not in agreement as to the value of adopting the proposed health care claim operating rule. Some believed there was no need for the operating rule while others indicated the operating rule should be enhanced to improve functionality of the claims transaction. As noted earlier, most testifiers indicated that the proposed rule should only address infrastructure requirements while others suggested the need to include data content requirements to provide complete information.

Recommendation #5: Address the Following Suggested Modifications:

5.1 The *Operating Rule Authoring Entity* should:

5.1.1 Reinforce industry understanding that system availability requirements included in business agreements between trading partners may be more stringent than the mandatory requirements in the mandatory operating rules, if trading partners agree to them, but may not be less than those specified in the operating rule.

5.1.2 Specify that payers should not request the submission of information that has been provided on the initial claim.

5.2 The *Standards Development Organization*, *Operating Rule Authoring Entity, health care industry and CMS* should identify options to encourage the industry to offer real-time adjudications.

5.3 The *Standards Development Organization* and the *Operating Rule Authoring Entity* should address the issues that continue to be barriers to full implementation of the standard transaction. This would include:

- Consistent application of the Current Procedural Terminology (CPT) Guidelines.
- Addition of information not required for claim adjudication.
- Request for additional information contained on the health care claim.
- Require employers to notify payers of a change in employee status.

Proposed Enrollment/Disenrollment and Health Plan Premium Payment Operating Rule

Testifiers reiterated testimony provided at the June 2015 Review Committee hearing that indicated 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 work with the 834 standard adopted for HIPAA covered entities, the 834 HIX standard, and the Center for Consumer Information and Insurance Oversight (CCIIO) Companion Guides for use in the enrollment of individuals participating in the insurance marketplaces. However, some testifiers acknowledged that changes in health care delivery models may require the need to verify enrollment and disenrollment and health plan premium payment.

Testifiers noted that utilization varies with large health plans using the 834 more than the 820; smaller plans are not using the 834 due to costs. Testifiers cited that employers requested other formats such as less complicated flat files than the 820 standard transaction.

Recommendation #6: Convergence of Enrollment Standard for Health Insurance Exchanges

As indicated in the NCVHS February 29, 2016[2] letter, we recommend that HHS explore ways to bring to full convergence the 834 HIX (used by the insurance marketplaces), [3] the CCIIO Companion Guides and the current 834 used by HIPAA covered entities for all other enrollment transactions, so they become one and the same. Additionally, explore expanding the definition of a covered entity. These steps would simplify and promote standardization across the health care industry and support reduction of administrative burden.

[2] Ibid

[3] This recommendation replaces recommendation 7.2 in the February 29, 2016 letter to Secretary Burwell

Proposed Prior Authorization Operating Rule

Testimony reiterated the comments made at the NCVHS June 2015 Review Committee hearing. 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 the current market practice is manual processes utilizing telephones, health plan portals or fax machine to complete the process and often are subject to different State laws. For Medicaid, prior authorization is not related to administrative simplification and is used as a utilization tool for cost control and fraud prevention measure. Some testifiers supported the adoption of the Phase IV operating rule on prior authorization. Supporters cited demonstrated value of existing mandated operating rules which have improved electronic exchange of health care information; increased standardization with rules addressing data content; and increased clarity of payment adjustment messages with rules requiring uniform use of codes. However, most testifiers did not support its adoption. The 2015 CAQH Index reports an electronic prior authorization use of the mandated HIPAA standard for 10.2 percent of prior authorizations that were submitted to commercial health plans. In addition to the HIPAA standard, the Index reports 58.2 percent of prior authorization transactions submitted using other partially electronic methods which include health plan-sponsored web portals and interactive voice response (IVR) systems[4]. Barriers to implementation included:

- Patient care delays.
- Administrative burden due to its complexity.
- Used as a utilization control mechanism by health plans.
- Little utilization because of limited value.
- Health plans' proprietary web portals viewed as more effective, have become predominant venues for providing greater level of functionality and information exchange to achieve prior-authorizations.
- Many practice management vendors do not support the 278 transaction.
- Current transaction standard does not support all the needed level of clinical data documentation, resulting in trading partners having to use manual data submission alternatives.

The complexity of the prior authorization transaction is exemplified by the Veteran's Administration (VA). Only a limited number of payers offer the 278 transaction (of the 700 payers exchange electronic transactions with the VA, only six offer the 278 transaction through the VA's clearinghouse). Of the six payers, several have delegated authorization for certain services to Utilization Management Organizations (UMOs). For those, the VA first exchanges a 278 with a payer to get a rejection message referring to the UMO for clarification. The UMO does not utilize the 278 transaction requiring manual exchanges with the VA by phone, fax or other online systems to obtain the authorization. For the payers that the VA exchanges the 278 transaction, responses are returned using reject reason codes found in the transaction in the 'AAA' segments of various loops. This requires investigation to determine the cause of the rejection requiring calls with the payer or clearinghouse.

[4] 2015 CAQH Index Report (CAQH)

Some testifiers questioned the requirement for a third business day response for requests by Batch Process Mode and a 20 second response for Real Time Processing mode. Testifiers supported the 20 second response yet expressed concern regarding delay in treatment while awaiting authorization. Others recommended that prior authorization only be used for outlier situations.

In November 2004, NCPDP formed a task force which determined the ASC X12N 278 could not accommodate necessary attachments for pharmacy prior authorization determinations. The HL7 claim attachments were identified as a potential solution as the ASC X12N 278 transaction could not support an attachment within the transaction and an ASC X12N 275 would be needed as a wrapper around the attachment. The task group further determined that it would create its own prior authorization with different therapeutic classes which contain drugs commonly requiring prior authorization. The Task Group created new transactions for medication prior authorization using the NCPDP SCRIPT standard. In May 2014, NCVHS recommended that HHS name the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information. Several testifiers recommended that stakeholders be incentivized to build the processes and implement the electronic prior authorization standard as was done for ePrescribing.

Testifiers were in agreement that the adoption of the proposed attachment standard would support and facilitate the use of the prior authorization transaction.

Testimony heard at both the NCVHS June 2015 Review Committee hearing and at the 2016 Phase IV Operating Rule hearing indicate that there is additional work required on the prior authorization process that is not provided by the proposed operating rule.

Recommendation #7: NCVHS reiterates its recommendations in the February 29, 2016 letter from the Review Committee. In addition, NCVHS recommends that the:

7.1. *Standards Development Organization, Operating Rules Authoring Entity*, *Healthcare* industry *and HHS* should:

7.1.1 Evaluate the value of the current prior authorization transaction and the adopted standard. And identify 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.

7.1.2 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.

7.1.3 Clearly and consistently define data content and requirements in the 278.

7.1.4 Consider requiring additional capabilities in the 278 as supplemental loops and data elements; electronic attachments; primary health care provider identity; health plan product information; and estimating copay, coinsurance and deductible costs.

7.1.5 Increase implementation of this transaction. This would include performing an analysis of the barriers impeding the adoption of the 278 and the development of operating rules that will address these barriers.

7.1.6 Encourage payers and providers to standardize across all systems to ensure consistency in transmitting and receiving information. This would include payer portals, service request systems etc.

7.2 *Operating Rule Authoring Entity* should:

7.2.1 Further develop the Operating Rule for the 278 standard to support greater adoption including shortening the response time for Batch Process Mode requests to ensure that required treatments are not delayed.

7.2.2 Consider developing additional operating rules for the X12 270/271 eligibility transaction that would require communicating procedure-specific information including prior authorization requirements.

7.3 *Standards Development Organization and Operating rules Authoring Entity* to address:

7.3.1 Providers need to inquire and health plans report if prior authorization is required for a particular service.

7.3.2 Health plans' need to indicate what specific information is needed to comply with the prior authorization requirements for a particular service.

7.3.3 Providers need to electronically submit and health plans receive supporting documentation as requested.

7.3.4 Health plans need to electronically send the final prior authorization determinations that will be received by the provider.

7.3.5 Need for multiple iterations of the 278 standard until a final prior authorization determination is made and sent to the provider.

Conclusion

In summary, the healthcare industry's adoption and implementation of administrative simplification standards and operating rules have presented many challenges. Multiple Operating Rule hearings and the first Review Committee hearing provided a significant opportunity for NCVHS to learn from the health care industry about the successes as well as the

barriers to successful implementation of administrative simplification regulations. Thank you for consideration of the recommendations outlined in this letter. NCVHS remains available to answer any questions and will continue to support HHS 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