May 15, 2014

Honorable Kathleen Sebelius Secretary, Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Re: Findings from the February 2014 NCVHS Hearing on Prior Authorization for the Pharmacy Benefit; Health Plan Identifier (HPID); Electronic Fund Transfer (EFT)/Electronic Remittance Advice (ERA); and, Remaining Operating Rules

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 and code sets for the HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) {Sec. 1104 (b) enacted on March 23, 2010, calls for NCVHS to assist in the achievement of administrative simplification to "reduce the clerical burden on patients, health care providers, and health plans."

Each year, NCVHS holds industry hearings to evaluate and review the standards, code sets, identifiers and operating rules adopted under the HIPAA and the ACA, and determine whether there is a need for updating and improving any of these standards and operating rules. NCVHS is pleased to present in this letter, findings from our February 2014 hearing. This letter summarizes common themes across various topics covered during the hearing, followed by findings, observations and recommendations on specific topics.

As we had indicated in our September 20, 2013 letter to you, significant changes continue to take place in terms of number, scale, pace and timing specifically with regard to implementation of the first set of standards and operating rules on electronic fund transfer (EFT) and electronic remittance advice (ERA); prior authorization; and, health plan identifier (HPID).

The following observations are drawn from the testimonies at the February 19, 2014 Subcommittee on Standards hearing.

Prescriber Prior Authorization for the Pharmacy Benefit

In 2004, the National Council for Prescription Drug Programs (NCPDP) organized a multi-industry, multi-Standards Development Organization task group to evaluate a prior authorization (PA) standard, particularly the medication prior authorization, that would support the needs for e-prescribing transactions and to develop a solution. Investigators found that the HIPAAnamed PA standard (the X12N 278 v4010 or v5010), was not adequate to support medication PA because it was designed for procedures/services or durable medical equipment (DME) prior authorization and did not accommodate the information necessary to facilitate prior authorization. It also did not have a mechanism for providers to provide relevant information for eprescribing. Consequently, the NCPDP developed and through its vetting process, received industry approval for e-Prescribing Prior Authorization transactions (included in the NCPDP SCRIPT Standard), which enables the healthcare industry to exchange prescriber-initiated prior-authorization requests for prescribed medications as part of the provider-patient encounter. The SCRIPT Standard was named in the Medicare Modernization Act (MMA) and is a requirement of Meaningful Use (MU) for e-prescribing transactions.

NCVHS had received a letter from the Designated Standards Maintenance Organization (DSMO) recommending the adoption of new electronic prior authorization transactions for use in electronic prescribing. Specifically the DSMO recommended naming the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions, for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit. The NCPDP and testifiers at the NCVHS hearing stated it is confusing to the industry to separate the SCRIPT Standard transactions into HIPAA transactions but it was unclear under which regulation prior authorizations would fall. Entities affected by the prior authorization processes include pharmacies, prescribers who use electronic prescribing, the Medicare Part D Program, and the Medicare Improvements for Patients and Providers Act (MIPPA) e-prescribing (eRx) incentive program, and the HITECH Electronic Health Record (EHR) Incentive Program.

While some testifiers indicated that the use of the SCRIPT Standard Version 2013101 Prior Authorization transactions would require completion of additional workflow processes at the prescriber level, there was overall consensus among the testifiers regarding the need for real time prior authorization at the provider level for electronic prescribing. Specifically, the prescriber needs to have at the point of service, access to the pharmacy benefit information to determine if the individual is covered under the pharmacy

benefit and what medications are available under the pharmacy formulary. This improves patient access to required medications.

Testifiers, including vendors, were in agreement that paper and telephonic prior-authorization is time consuming for prescribers and adds overhead costs. One testifier provided estimates obtained from journal articles that indicated that, prior-authorization accounts for a cost of \$2,161 to \$3,430 annually for each full-time equivalent physician.

Subsequent to the February 2014 hearing, NCVHS received supporting testimony from the America's Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association (BCBSA) in favor of adoption of the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions.

Recommendation1: HHS should name the NCPDP SCRIPT Standard Version 2013101 Prior Authorization transactions as the adopted standard for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit.

Recommendation 2: HHS should adopt Recommendation 1 under the most appropriate regulatory sections and processes that would enable prompt industry implementation and at the earliest possible implementation time.

Health Plan Identifier (HPID)

Testifiers indicated that there is confusion on how the HPID/Other Entity Identifier (OEID) should be used. Many health plans face challenges with respect to the definitions of controlling health plan (CHP) and subhealth plan (SHP); the use of HPID for group health plans that do not conduct HIPAA standard transactions; and the cost to health plans, clearinghouses and providers if software has to be modified to account for the HPID. Testifiers questioned the impact on health plans, third-party payers (TPAs) and Administrative Services Only (ASO) self-insured groups and the degree of granularity required to enumerate. Others expressed concerns that the HPID database would not be accessible and without public access to the HPID database the identifier is of no value to trading partners; validation could not be performed; a crosswalk would not be possible among Medicaid proprietary plans; and the data collection does not include reference to the Bank Identification Number/Processor Control Number (BIN/PCN) used in pharmacy claims processing. Concern was also expressed that self-insured health plans are not aware of the requirements that apply to them.

NCVHS heard the challenges expressed by testifiers at the hearing relating to the value of the HPID and its relationship to the payer ID and whether the HPID is intended to replace any existing identifiers. Because of the questions raised, NCVHS plans to probe the HPID issues further at its Standards Subcommittee hearing in June 2014.

Recommendation 3: To mitigate the confusion about the HPID among the health care industry, HHS should:

- provide more guidance on the HPID /OEID specifically, clarifying when an HPID should be requested;
- clarify the definition of health plan, CHP and SHP;
- define how health plans determine whether they have CHPs or SHPs;
- identify whether HPID, which is not intended to replace the payer ID, should be used for payer identification;
- explain the applicability of HPID to self-insured and fully-insured group health plans, specifically the extent to which all self-insured plans are required to obtain a HPID, where the HPID is to be used in the transaction and when a third party administrator is the entity processing the transaction on behalf of the self-insured plan;
- define the purpose of the OEID;
- provide clarification with respect to public access to HPID/OEID data bases;
- provide educational outreach to explain the use and requirements of the HPID/OEID; and
- provide guidance on benefits and value of the HPID for health plans and providers and administrative simplification requirements;

Electronic Fund Transfer (EFT)/Electronic Remittance Advice (ERA)

Adoption of the EFT and ERA operating rules started January 1, 2014. Testifiers reported that most HIPAA covered entities have implemented the EFT and ERA operating rules and the EFT standard and, it appears implementation has been reasonably smooth. A testifier reported that some EFTs received from CMS are not formatted according to the EFT standard or the NACHA Operating Rules. The rate of adoption and the effect of adopting EFT and ERA operating rules will be evaluated by the health care industry this year.

The volume of EFTs has grown each year and it is expected that this trend will continue through 2014. Enrollment is seen as a factor in the success of the

EFT and reducing inconsistency across the payers should facilitate further adoption and reduce costs. Testifiers were in agreement that the use of EFTs and ERAs has resulted in savings of \$.50 to \$1.25 per payment with the capability of saving approximately \$3.00 for each electronically settled claim.

Concerns were expressed by many testifiers with a new emerging issue, the use of virtual cards and credit cards by health plans to pay and transfer funds to providers for health services rendered.

Virtual cards are generally 16-digit credit card numbers (without the plastic card) sent by a payer to a provider to pay for services. Providers then enter the virtual card number in their regular payment system to authorize the payment, and subsequently receive the payment via the Automated Clearing House (ACH) in their merchant bank account.

Issues raised by testifiers included the additional fees charged for each virtual card authorization transaction (as much as 5% of the payment); transaction fees that are not always transparent; staff time required to manually key in credit card information; additional time required to resolve for entry errors; standard electronic remittance advice not being equipped to carry credit card information; multiple claims being represented on one virtual credit card complicating reconciliation; providers not being afforded the opportunity to choose using a virtual credit card; and, questions if using virtual cards are in compliance with HIPAA standards. Other testifiers described situations where virtual credit cards with a fee was the only payment option offered to providers; applying a fee if providers used the standard; incentives such as providing faster payment, if the virtual credit card is used; disincentives such as slower payments and application of a fee, if providers wished to use the standard; and excessive fees to conduct standard transactions. However, some testifiers described advantages to using the virtual credit card indicating that large numbers of providers currently accept credit cards, as well as ACH; provider enrollment is not necessary; it results in reduction in payer print/mail costs; and, there are near zero payer bank fees, as the provider carries all the costs. Use of the trace number (TRN), that is, re-association of payment and the remittance advice, is seen as the key to improving efficiency for providers with the healthcare EFT standard. The TRN cannot be used with the virtual card, as a HIPAA compliant X12 835 version 5010 ERA cannot be created to support a credit card payment.

Recommendation 4: To address the concerns raised by the health care industry regarding the use of credit cards, including virtual cards, for electronic fund transfer transactions, HHS should:

 explore the use of virtual credit card payments to determine if its use is compliant with the EFT standard and if providers are afforded the opportunity to use the HIPAA EFT standard rather than the virtual credit card;

- work with the health care industry to be aware of the practices that exist to encourage the use of the standard for the EFT, instead of the virtual card; and
- work with the health care industry to ensure greater transparency.

Recommendation 5: HHS should assure that all HIPAA covered entities comply with the adopted EFT standard. Specifically, entities should:

- correctly format the TRN Segment in the Addenda portion of the CCD+ to assure that providers are able to match an EFT to its associated ERA;
- use the standard description required by the NACHA rules so that the health care EFT is easily recognizable by someone reading an account statement; and
- use the X12 835 version 5010 TR3 Report in place of the version 4010 for the TRN Reassociation Trace Number.

Operating Rules for Remaining Transactions

Progress has been made and continues to be made in developing the remaining operating rules, which are expected to be drafted by the end of 2014. The remaining operating rules include health claims or equivalent encounter information; enrollment/disenrollment in a health plan; health plan premium payments; referral certification and authorization; and, health claims attachments. Many challenges exist for developing the operating rules for the health claim attachments particularly relating to ensuring privacy, transport and enveloping attachments, security and authentication, message interaction, response times and determining return on investment. Standards have been adopted for health claims or equivalent encounter information; enrollment/disenrollment in a health plan; health plan premium payments; and, referral certification and authorization. A standard has not been developed for the health claim attachments.

Section 1173(a)(2)(B) of the HIPAA, identified a health claim attachment as one of the transactions for which electronic standards were to be adopted. The NCVHS Subcommittee on Standards held a hearing on health care claim attachments on November 17, 2011 and a second review at the February 27, 2013 hearing. In the June 21, 2013 letter, we explained that a final rule had not be developed subsequent to the publication of a proposed rule in 2005, due in part to questions about the maturity of the standards that had been

recommended for adoption and the ability for users to implement them. We provided many recommendations for the development of a rule to adopt standards for electronic attachments.

Health care clinical attachments continued to be addressed at the February 2014 hearing with regard to the development of the remaining operating rules. Testifiers opined that operating rule development be aligned with meaningful use and the health insurance marketplace/exchanges. Future operating rules should be evaluated based on return on investment (ROI), industry readiness, and industry constraints. Additional hearings on these issues will be planned in the future.

NCVHS does not have any recommendations regarding this topic at this time. Rather, we will continue to work with the operating rule authoring entity to monitor the development of operating rules for the remaining transactions and receive the recommended operating rules later this year. NCVHS anticipates that recommendations will be provided to the Secretary after the operating rules have been developed and submitted to NCVHS for evaluation.

Closing Comments

NCVHS recognizes the challenges that the health care industry faces today and will continue to experience over the coming years as they adjust to these transformative changes. NCVHS will continue to support your efforts to increase the adoption of standards and operating rules that help move the industry forward with technology to achieve greater efficiency.

Sincerely,

/s/

Larry A. Green, M.D. Chairperson, National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs