Observation 3 (Prescription Messages)
Recommendation:
HHS should
- recognize as a foundation standard the most current version of NCPDP SCRIPT for
  ⇒ new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers.
  ⇒ The NCPDP SCRIPT Standard would include its present code sets and various mailbox and acknowledgement functions, as applicable.
- include the <u>fill status notification function of the NCPDP SCRIPT Standard in the 2006 pilot tests</u> to assess the business value and clinical utility of the fill status notification function, as well as evaluate privacy issues and possible mitigation strategies.
  ⇒ *Status:*
    - *NCPDP Work Group 11 Prescriber/Pharmacist Interface RXFILL Task Group has created implementation and operational guidance to pharmacy and prescriber system participants for the consistent utilization for the Fill Status Notification transactions. The Task Group leader is Teresa Strickland of Healthcare Computer Corporation.*
    - *This task group has met one-two times per week.*
    - *The guidance recommendation has been submitted for approval at the next NCPDP Work Group meetings in March 2005. If the guidance is approved, the updates will be made to the next version/release of the SCRIPT Implementation Guide and given to the NCPDP Board of Trustees for approval. (Approval of the BOT would be expected in April/May timeframe.)*
      - *Guidance includes operational challenges such as automatic triggering of fill status notifications, triggering on return to stock, inferring pick up, privacy, liability, coordination with medication history, a patient changing physicians, etc.*

Observation 4 (Coordination of Prescription Message Standards)
Recommendation:
HHS should
- financially support the acceleration of coordination activities between HL7 and NCPDP for electronic medication ordering and prescribing. HHS should also support ongoing maintenance of the HL7 and NCPDP SCRIPT coordination.
- recognize the exchange of new prescriptions, renewals, cancellations, changes, and fill status notification *within the same enterprise* as outside the scope of MMA e-prescribing standard specifications.

- require that any prescriber that uses an HL7 message within an enterprise convert it themselves, or utilize a switch, to NCPDP SCRIPT if the message is being transmitted to a dispenser outside of the enterprise. HHS also should require that any retail pharmacy within an enterprise be able to receive prescription transmittals via NCPDP SCRIPT from outside the enterprise.
  - ⇒ *Status:*
    - *HL7/NCPDP collaboration is actively underway as attendees met at HL7 last week to demonstrate the interoperability of new prescriptions and medication history transactions. The demonstration went very well and had quite abit of interest in the transactions flying around!*
    - *The mapping team meets 2 calls per week to discuss the mapping of the standards.*
      - *Mapping continues on Refills and code sets.*
      - *Determining a face-to-face meeting for mappers during the HIMSS demonstration and possible education session during NCPDP March Work Group meetings.*
    - *The mapping working documents will be turned into an industry guidance document.*
    - *Other work items have been identified such as*
      - *Change management*
      - *Process flow*
      - *Education in HL7 version 3*

Observation 5 (Formulary Messages)
Recommendation:
- HHS should actively participate in and support the rapid development of an <u>NCPDP standard for formulary and benefit information file transfer, using the RxHub protocol as a basis.</u>
- *NCVHS will closely monitor the progress of NCPDP's developing a standard for a formulary and benefit information file transfer protocol, and provide advice to the Secretary in time for adoption as a foundation standard and/or readiness for the 2006 pilot tests.*
  - ⇒ *Status:*
    - *NCPDP Work Group 11 Prescriber/Pharmacist Interface Formulary and Benefit Task Group is led by Teri Byrne of RxHub, LLC and consists of many industry representatives.*
    - *The task group will be submitting a standard for approval to NCPDP at the March 2005 work group meetings.*
    - *The draft standard includes the sharing of*
      - *Formulary status lists (codes to explain how to treat non-listed brand, generic, OTC; whether the drug is on formulary or preferred status; relative value limit, etc)*
      - *Formulary alternatives lists (alternatives for specific drugs – the source/ the alternative)*

- *Benefit coverage lists (conditions under which the patient's pharmacy benefit covers a medication)*
- *Benefit copay lists (the extent to which the patient is responsible for the cost of a prescription. The specification supports multiple ways to state this cost, including flat dollar amounts, percentages, and tier levels.)*
- *Cross-reference file of user-recognizable health plan product name to the identifiers used for the Formulary, Alternative, Coverage, and Copay.*
  - *Discussion is continuing about the use of RxNorm. At this point a placeholder is included in the implementation guide, but no detail has been determined. The implementation guide currently supports multiple drug identifiers. Further analysis will be done to understand how/if RxNorm may be used and what level RxNorm will be qualified.*

Observation 6 (Eligibility and Benefits Messages)
Recommendation:

HHS should

- recognize the ASC X12N 270/271 Health Care Eligibility Inquiry and Response Standard Version 004010X092A1 as a foundation standard for conducting eligibility inquiries from prescribers to payers/PBMs.
- support <u>NCPDP's efforts to create a guidance document to map the pharmacy information on the Medicare Part D Pharmacy ID Card to the appropriate fields on the ASC X12N 270/271</u> in further support of its use in e-prescribing.
  - ⇒ *Status*:
    - *NCPDP Work Group 3 Standard Identifiers formed a task group, led by Todd Walbert of Walgreens. They are collaborating with X12N WG1 Health Care Eligibility as needed.*
- work with ASC X12 to determine if there are any requirements under MMA with respect to how situational data elements are used in the ASC X12N 270/271, especially concerning the quality of information needed for real-time drug benefits. Use of these situational data elements could be addressed in trading partner agreements. Specifications of use of situational data elements, as well as proper usage of the functional acknowledgments, should be included in the 2006 pilot tests.
- ensure that the functionality of the ASC X12N 270/271, as adopted under HIPAA, keeps pace with requirements for e-prescribing and that new versions to the Standard be pilot tested.

Observation 7 (Prior Authorization Messages)
Recommendation:

HHS should

- support ASC X12 in their efforts to incorporate functionality for real-time prior authorization messages for drugs in the ASC X12N 278 Health Care Services

Review Standard Version 004010X094A1 for use between the prescriber and payer/PBM.

- support standards development organizations and other industry participants in <u>developing prior authorization work flow scenarios to contribute to the design of the 2006 pilot tests</u>.
- evaluate the economic and quality of care impacts of <u>automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests</u>.
- ensure that the functionality of the ASC X12N 278, as adopted under HIPAA, keeps pace with requirements for e-prescribing and that new versions to the Standard be pilot tested.

⇒ *Status:*

- *NCPDP Work Group 11 Prescriber/Pharmacist Interface Prior Authorization Workflow-To-Transactions Task Group is led by Tony Schueth of Point of Care Partners and consists of X12N WG10 Health Care Services Review Co-Chairs and other interested stakeholders.*
- *The task group has created draft flows of the medication prior authorization process and identified where standards exist and gaps exist.*
- *The task group is working to understand the dialogue (questions with answers) that is necessary for prior authorization processing.*
- *(Please see presentation.)*

Observation 8 (Medication History Messages from Payer/PBM to Prescriber)
Recommendation:

- The following recommended actions address *only* exchange of medication history from payers/PBMs to prescribers. NCVHS plans to address other medication history communications in its March 2005 recommendations.
  - o HHS should actively participate in and support rapid development of an <u>NCPDP standard for a medication history message for communication from a payer/PBM to a prescriber, using the RxHub protocol as a basis</u>.

⇒ *Status:*

- *RxHub submitted a Data Element Request Form (DERF) at the November NCPDP work group meeting for the protocol (based on SCRIPT). The request is being balloted now, with adjudication of the ballot at the March work group meetings.*

Observation 9 (Clinical Drug Terminology)
Recommendation:

HHS should

- include in the <u>2006 pilot tests the RxNorm terminology in the NCPDP SCRIPT Standard for new prescriptions, renewals, and changes.</u>
  - o RxNorm is being included in the 2006 pilot tests to determine how well the RxNorm clinical drug, strength, and dosage information can be translated from the prescriber's system into an NDC at the dispenser's system that

represents the prescriber's intent. This translation will require the participation of intermediary drug knowledge base vendors until the RxNorm is fully mapped.

⇒ *Status:*

- *In August, NCPDP requested NLM map examples to show the flow of a prescribed clinical drug using RxNorm through to the pharmacy dispensing of an NDC.*
  - *Examples were created by NCPDP members and presented during the November Work Group meeting.*
- *NCPDP Work Group 2 Product Identification RxNorm Task Group has met to discuss RxNorm, and begin discussions of how it would be used in electronic prescribing, medication history, prior authorization, identify gaps in usage, and recommendations. The task group is led by George Robinson of First DataBank and Karen Eckert of Medi-Span.*
- *More information will be given in the RxNorm agenda item.*
- *During the NCPDP Annual Conference in March 2005, the NLM has accepted an invitation to speak on RxNorm.*

- accelerate the promulgation of FDA's Drug Listing rule and hence the ability to support the correlation of NDC with RxNorm (e.g., for passing daily updates of the SPL to NLM for inclusion in the DailyMed). Timely rulemaking is critical to sustain the daily use of RxNorm beyond the 2006 pilot tests.

⇒ *Status:*

- *NCPDP Work Group 2 Product Identification created an SPL Task Group to collaborate with HL7. The task group is led by Tom Bizzaro of First DataBank.*
- *The task groups goals:*
  - *The group will review the HL7 SPL Implementation guide and Structured Product Labeling, Release 2 document. The TG will review and suggest improvements/changes to Release 2.*
  - *The group will review areas in SPL that would benefit from codification. If there is consensus on what code systems should be used in specific areas, the group will suggest the use of those code systems.*
  - *Ensure that, if the Medicare Part D Model Guidelines and NDF-RT differ, an accurate mapping exists so they both can be used successfully.*

Observation 10 (Structured and Codified SIG)
Recommendation:

HHS should

- support <u>NCPDP, HL7, and others (especially including the prescriber community) in addressing SIG components in their standards</u>. This should include preserving the ability to incorporate free text whenever necessary (e.g., for complex dosing

instructions, and to address special cultural sensitivities, language, and literacy requirements).

⇒ *Status:*

- *NCPDP Work Group 10 Professional Pharmacy Services Industry SIG Task Group led by Laura Topor of Allina Hospitals and Clinics, and Keith Fisher of SXC Health Solutions, Inc., with over 50 members including MDs, R.Phs, SNOMED, ISMP, HL7, CMS, VA, NCPDP, chain pharmacy, health plans, vendors, processors, clearinghouses, etc.*
- *Meets biweekly via conference calls. Another working face-to-face will be held during the NCPDP March work group meetings.*
- *A draft implementation guide is being prepared.*

Data Gathering

- *Work by NCPDP, HL7, CCR, Dr. First and others have been reviewed.*
- *Looking for potential consistency and efficiency between inpatient and outpatient settings.*
- *Focus has been on US activities, with an eye to international work*

Scope Definition and Management

- *Maximize the use of the standard for inpatient and outpatient, wherever possible, to simplify process for prescribers and pharmacies and address safety concerns*
- *Accept that some SIGs won't lend themselves to the standard, but focusing on 80/20 (or 90/10). Input from pediatric prescriptions is being sought.*
- *Optimize technology - computable fields, etc.*

Draft Operating Assumptions

- *No abbreviations*
- *Leverage/maximize existing: 1) standard vocabularies, i.e. SNOMED; 2) external code lists; 3) data dictionaries*
- *Defaults may be overridden (Verb (take, apply, etc), then the user must be able to change that to something else (dissolve under tongue, etc); or if a system defaults a common set of instructions (1 po 2 times daily), the user must be allowed to change to 2 po 1 time daily if desired).*
- *Textual representation will accompany codified SIG*
- *Have mathematical/computable option whenever possible*
- *The standard is about interoperability transfer, not interface creation*
- *The standard should be able to be incorporated into various standards as applicable - HL7, NCPDP, CCR, etc.*

Next steps
- *Mapping common scripts into proposed format – final reviews underway.*
- *Draft implementation guides for NCPDP and HL7 versions to demonstrate flexibility of model. Continue work refining data elements and code sets.*
- *Continue bi-weekly calls; schedule face to face meetings as needed*
- *Identify other stakeholders/audiences and develop communication plan for 2005 (TEPR, HIMSS, ASAP, etc.)*

Timeline
- *January 2006 - implementation*
- *Summer 2005 - release proposed standard for coding and testing (CMS/NCVHS has acknowledged that timeline does not allow for completion of ANSI standards process)*

- include in the 2006 pilot tests the structured and codified SIGs as developed through standards development organization efforts.

Observation 13 (Pilot Test Objectives)
Recommendation :
HHS should
- support the efforts of standards development organizations to incorporate in the foundation standards as many as possible of the additional functions required for MMA, as identified in these recommendations.
- include foundation standards with as many as possible of the additional functions required for MMA in the 2006 pilot tests.
- immediately begin to work with the vendors to ensure readiness for the pilot tests on January 1, 2006.
- identify and widely publicize specific goals, objectives, timelines, and metrics to guide the design and assessment and increase industry awareness of the 2006 pilot tests. HHS should include metrics that address economic, quality of care, patient safety, and patient and prescriber satisfaction factors.
- After the pilot tests, HHS should develop and widely disseminate information concerning any economic and quality of care benefits of e-prescribing, provide comprehensive education on implementation strategies, describe how e-prescribing can be implemented consistent with the privacy protections under HIPAA, and address other elements that contribute to successful and widespread prescriber adoption and patient acceptance.
    - ⇒ *Status:*
        - *Jill Helm of Allscripts suggested to me that an approach might be to develop a matrix with the NCVHS recommendations and standards as a benchmark to what is in use today. Then apply some best practice intelligence to determine what features/functions seem to fit together. Then add what estimates are in terms of number of physicians/pharmacies/health plans needed for a pilot. Determine*

what the interdependencies are between the attributes, suggested metrics to be collected, define success criteria. Jill is beginning the work. Once there is a rough draft, NCPDP will ask electronic prescribing organizations to join the effort. CMS active participation is critical. This would provide CMS with guidance and a framework; but much would still need to be done by CMS to actually coordinate and execute the pilots.

Next Steps

Other items not addressed in this initial set of recommendations. NCVHS plans to receive testimony on as many of these topics as possible between now and March 2005; and make further recommendations in March 2005. The topics include:

- <u>Electronic signature for use in e-prescribing.</u>
  - ⇒ *Status:*
    - *The NCPDP WG11/12 Joint task group, led by Dan Staniec of Caremark and Ken Whittemore of SureScripts, has been working on an authentication practices document, but some questions remain, which they will be discussing the committee members. Further modifications will be made based on that input. The document will be given to NCVHS when it is completed.*
- <u>A directory that would identify prescribers, nursing facilities, and pharmacies that are able to accept e-prescribing transactions.</u>
  - ⇒ *Status:*
    - *Work Group 11 Prescriber/Pharmacist Interface Provider Broadcast Task Group, led by Allan Smith of ProxyMed, is completing an implementation guide based on NCPDP SCRIPT syntax.*
    - *The implementation guide is planned to be presented to NCPDP for approval in May 2005. If approved, the implementation guide will be balloted in summer.*

Thank you.