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 formed a task group in August to work on guidance 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 and is building the guidance. Their goal is to provide Implementation and Operational guidance to Pharmacy and Physician participants for the consistent utilization of the fill status notification transactions.*
    - *The guidance recommendation will be 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 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.*
    - *Future steps may include requests for additions to the SCRIPT Standard.*

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 actively underway with 2-3 calls per week. Ross Martin, MD of Pfizer will provide a detailed status.*

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:*
    - *In August, NCPDP Work Group 11 Prescriber/Pharmacist Interface formed a Formulary and Benefit Task Group, led by Teri Byrne of RxHub, LLC.*
    - *The task group consists of approximate 60 industry representatives. They have met via conference calls and in a two-day face-to-face meeting in November.*
    - *An aggressive work plan has been developed. The task group is striving to submit a standard 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.*

- *There was much discussion about the identification of drugs. The task group decided to support 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 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 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 and they are building their scope now. They will be collaborating with X12N WG1 Health Care Eligibility as appropriate.*
- 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 developing prior authorization work flow scenarios to contribute to the design of the 2006 pilot tests.
- evaluate the economic and quality of care impacts of automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests.
- 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.

- *NCPDP Work Group 11 Prescriber/Pharmacist Interface formed the Prior Authorization Workflow-To-Transactions Task Group during the November Work Group meeting. The Task Group leader is Tony Schueth of Point of Care Partners.*
- *NCPDP extended an invitation to X12N WG10 Health Care Services Review Co-Chairs to work jointly on prior authorization from workflow to transactions.*
- *The task group welcomes all interested stakeholders.*
- *The task group will work with X12N participation to understand the identified gaps of medication prior authorizations in the 278 and recommend modifications to the standard.*
- *The task group will be working to understand the dialogue (questions with answers) that is necessary for prior authorization processing.*
- *It is possible this task group may require support and funding of face-to-face meetings or web casts.*

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.
  - 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 DERF was approved with the modification that pharmacies be added as participants in the sharing of medication history information. Although RxHub does not have experience in pharmacy-to-prescriber or payer-to-pharmacy information transfer, the standard will handle the exchange.*
    - *The request will be balloted in January 2005, with adjudication of the ballot at the March work group meetings.*
  - *NCVHS will closely monitor the progress of NCPDP's developing a standard medication history message for communication from a payer/PBM to a prescriber, and provide advice to the Secretary in time for adoption as a foundation standard and/or readiness for the 2006 pilot tests.*

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 not yet available.*
      - *During the NCPDP November Work Group meetings, a presentation was given by members to help explain RxNorm in pharmacy vernacular. The presentation included mapping from RxNorm to drug databases, and discussed where gaps exist and recommendations to close the gaps.*
      - *NCPDP Work Group 2 Product Identification formed a task group to clarify how RxNorm would be used in electronic prescribing, identify gaps in usage, and present recommendations to NCVHS during the January NCVHS Subcommittee hearings.*
      - *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:*
    - *During the NCPDP November Work Group meetings, Randy Levin, MD, FDA, presented on SPL, followed by an informative question and answer session.*
- 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:*
    - *In August, NCPDP Work Group 10 Professional Pharmacy Services created an Industry SIG Task Group.*

- Participants who testified on the SIG were invited, as were other industry stakeholders.
- Over 50 members, including MDs, R.Phs, SNOMED, ISMP, HL7, CMS, VA, NCPDP, chain pharmacy, health plans, vendors, processors, clearinghouses, etc.
- Task Group leaders are Laura Topor of Allina Hospitals and Clinics, and Keith Fisher of SXC Health Solutions, Inc.
- The task group began meeting in September 2004 and have met numerous times to propose foundational working documents. CMS is sponsoring the calls.
- Some members of the TG were able to meet during NCPDP JTWG meeting in Atlanta, 11/04.
- A face-to-face meeting is being discussed with sponsorship by ANSI HISB and AHRQ.

Data Gathering
- Work by NCPDP, HL7, CCR, Dr. First and others have been reviewed.
- The task group is researching current medical practice management systems to understand prescriber workflow and processes.
- 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, etc.*

Next steps
- *Mapping common scripts into proposed format - begun at TG meeting 11/18/04 -and send to TG to review/validate*
- *Draft implementation guides for NCPDP and HL7 versions to demonstrate flexibility of model.*
- *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)*
- *March 2005 - NCPDP JTWG*
- *November 2004 - NCPDP JTWG*

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

Observation 11 (Dispenser Identifier)
Recommendation:
HHS should
- ensure that the NPI, when it becomes available, is incorporated as the primary identifier for dispensers in the NCPDP SCRIPT and other e-prescribing standards.
  - ⇒ *Status:*
    - *SCRIPT supports the NPI.*
- accelerate the enumeration of all dispensers to support transition to the NPI for e-prescribing.
- permit the industry to use the NCPDP Provider Identifier Number in the event that the NPS cannot enumerate dispensers in time for Medicare Part D implementation.
- evaluate how mass enumeration of dispensers for the NPI can occur using the NCPDP Provider Identifier Number database.
- when requiring the NPI as the primary identifier for dispensers, should protect the ability to maintain linkages to the NCPDP Provider Identifier Number database for current claims processing purposes.
  - ⇒ *Status:*
    - *No specific action items for NCPDP.*

Observation 12 (Prescriber Identifier)
Recommendation:
HHS should
- ensure that the NPI, when it becomes available, is incorporated as the primary identifier for prescribers in the NCPDP SCRIPT and other e-prescribing standards. It should be noted that the NPI must be at the individual prescriber level, because a prescription cannot be written at a group level.
  - ⇒ *Status:*
    - *SCRIPT supports the NPI. However, there may need to be input from industry participants for any modifications/clarifications to the SCRIPT Standard because of the lack of location specificity. If needs are shown, NCPDP expects modifications to requested from the industry via the Data Element Request Form (DERF) process.*
- accelerate the enumeration of all prescribers to support transition to the NPI for e-prescribing.
- permit the industry to use the NCPDP HCIdea in the event that the NPS cannot enumerate prescribers in time for Medicare Part D implementation.
- work with the industry to identify <u>issues and possible solutions that deal with all elements of the prescriber location and include those solutions in the 2006 pilot tests.</u>
- evaluate how mass enumeration of prescribers for the NPI can occur using the NCPDP HCIdea database.
- when requiring the NPI as the primary identifier for prescribers, should protect the ability to maintain linkages to the NCPDP HCIdea database for e-prescribing routing functions.
  - ⇒ *Status:*
    - *No specific action items for NCPDP.*

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:*
   - *No specific action items for NCPDP.*

Observation 14 (Support for Standards Collaboration)
Recommendation:

HHS should
- financially support standards coordination activities to ensure a seamless e-prescribing process across provider domains (e.g., physician office, hospital, long term care), dispensers, and payers/PBMs.
- encourage standards development organizations to adopt a change management process that permits versions to maintain interoperability.

⇒ *Status:*
   - *No specific action items for NCPDP.*

Observation 15 (Policies to Remove Barriers)
Recommendation:
- HHS should ensure that regulations define the parameters of safe harbor, ensure preservation of provider/patient choice, and require that e-prescribing messages received through e-prescribing applications be free from commercial bias.

⇒ *Status:*
   - *No specific action items for NCPDP.*

Observation 16 (Conformance Testing and Certification)
Recommendation:

HHS should
- support standards development organizations in their development of conformance tests for the e-prescribing standards and their implementation guides.

⇒ *Status:*
   - *NCPDP is looking for guidance on exactly what needs to be stated. We may already satisfy this; unknown.*
- require that e-prescribing system vendors validate the conformance of their e-prescribing messages.
- The HHS Office of the National Coordinator for Health Information Technology should investigate how e-prescribing applications might best be certified.

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:

- Electronic signature for use in e-prescribing.
    - ⇒ *Status:*
        - *Testimony on 12/8-10/2004.*
- A directory that would identify prescribers, nursing facilities, and pharmacies that are able to accept e-prescribing transactions.
    - ⇒ *Status:*
        - *During the NCPDP November work group meetings, Work Group 11 Prescriber/Pharmacist Interface created a Provider Broadcast Task Group. Allan Smith of ProxyMed is Task Group leader. In the past, a standard was designed, using common segments/fields from NCPDP SCRIPT, but was abandoned due to other electronic prescribing work items. Trading partners are using this draft standard based on SCRIPT, as a starting point. Other methods used by the industry are welcome to the discussion to reach a standard for balloting.*

Thank you.