Work Plan for E-Prescribing Standards
Version 9, *June 3*, 2004

Work Plan Outline

I. Applicability of the Electronic Prescription Drug Program

II. Deadlines Set Forth in the Law

III. Workplan Requirements and Schedules

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- E-Prescribing Program and Standards Requirements List
- NCVHS Consultation Responsibilities
- Develop and Agree on Questionnaires for Testifiers
- Testimony Schedule
- Development and Approval of Recommendations

IV. Appendix

- Public Law 108-173 Medicare Prescription Drug Improvement and Modernization Act of 2003; Subsection (e) ELECTRONIC PRESCRIPTION PROGRAM

I. Applicability of the Electronic Prescription Drug Program

- The electronic prescription program is applicable to eligible individuals within the Voluntary Prescription Drug Benefit Program (Part D) and the covered Part D drugs.

II. Deadlines Set Forth in the Law

- The NCVHS will need to submit its recommendations for electronic prescribing standards to the Secretary of HHS by June 2005 (this deadline is not specified in the law)

- Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics.

III. Workplan Requirements and Schedules

1. Develop and Agree to the Work Plan, and Define Initial Scope of Work for a Consultant to Assist the Subcommittee:

- Develop preliminary plan (December 6, 2003)
- Review preliminary plan with the Subcommittee (December10, 2003)
- Update the work plan with feedback (January 16, 2004)
- NCVHS SSS agrees to the work plan (January 28, 2004)
- Define Initial Scope of Work for a Consultant to Assist the Subcommittee (February 2004)

2. Program requirements:

The following list was derived from the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 - Title 1, Section 101(e)(2) Program Requirements

(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists:
- Electronic transmittal of the prescription
- Electronic transmittal of information on eligibility and benefits including:
  - Drugs in the applicable formulary
  - Any tiered formulary structure
  - Any requirements for prior authorization

- Information on the prescribed drug and other drugs within the medication history:
  - Drug to Drug Interactions
  - Warnings or Cautions
  - Dosage Checking against Patient's Weight
  - Dosage Checking against Patient's Age
- Information on Lower Cost Drug/Therapy Alternatives

(B) Provision for Electronic Transmittal of Medical History Information
Title I, Section 101(e) did not reference drug to allergy checking or drug to lab test checking, but these requirements should probably be added here

(C) Electronic Provision of Information under paragraphs (A) or (B) must comply with the HIPAA Privacy Regulations

(D) Electronic Transmittals should be interactive and real-time

3. Standards Requirements: Standards shall…

(A) Be consistent with program requirements described in paragraph 2

(B) Have the objective of improving…
- Patient Safety
- Quality of Care
- Efficiency (including cost savings)

(C) Meet these design criteria…
- Not present an undue administrative burden on prescribers and pharmacists
- Be compatible with other standards including part C of title XI (HIPAA?) and subsection (b)(2)(B)(i)?
  Title I, Section 101(e) did not reference federal drug terminologies recommended by NCVHS, but this should probably be considered
- Permit electronic exchange of drug labeling and drug listing information maintained by FDA / NLM

(D) Include quality assurance measures and systems referred to in subsection (c)(1)(B): *"… to reduce medication errors and adverse drug interactions and improve medication use."*

(E) Permit patient designation of dispensing pharmacy so there is…
- No Change in patient benefits…
  - No prescription drug plan constraint of electronic access to/from pharmacies

- No differences in benefits or payments based on the dispensing of a part D drug

(F) ***Title I, Section 101(e) did not reference Electronic Signatures, but needs to be considered***

4. NCVHS Consultation Responsibilities

The following entities were specifically identified in the law

The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

- Standard setting organizations (as defined in section 1171(8))
- Practicing physicians
- Hospitals
- Pharmacies
- Practicing pharmacists
- Pharmacy benefit managers
- State boards of pharmacy
- State boards of medicine
- Experts on electronic prescribing
- Other appropriate Federal agencies

In addition, the NCVHS subcommittee has determined that testimony should also be obtained from:

- E-Prescribing Software Developers, Networks and Service Organizations
- Existing E-Prescribing Implementations
- E-Prescribing Demonstration Programs
- Consumer Advocacy Groups
- Other E-Prescribing Users

5. Develop and agree on questionnaires for testifiers, which is to be completed before testimony is given.

6. The NCVHS Schedule for Testimony will attempt to support the following priorities:

Priority 1: Identify candidate standards for basic prescribing functions between a physician and the pharmacy, and identify gaps.

Priority 2: Identify standards to support eligibility verifications (including individual formularies) and gaps.

Priority 3: Develop interim recommendations for decision support functionality (i.e. drug utilization review functions) and identify gaps.

Priority 4: Develop strategies and timelines to address or close gaps identified in Priorities 1 through 3 (above)

Priority 5: Identify candidate standards for electronic signatures and identify gaps.

7. Testimony Schedule:

A. Sessions that address Priorities 1, 2, 3, 4:

Session 1 Testimony (1 day): March 30, 2004

Purpose: Provide a general overview of e-prescribing including the Drug Benefit from the Federal perspective, the status of the e-prescribing marketplace, implementations, standards, and state & federal requirements.

Detailed Agenda on NCVHS Website

Session 2 Testimony (2 days): May 25, 2004 & May 26, 2004

Day 1: May 25, 2004

Purpose: To determine the current state of implementation and identify related issues, gaps and need; and to obtain input/reaction from the physician and hospital perspective.

- Current e-prescribing implementations, demonstration projects and Networks (e.g., Mass Medical Society, RI Quality Institute, BCBS/Tufts Health Plan, HIMSS/Cleveland Clinic, RxHub and SureScripts networks) (3 hrs)
- Physician and Hospital Associations [Reactor Panel?] (examples: AMA, AAFP, ACP, AHA, etc.) (2 hrs)
- Discussion (1 hr)

Day 2: May 26, 2004

Purpose: Identify the use, adequacy and gaps of standards from the perspective of vendors.

- E-Prescribing Software Developers (examples: AllScripts, Epic, Cerner, ePocrates, Wellinx, etc.) (2 ½ hrs)
- Drug Knowledge Base Vendors (e.g., FDB, Medispan, Multim) (1 ½ hrs)
- Discussion (1 hr)

3. Session 3 Testimony (3 days)

The testimony from these user groups will be scheduled for July 28-30, 2004

Purpose: Hear testimony from all other e-prescribing users and interested parties and compile a list of standards/code set gaps and issues that will be sent to the e-prescribing SDOs and code set developers so they can assess how they can address these gaps and issues when they testify on August 17-18.

Day 1

- Pharmacists & Pharmacies (3 hrs)
- Pharmacy Benefit Managers (2 hrs; approx. 4 testifiers)
- Pharmaceutical Manufacturers (1 ½ hrs)
- Discussion (1/2 hr)

Day 2

- Private Sector Payers (e.g., BCBS, HIAA) (2 hrs)
- Federal Agencies/Regulators (e.g., DoD, VA, FDA) (2 hrs)
- Consumer Advocacy Groups (1 hour)
- Other Healthcare Providers: Chiropractors, Alternative Medicine Practitioners, Infusion Therapists, Home Therapists (1 ½ Hrs)
- Discussion (1/2 hr)

Day 3

- State Boards of Medicine, Pharmacy, Nursing (2 hrs)
- State Medicaid Agencies (1 hr)
- Discussion: Review and agree upon the complete list of new requirements/gaps that will be sent to the SDOs and Terminology Developers as guidance for their preparation for their testimony in August 2004. (2 hrs)
- Adjourn 2:30 pm

4. Session 4 Testimony (2 days)

The testimony from these user groups will be scheduled for August 17-18, 2004

Purpose: E-prescribing SDOs and code set developers will testify how they plan to address the gaps and issues identified by users and other interested parties during the May/July hearings. Additionally, testimony will be given on the plans to harmonize e-prescribing standards used in the ambulatory environment (NCPDP Script) and in the acute care environment (HL7).

Day 1

- Gaps and issues in Script messages (2 ½ hrs)
- Drug Terminology Developers/Mappers address gaps and issues (*examples:* NLM, FDA, VA) (2 hrs)
- Review of HL7 prescribing related standards (including messages, decision support, code sets, etc.) and the HL7/NCPDP Coordination Initiative (2 ½ hrs)

Day 2

- Identifier developers for Patients, Prescribers, Pharmacies, and Health Plans (HHS-NPI, DEA, NCPDP HCIdea, Pharmacy number) (2 hrs)
- Develop preliminary observations regarding standards/code sets in use, standards gaps and issues, and recommendations identified by testifiers. Additionally, we hope to include those areas where SDOs/code developers can quickly address gaps prior to the beginning of federally funded demonstration projects for e-prescribing. Finally, if there is time, we hope to identify other important issues or gaps that cannot be addressed in time for the demonstration project but still need to be addressed. (3 hours)
- Adjourn at 2:00 pm

5. Session 5: Full Committee Meeting (2 days)
   Sept 1-2, 2004

   Purpose: Review and Approval by the Full Committee of preliminary observations for e-prescribing standards

   Approval by the Full Committee of preliminary observations for e-prescribing standards

6. Session 6 (2 days)
   Sept 22-23, 2004

   Purpose: Prepare first draft of the recommendations for the first phase of e-prescribing standards. This phase does not include electronic signatures, authentication, or other issues.

   Day 1: First draft of the recommendations for the first phase of e-prescribing standards. This phase does not include electronic signatures, authentication, or other issues.

   Day 2: First draft of the recommendations for the first phase of e-prescribing standards. This phase does not include electronic signatures, authentication, or other issues.

6. Session 7 (1 ½ days) – October 12-13, 2004

Purpose: Prepare second draft of the recommendations for the first phase of e-prescribing standards. This phase does not include electronic signatures, authentication, or other issues.

- Second draft of phase one recommendations.

7. Session 8: Full Committee Meeting (1/2 day)
November 4-5, 2004

Purpose: Review and obtain agreement to the first phase E-Prescribing recommendations

- Review and obtain agreement to the first phase E-Prescribing recommendations (2 hrs)

B. Sessions that address Priority 5: E-Signatures

1. Session 9 Testimony (1 day) – February 2005

Purpose: Receive testimony on standard and gaps for E-signatures

- Overview of the issues (1-1/2 hrs)
- E-signature work in progress (e.g., ASTM, HL7, DEA, NIST) (1 hr)
- E-Signature Vendors (1 ½ hrs)
- Healthcare Provider Users of E-Signatures (2 hrs)
- Discussion Time (1 hr)

2. Session 10 Testimony (1 day) March 2005

- Testimony from other stakeholders for e-signatures (3 hours)
- Develop recommendations on standards/gap filling related to the use of e-signatures, which then will be included in the final recommendations to be prepared in April (2 hours)

8. Development and Approval of Recommendations:

A. Interim Recommendations would follow the testimony from the first 4 sessions, which cover the first 4 priorities. The subcommittee would develop these recommendations in September and October of 2004 and submit them to the full NCVHS Committee for approval at the November 2004 meeting.

B. Develop Final Recommendations:

- Final recommendations will include the initial recommendations, the recommendations for e-signatures, and any additional updates gathered in the first quarter of 2005.
- Subcommittee and Consultant will prepare the first draft of phase two of the E-Prescribing recommendations and review them via e-mail in April 2005.
- Review second draft of phase two of the recommendations at the Subcommittee meeting in May 2005.
- Review the third draft of phase two of the E-Prescribing recommendations with the full NCVHS Committee in June 2005.

APPENDIX I

Medicare Prescription Drug Improvement and Modernization Act of 2003

December 8, 2003

TITLE I--MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. MEDICARE PRESCRIPTION DRUG BENEFIT

``(e) Electronic Prescription Program.--

``**(1) <<NOTE: Deadline.>> Application of standards**.--As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

``**(2) Program requirements.**--Consistent with uniform standards established under paragraph (3)--

``(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists.--An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

``(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

``(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

``(B) Application to medical history information.--Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

``(C) Limitations.--Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

``(D) Timing.--To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

``(3) Standards.--

``(A) In general.--The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

``(B) Objectives.--Such standards shall be consistent with the objectives of improving--

``(i) patient safety;

``(ii) the quality of care provided to patients; and

``(iii) efficiencies, including cost savings, in the delivery of care.

``(C) Design criteria.--Such standards shall--

``(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

``(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

``(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

``(D) Permitting use of appropriate messaging.--Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

``(E) Permitting patient designation of dispensing pharmacy.--

``(i) In general.--Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

``(ii) No change in benefits.--Clause (i) shall not be construed as affecting--

``(I) the access required to be provided to pharmacies by a prescription drug plan; or

``(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

``**(4) Development, promulgation, and modification of standards**.--

``(A) <<NOTE: Deadline.>> Initial standards.--Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

``(B) Role of NCVHS--The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

``(i) Standard setting organizations (as defined in section 1171(8))

``(ii) Practicing physicians.

``(iii) Hospitals.

``(iv) Pharmacies.

``(v) Practicing pharmacists.

``(vi) Pharmacy benefit managers.

``(vii) State boards of pharmacy.

``(viii) State boards of medicine.

``(ix) Experts on electronic prescribing.

``(x) Other appropriate Federal agencies.

``(C) Pilot project to test initial standards.--

``(i) In general.--During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards

under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

``(ii) Exception.--Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

``(iii) Voluntary participation of physicians and pharmacies.--In <<NOTE: Contracts.>> In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

``(iv) Evaluation and report.--

``(I) Evaluation.--The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

``(II) Report <<NOTE: Deadline.>> to congress.--Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

``(D) Final <<NOTE: Deadline.>> standards.--Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

``**(5) Relation to state laws.**--The standards promulgated under this subsection shall supersede any State law or regulation that--

``(A) is contrary to the standards or restricts the ability to carry out this part; and

``(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

``**(6) Establishment of safe harbor**.--The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under

paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection--

``(A) in the case of a hospital, by the hospital to members of its medical staff;

``(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

``(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

APPENDIX II

Potential Areas for E-Prescribing Standards

Potential Areas for E-Prescribing Standards

1. Message format standards: NCPDP SCRIPT
2. Drug terminologies: RXNorm, NDF-RT, FDA
3. Authentication Standards
4. Formulary Standards
5. Reference Information Standards
    a. Drug-Drug Interactions
    b. Indications
    c. Contra-Indications
    d. Adverse Drug Reactions
6. Eligibility Standards
7. Harmonization of standards required for seamless decision support
    a. NCPDP and HL7 Pharmacy
    b. Contra-indications with HL7 Lab Results
    c. Contra-Indications with patient allergies, medication lists, problem list
8. Coordination of Benefit Standards