

Work Plan for E-Prescribing Standards
Version 2 - 1/16/04

Work Plan Outline

I. Applicability of the Law

II. Deadlines Set Forth in the Law

III. NCVHS Consultation Responsibilities Set Forth in the Law

IV. Version 2 Work Plan

- Development and agreement of the Work Plan and Exploration of Consultant for assistance
- Development of e-prescribing requirements list
- Develop and agree on questionnaires for testifiers
- Testimony Schedule
- Development and Approval of Recommendations

V. Appendix

- Title I – Medicare Prescription Drug Benefit, Part D – Voluntary Prescription Drug Benefit Program, Subsection E ELECTRONIC PRESCRIPTION PROGRAM.— (from Conference Report)

I. Applicability of the Law

- 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.
- 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. NCVHS Consultation Responsibilities Set Forth 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

IV. Version 2 Work Plan

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 (December 10, 2003)
 - Update the work plan with feedback (January 16, 2004)
 - Define Initial Scope of Work for a Consultant to Assist the Subcommittee (January 2004)
 - NCVHS SSS agrees to the work plan (January 28, 2004)

2. Develop Initial E-Prescribing Requirements List:

- *The following list was derived from the Medicare Prescription Drug, Improvement, and Modernization Act:*
 - E-Prescribing Messaging Standards
 - Drug Terminology Standards
 - Verify Eligibility of the Patient
 - Verify Eligibility for Specific Drugs within the Healthcare Plan Formulary
 - Drug to Drug Interactions
 - Drug to Allergy Checking
 - Drug to Laboratory Results Checking
 - Dosage Checking against Patient's Weight
 - Dosage Checking against Patient's Age
 - Electronic Signature Standards
 - Compatibility with other standards

3. The policy to develop and agree on questionnaires for testifiers is to define and review the testifier questionnaires at each SSS meeting prior to receiving the testimony:

- ❖ The questionnaires for the standards developers, terminology developers and e-prescribing vendors and services, will ask whether they can meet all of the requirements outlined in the Medicare Prescription Drug Benefit Program related to e-prescribing information and standards.
- ❖ The questionnaires for the users of e-prescribing systems and services will ask for verification of the capabilities of these systems and services and will ask if the users have additional information requirements.
- ❖ The questionnaires for the state boards and government agencies will ask if there are any additional requirements that need to be considered.

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

Priority 1: Identify standards for basic prescribing functions between a physician and the pharmacy, such as message format standards and drug terminologies

Priority 2: Identify standards to support eligibility verifications

Priority 3: Identify standards necessary for decision support functions such as drug to drug interactions, drug to allergy, drug to lab results, dosage levels against patient's age & weight, etc...

Priority 4: Identify information and requirements that may be needed by local, state and federal public health departments and oversight agencies

Priority 5: Identify standards for electronic signatures

5. Initial Testimony Schedule:

A. Testimony to Support Priorities 1, 2, 3:

1. Session 1 Testimony (1 day)

Purpose: Identify the requirements for e-prescribing standards from users and vendors.

- E-Prescribing Vendors and Services: *examples...*
[RxHUB, SureScript, AllScript, PocketScript, FDB, etc...] (2 hrs)
- E-Prescribing Implementations: *examples...*
[Mass Medical Society, Rhode Island Quality Institute, BCBS/Tufts Healthplan, etc...] (2 hrs)
- Demonstration Projects: *examples...*
[HIMSS/Cleveland Clinic, etc...] (1 hr)
- Discussion Time (1 hr)

2. Session 2 Testimony (1 day)

Purpose: Identify requirements for standards from providers and payers

- Physicians: *examples...*
[AMA, AAFP, ACP, etc...] (2 hrs)
- Hospitals (1 hr)
- Health Plans/Payers: *examples...*
[BCBS, CMS, State Medicaid Agencies, etc...] (2 hrs)
- Discussion Time (1 hr)

3. Session 3 Testimony (1 day)

Purpose: Identify requirements from pharmacists and PBMs, and the ability of SDOs/Terminologies to meet these requirements

- Pharmacies (1 hr; approx. 5 testifiers)
- Practicing Pharmacists (1 ½ hrs; approx. 5 testifiers)
- Pharmacy Benefit Managers (1 hr; approx. 4 testifiers)
- SDOs and Terminology Developers: *examples...*
[NCPDP, HL7, NLM, VA, FDA, etc...] (2 hrs)
- Discussion Time (1 hr)

B. Testimony to Support Priority 4:

1. Session 4 Testimony (full day)

- State Boards of Pharmacy (1 ½ hrs; approx. 4 testifiers)
- State Boards of Medicine (1 ½ hrs; approx. 4 testifiers)
- Government Agencies: *examples...*
[DEA, CDC, AHRQ, HRSA, etc.] (2 hrs)
- Discussion Time (1 hr)

C. Testimony to Support Priority 5:

1. Session 5 Testimony (1 day)

- E-Prescribing Vendors and Services (1 ½ hrs)
- E-Signature Vendors (1 ½ hrs)
- Healthcare Provider Users of E-Signatures (2 hrs)
- Discussion Time (1 hr)

D. Testimony to Resolve Open Issues in Preparation for Final Recommendations:

1. Session 6 Testimony (1 day)

- Follow-up Testimony, tbd...

6. Development and Approval of Recommendations:

- A. Interim Recommendations would follow the testimony from the first 3 sessions which cover the first 3 priorities. The subcommittee would develop these recommendations in September of 2004 and submit them to the full NCVHS Committee for approval at the November 2004 meeting.

B. Interim Recommendations would follow the testimony from Session 4 which would cover Priority 4. The hearings for Session 4 will probably be scheduled in December 2004 and the final NCVHS recommendations would probably be February 2005.

C. Final Recommendations:

- First Draft – April 2004
- Second Draft – May 2004
- Final Draft – June 2005

Appendix

**Title I – Medicare Prescription Drug Benefit
Part D – Voluntary Prescription Drug Benefit Program
Subsection E ELECTRONIC PRESCRIPTION PROGRAM
(from Conference Report)**

TITLE I – MEDICARE PRESCRIPTION DRUG BENEFIT

Section 101 – Medicare Prescription Drug Benefit

PART D – Voluntary Prescription Drug Benefit Program

Subsection E

(e) ELECTRONIC PRESCRIPTION PROGRAM.—

(1) APPLICATION OF STANDARDS.— All prescribing health care professional and dispensing pharmacies and pharmacists that are transmitting prescriptions electronically, must comply with the e-prescribing standards no later than April 1, 2009. The electronic prescription program is applicable to eligible individuals within the Voluntary Prescription Drug Benefit Program (Part D) and the covered Part D drugs.

(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.— The electronic prescription program shall provide:

- (1) transmittal of the prescription
- (2) information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization)
- (3) 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.
- (4) Information on the availability of lower cost and therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) APPLICATION TO MEDICAL HISTORY INFORMATION.— In addition to the standards for transmission and information identified in subparagraph A, the Secretary will also provide standards to facilitate the transmission of 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) 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

(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 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 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 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.

Potential Areas for E-Prescribing Areas

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
 - a.