E-Prescribing and the Medicare Prescription Drug, Improvement, and Modernization Act
Applicability

- The electronic prescription program is applicable to eligible individuals within the Voluntary Prescription Drug Benefit Program (Part D) and the covered Part D drugs.
- E-prescribing is voluntary
- But prescriptions transmitted electronically MUST use standards
Objectives

1. Patient safety
2. Quality of care
3. Efficiencies in delivery of care
   -- including cost savings
Specifics

- Basic Prescription
- Eligibility (including formulary)
- Drug information (including history)
- Related medical history
Standards Needed

- Messaging
- Vocabulary
- Knowledge representation
- Electronic signature
Links to Ongoing Initiatives

- FDA’s physician labeling and electronic drug listing regulations
- NLM’s Rx Norm
- FDA’s structured product label
What Will the E-Prescribing Standards Cover?

- Enable transmission of basic prescription data to and from doctors and pharmacies, including the e-label
- Transmission of data about patient’s drug utilization history, possible drug interactions, the drug plan (including information about formulary and cost sharing), and lower-cost, therapeutically appropriate alternatives
- Standards must comply with HIPAA privacy rules
- Messaging unrelated to appropriate prescribing (such as marketing) will not be allowed
NCVHS Role

- NCVHS to make recommendations to the Secretary on e-prescribing standards in consultation with:
  - Physicians and hospitals
  - Pharmacists and pharmacies
  - PBM
  - State Boards of Pharmacy and Medicine
  - Federal Agencies
  - Electronic prescribing experts
Within a year of promulgation of final standards, any prescriptions for covered Part D drugs prescribed for Medicare beneficiaries that are transmitted electronically must be transmitted according to the standards.

PDPs to issue a card that enrollees use to purchase prescription drugs under the plan.
- Card to use formatting standards developed in consultation with NCPDP.
What the Law Requires: Pilot Project

- Will test initial standards
- Runs from 1/1/06 to 12/31/06
- Prior to promulgation of final uniform standards
- Pilot not needed if there is already adequate industry experience.
- Voluntary participation via agreements with the Secretary
- Evaluation and Report to Congress NLT 4/1/07
What The Law Requires: Safe Harbors

- The Secretary, in consultation with the Attorney General, will develop safe harbors under the anti-kickback and physician self-referral laws
  - Allows hospitals, medical practices, PDPs and MA plans to provide physicians with non-monetary remuneration to be used for e-prescribing
  - This can take the form of hardware, software, information technology services and training.
Timelines

- NCVHS conducts hearings – ongoing through 09/05
- The NCVHS to submit recommendations for electronic prescribing standards to the Secretary 06/05.
  - Announce initial standards—9/01/05
  - Begin pilot program—1/01/06
  - Complete pilot program—12/31/06
  - Report to Congress—4/01/07
  - Final standards announced—4/01/08
  - Implement standards—4/01/09
Critical Challenge

- Assuring that e-prescribing standards can be successfully integrated into the Medicare Part D implementation
What’s in Part D

- Coverage includes most FDA-approved drugs and biologicals
  - Uses Medicaid coverage definitions
- There are a few exceptions
- Part D includes other items such as
  - Smoking cessation agents
  - Vaccines and insulin
  - Insulin-related supplies, such as syringes, needles, alcohol swabs and gauze (but not lancets and test strips)
What’s Excluded from Part D

- Drugs currently covered under Medicare Parts A and B
  - Oral drugs (like EPO) that are currently covered under Part B
  - Outpatient hospital drugs
What’s Excluded from Part D

- **Agents used**
  - For anorexia, weight loss, or weight gain
  - To promote fertility
  - For the symptomatic relief of cough and colds
- **Prescription vitamins and mineral products, except for prenatal vitamins and fluoride preparations**
- **Nonprescription drugs**
- **Outpatient drugs for which the manufacturer seeks to require associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale**
- **Barbituates and benzodiazepines**
Discussion

Comments?
Questions?