

**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

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- ◆ 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
  - PBMs
  - State Boards of Pharmacy and Medicine
  - Federal Agencies
  - Electronic prescribing experts

## What the Law Requires: E-Prescribing by Participating Prescription Drug Plans (PDPs)

- ◆ 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 benzodiazapenes**

## *Discussion*

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Comments?

Questions?