



# Electronic Prescribing of Controlled Substances: States Perspectives

Drug Enforcement Administration Public Meeting:  
Electronic Prescriptions for Controlled Substances  
Arlington, VA  
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# Objectives

- ◆ NABP Initiatives & E-Rx (electronic prescriptions)
- ◆ NABP Model Act & E-Rx
- ◆ State Laws/Regulations and E-Rx
- ◆ Considerations for E-Rx for CS (controlled substances)

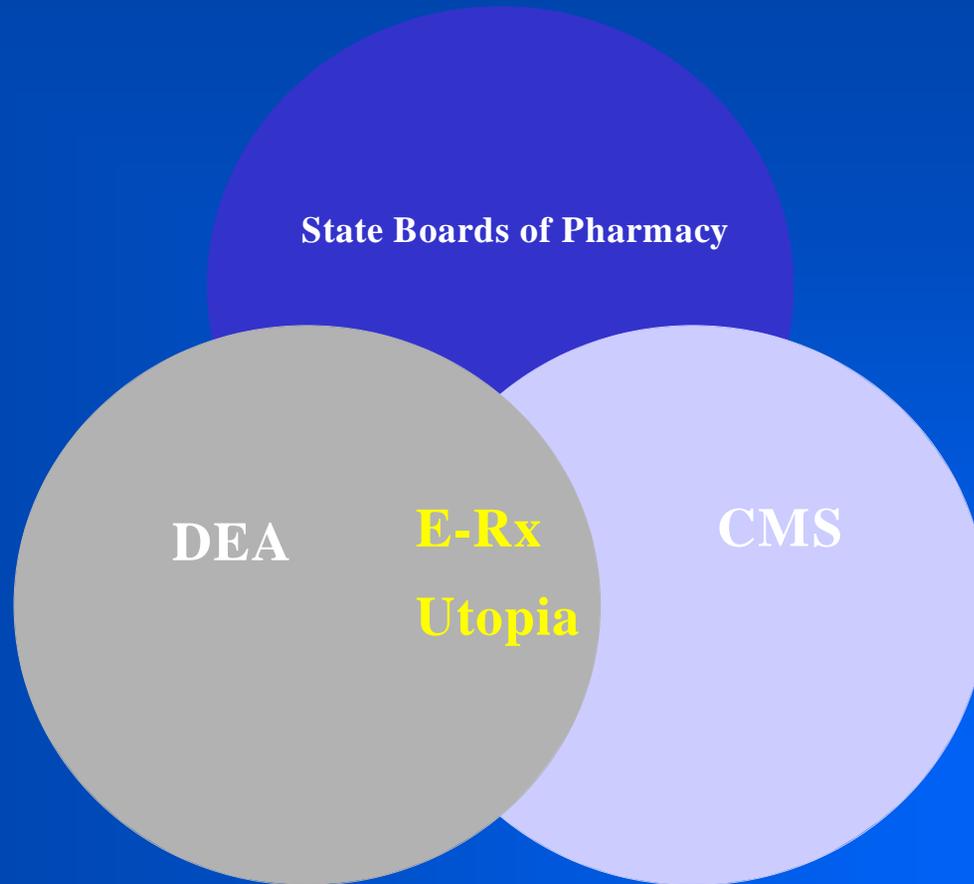


“The near future will reveal a federally approved Drug Enforcement Administration electronic prescription prescribing system. The Board office has been hesitant to establish one mechanism, soon to be superceded by another. Regardless, any electronic signature transmission system needs Board of Pharmacy approval and none have been given.”

Source: January 2005 Nevada State Board of Pharmacy State Newsletter



# Total E-Rx Regulatory Compliance





## NABP Initiatives: E-Rx

- ◆ 1996 - Resolution 92-4-96, Electronic Transmission of Rx for CS
- ◆ 2001 – Resolution 97-2-2001, Task Force on Electronic Transmissions
- ◆ 2004 – Resolution 100-2-2004, NCVHS testimony (July/December)



## *NABP Model Act: E-Rx's*

- ◆ “**Electronic Transmission** means transmission of information in electronic form *or* the transmission of the exact visual image of a document by way of electronic equipment.”
  - ◆ Computer to Computer/Fax to Fax
  - ◆ Computer to Fax/Fax to Computer (?)
  - ◆ Electronically Produced Rx with E-Signature (hard copy with security paper)



## *NABP Model Act: E-Rx's*

- ◆ “**Electronic Signature** means an electronic sound symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record”
- ◆ “**Digital Signature** means an electronic signature based upon cryptographic methods of originator authentication and computed by using a set or rules and a set or parameters so that the identify of the signer and the integrity of the data can be verified”



## *NABP Model Act: E-Rx's*

- ◆ **Electronic Transmission of Rx:**
  - ◆ To Pharmacist or Certified Pharmacy Technician only
  - ◆ Transmitter's phone number (or other suitable means), Transmitter's identity, time/date of transmission, identity of the pharmacy intended to receive the Rx
  - ◆ Must be immediately reduced to a form for recordkeeping purposes
  - ◆ Prescriber's Agent can also transmit
  - ◆ Equipment to prevent unauthorized access
  - ◆ Pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity
  - ◆ Electronic Signature or Digital Signature (if Rx is hard copy produced from electronic media, must utilize security paper)



# NABP *Survey of Pharmacy Law:* E-Rx's

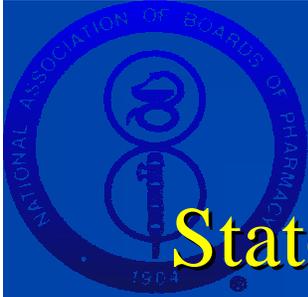
- ◆ **Electronic Transmission** (computer to computer) of Rx:
  - ◆ **Prescriber's Computer to Pharmacy Computer:**
    - ❖ ? 44 states allow; 5 states do not address
    - ❖ 2 do not allow for non-resident prescribers
  - ◆ **Recognition of Electronic Signatures (non-CS):**
    - ❖ 38 states recognize; 4 states do not address

Source: 2006 NABP Survey of Pharmacy Law



# State vs Federal E-Rx Laws for CS

- ◆ Federal
  - ◆ CII: No Electronic Transmission (fax only)
    - ❖ Fax allowed to expedite dispensing; Rx presented prior to dispensing
    - ❖ Emergency Dispensing Provision (Rx presented in 7 days)
    - ❖ Home Infusion/LTC/Hospice Patients
  - ◆ CIII-CV:
    - ❖ Fax allowed; and via computer, but treated like oral (per advice of DEA in September 2001?)
- ◆ State
  - ◆ CII: Same as DEA
  - ◆ CIII-V: Same as DEA but:
    - ❖ Recognizes electronic signatures for CS (CA, WA, ND)
    - ❖ No Faxing of CS Rx allowed (UT, NY)



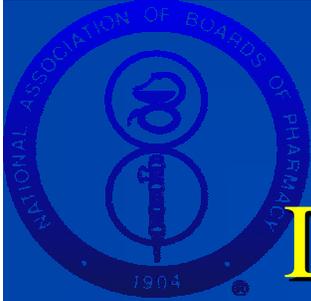
# State Board of Pharmacy E-Rx Survey

- ◆ Barriers/Challenges:
  - ◆ Technology
    - ❖ Changing Technology
    - ❖ Regulations reflecting advances in technology
    - ❖ Lack of reasonably affordable technology
  - ◆ Security
    - ❖ Security of Rx (verifying authenticity)
    - ❖ Intervention by a third party
    - ❖ Patient confidentiality
    - ❖ Forgery
    - ❖ Incorporating biometrics/assuring irrefutability



# CMS E-Rx Final Rule: Preemption of State Laws/Regs

- ◆ State Laws/Regs preempted (jurisdictions affected):
  - ◆ Expressly prohibit electronic prescribing (n=1)
  - ◆ Prohibit transmission through intermediaries (network switches or PBMs) or access to E-Rxs by plans, their agents, or authorized third parties (n=16)
  - ◆ Require certain language such as “dispense as written” (n=25)
  - ◆ Require handwritten signatures or other handwriting (n=25)



# Deterring Diversion of CS

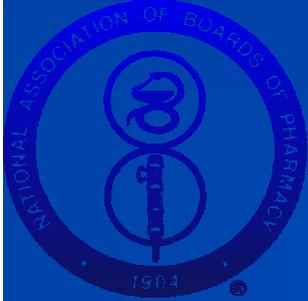
- ◆ Triplicate Prescription Program
- ◆ \*Prescription Monitoring Programs (PMPs)
  - ◆ 26 states use PMPs
  - ◆ Most collect schedule II CS data only
  - ◆ Most incorporate electronic based systems for collection and analysis
  - ◆ Proactive vs Reactive Monitoring
- ◆ Tamper Resistant Rx
  - ◆ CA, ID, IN, NY (for all Rx's)
  - ◆ Incorporate various security features

\*Source: DEA; A Closer Look at State Prescription Monitoring Programs



## Electronic Transmission Core Principles

- ◆ Ensure Against Unauthorized Access
- ◆ Authenticity and Security of Prescription
- ◆ Privacy and Patient Confidentiality
- ◆ Prescriber-Pharmacist Collaboration
- ◆ Patient Choice



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