



Office of Diversion Control  
May 2001

# Electronic Prescriptions for Controlled Substances

Healthcare PKI Working Group

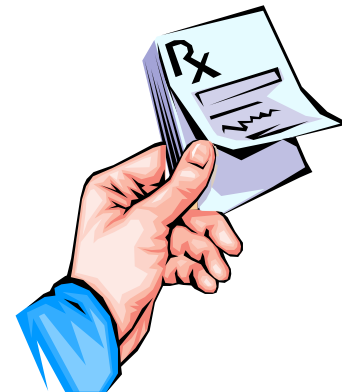
May 22, 2001



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# Agenda

- Controlled Substance Act
- Objectives / Anticipated Advantages
- PKI Architecture
- Participant Obligations
- Status
- Questions





# Objectives

- ✓ To design a system that would support the secure electronic transmission of controlled substance prescriptions.
- ✓ To allow the continued use of commercially designed, implemented systems with minimal impact.

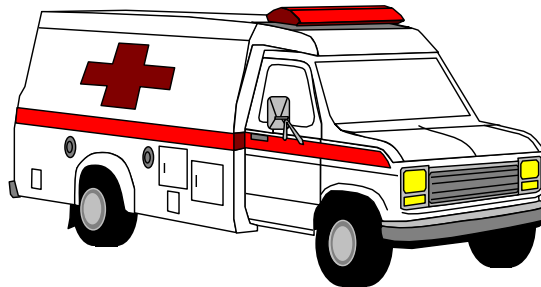




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# Anticipated Advantages

- Improved healthcare efficiency
- Reduced medical mistakes
- Reduced prescription forgeries
- Reduced overall costs
- An allowance, NOT a requirement





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# EPCS Hierarchical PKI...

## One Root Certification Authority

(DEA)

Authorizes  
(Issues/Revokes)

## Numerous Subordinate Certification Authorities

(Commercial, State Governments, Professional Associations, etc.)

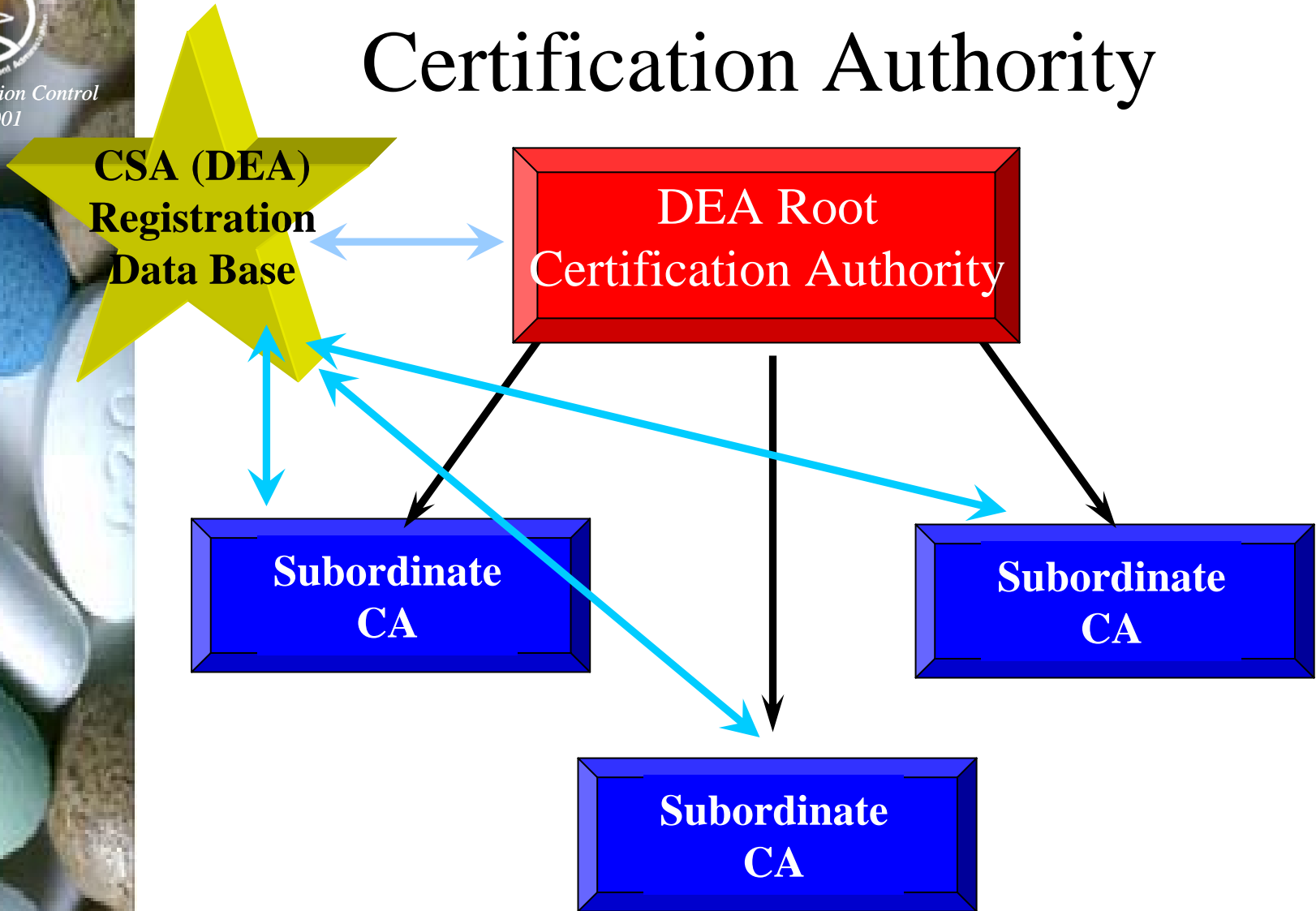
Authorizes  
(Issues/Revokes)

## Close to 1,000,000 Individual Certificates

(Individual Registrants/Practitioners)



# Certification Authority





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# EPCS Policy Requirements

- Certification Authorities
- Application
- Practitioner
- Pharmacy
- Miscellaneous (clearinghouses, LTCF)



# Root CA Requirements

- Establishes a single trust framework
- Maintains PKI oversight responsibility
- Approves Subordinate CAs (Issues certificates to CAs)
- Ensures interoperability between Subordinate CAs
- Provides a mechanism for recourse against a Subordinate Certification Authority





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# Root CA

- Establishes Certificate Policy (CP) that defines obligations and standards for participants...
  - Certification Authorities
  - Practitioners
  - Vendors
  - Pharmacies
- Defines digital certificate format (Certificate Profile)



# Subordinate CA Obligations

- Operate in accordance with EPCS CP
- Enroll practitioners
  - Perform required identity checks / verifications
  - DEA registration checks
  - Issue Certificate
- Perform revocations as required; publish revocation information every four hours
- Undergo annual audit for “approved” status
- Audit performed by outside organization



# Application Requirements

- EPCS is application neutral
- EPCS does not mandate the use of a particular EDI standard.
  - NCPDP SCRIPT
  - HL7
- Efforts are underway by standards organizations to PKI-enable these EDI transactions
- E-prescription must be digitally signed by practitioner, and validated by pharmacy



# Required Prescription Content

Date

Patient name and address

Drug name, strength, dosage form, quantity prescribed, and directions for use

Practitioner's name, address, and DEA registration number

- *Data in archive must be readily retrievable in an electronic form*



# Application Compliance Auditing

- Initial compliance audit required for all EPCS-enabled applications
- Follow-up audits required upon major application revisions
- Pharmacy required to ensure that their software complies with DEA regulations



# Practitioner Obligations

- Must be registered with DEA to handle controlled substances
- Apply for digital certificate... **valid up to 3 years. (equiv. with Controlled Substance Act)**
- Safeguard the private key
  - Hardware key storage device
  - Under the sole control of the practitioner
- Notify the CA if key is lost/stolen
- Digital certificate can be used for non-controlled substances



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# Practitioner Enrollment Process



## **1 Practitioner Applies to Certification Authority**

- › Applicant provides required credentials
- › Reads obligations
- › Signs application
- › Has application notarized
- › Returns completed application to CA



## **2 Certification Authority performs Identity Checks**

- › Are submitted credentials enough?
- › If so, sends a one-time access code



## **3 Registration**

- › Practitioner accesses the CA using the code
- › Sends public key to CA
- › CA returns a certificate



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## Practitioner Enrollment Process (continued)

- Re-enrollment based on original application, can be electronic
- CAs will be required to “remind” practitioners to renew their digital certificate







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# Pharmacy Obligations

- Pharmacies/Pharmacist will not require EPCS certificates (will require a certificate for electronic orders)
- Refills based on validity of original prescription.
- Re-verification at time of refill is unnecessary.



# Pharmacy Checks

- ✓ Check Certificate Status, Is it valid?
  - › Check Practitioner's Certificate, Has it expired?
  - › Check Issuing CA's Certificate, Has it expired?
  - › Has either been revoked?
  - › Check the institution's certificate in case of agents
- ✓ Check prescription integrity, Has it been altered?
- ✓ Leverage trusted certificate to check:
  - › Does practitioner have authority to prescribe specific substance listed?
  - › Is the practitioner an agent of an institution?



# Pharmacy Record Keeping

- Pharmacist must electronically sign the prescription
- E-signature performed as a separate act
- Access code/PIN is an acceptable solution
- Authentication must be time limited
- Maintain electronic archive for two years
- Software audit for DEA compliance, **NOT** a site audit

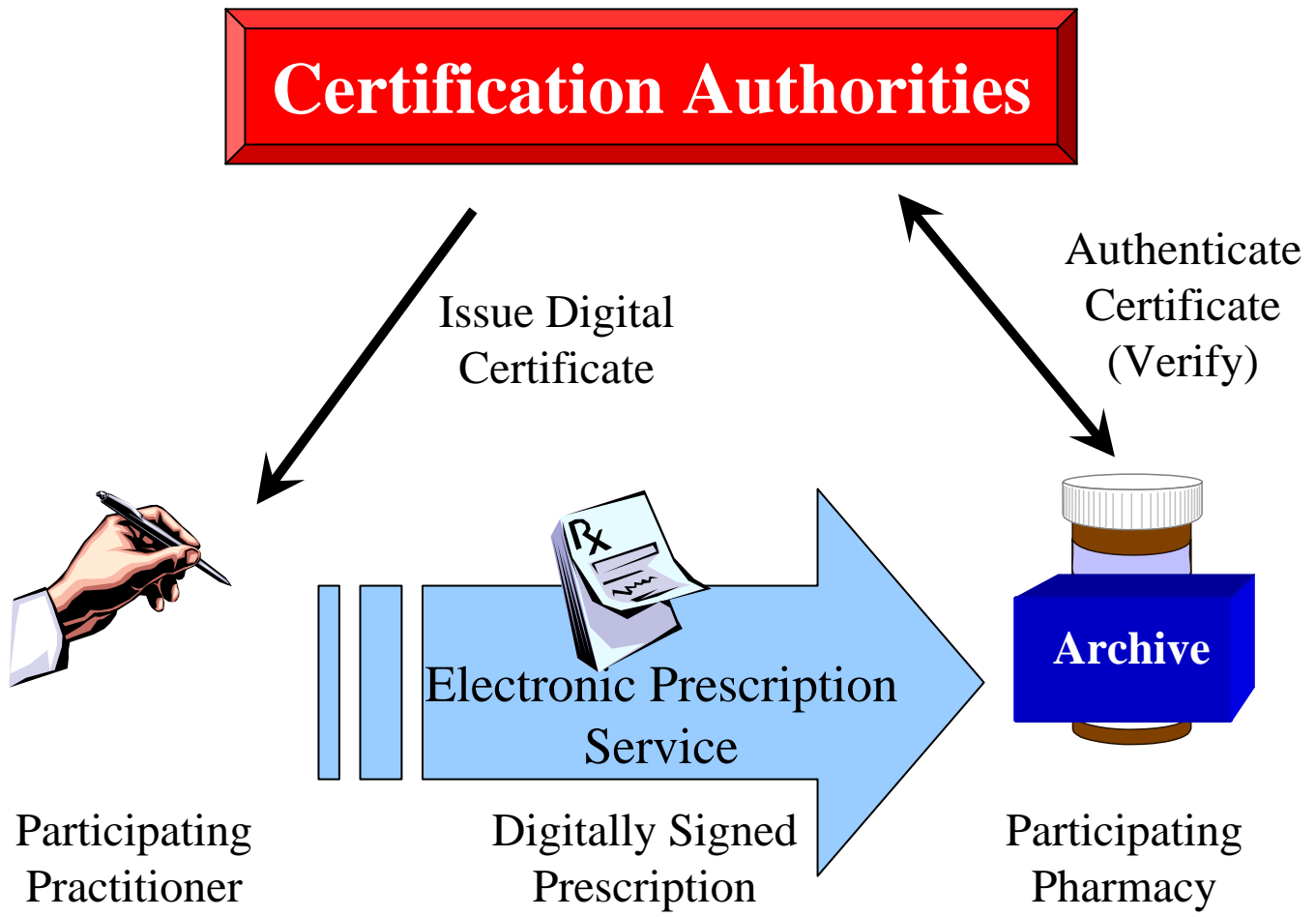


# Miscellaneous Requirements

- Clearinghouses
  - Clearinghouses cannot act as a trust-proxy
  - Pharmacy must validate all prescriptions
- Long Term Care Facilities
  - LTCFs do not currently register with DEA
  - Electronic prescriptions would be between practitioner and pharmacy



# EPCS in Operation





# DEA Efforts to date

- Gathering security requirements
  - Interviewed over 60 registrants and regulators
- Review of existing industry IT infrastructure
  - Conducted extensive interviews to determine what systems are currently in use
- PKI testing and product review
  - Baltimore technologies UniCert Selected for Root
- Analysis: Policy Requirements, Concept of Operations (ConOps), CP, CPS, Certificate Profile



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# Ongoing DEA Efforts

- Current regulations do not permit electronic prescriptions for controlled substances
- Developing new regulations and modifications to existing regulations
- Implementing EPCS Root CA
- Continued solicitation of industry input / comments
- Pilot Programs conducted in concert with the Veterans Administration (VA) Outpatient Pharmacies



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# Summary

- Much progress has been made toward the goal of electronic prescriptions
- Much work remains to be accomplished
- Efforts are being made with attention to impact on industry and regulators
- The ultimate goal remains to provide controlled substances to the public while preventing diversion





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## ...More Information

Supporting documents are published on  
DEA's Internet Web Site:



As more documents are developed, they  
too will be made available through DEA's  
Internet Web Site



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# Questions





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## To contact the DEA:

**U.S. Department of Justice**  
Drug Enforcement Administration  
*Office of Diversion Control*  
Liaison & Policy Section  
Washington, D.C. 20537

Telephone: (202) 307-7295  
Facsimile: (202) 307-8570

Internet Site: <http://www.deadiversion.usdoj.gov>

