DEA Electronic Commerce PKI Initiatives

Health Care PKI Working Group

January 22, 2002

Agenda

- DEA E-Commerce Initiatives
- Objectives & Anticipated Benefits
- PKI Architecture
- Key Policy Provisions
- Status
- Questions

Two "Key" E-Commerce Initiatives

- **Electronic Prescriptions for Controlled Substances (EPCS)**
  - Over 1M DEA Registered Practitioners
  - Over 600M Controlled Prescriptions

- **Controlled Substance Ordering System (CSOS)**
  - Over 300K Registrants

EPCS - 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.

☑️ Allow DEA certificates to be used for other health care related transactions
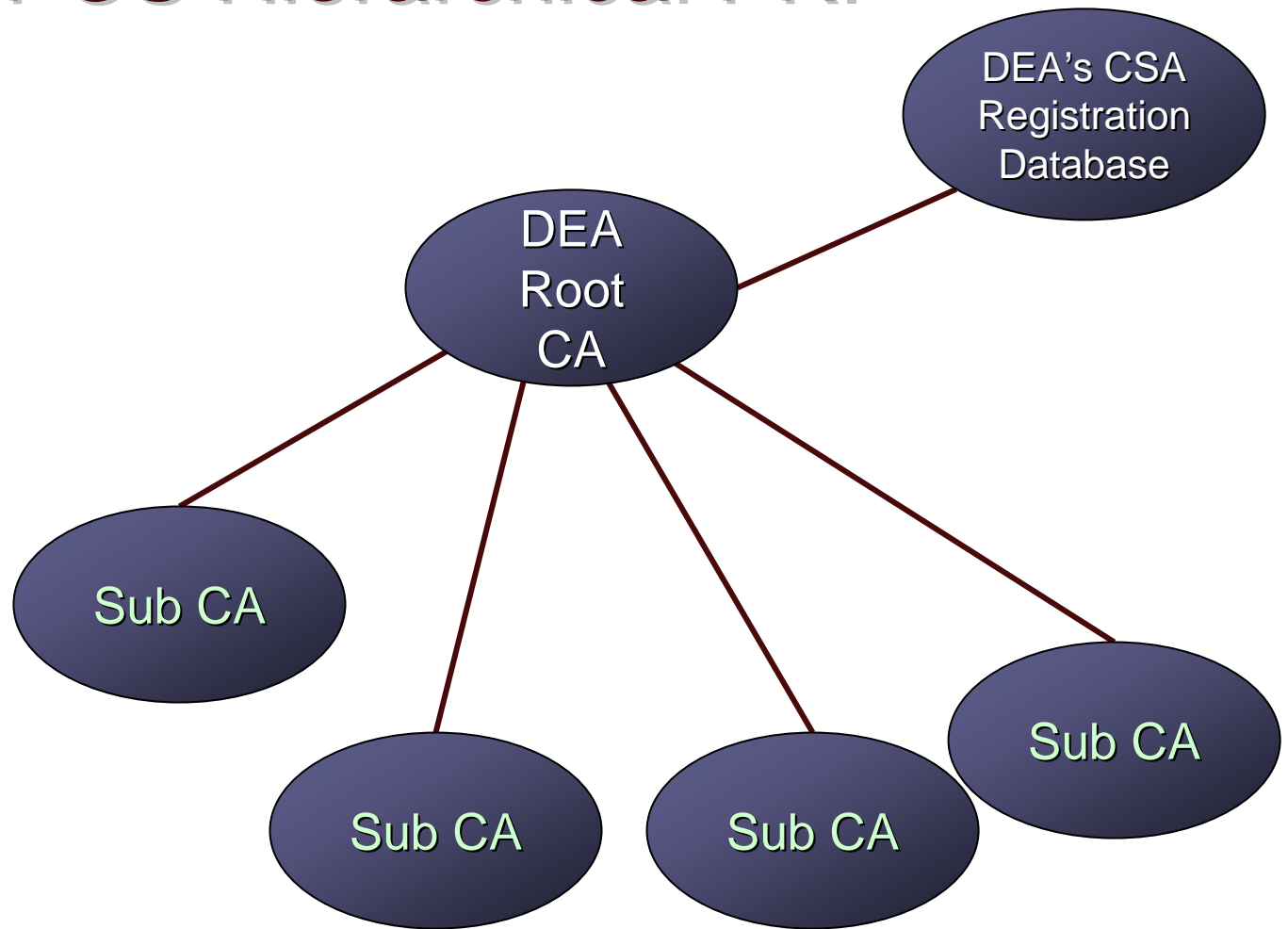
EPCS - Anticipated Benefits

- Improved health care efficiency

- Reduced medical mistakes

- Reduced prescription forgeries

- Reduced overall costs

- *An allowance, NOT a requirement*

EPCS Hierarchical PKI

DEA's CSA Registration Database

DEA Root CA

Sub CA

Sub CA

Sub CA

Sub CA

Over 1M DEA Registered Practitioners - *Subscribers*

Root Certification Authority

Establishes FBCA-interoperable trust framework

Maintains PKI oversight responsibility

Issues certificates to Approved Subordinate CAs

Ensures trust interoperability between Subordinate CAs

Provides a mechanism for recourse against a Subordinate Certification Authority

Root CA

Establishes Certificate Policy that defines obligations and standards for participants…

- Sub CAs
- Practitioners (subscribers)
- Pharmacies (relying parties)
- E-Rx System Vendors

Defines Certificate Profile

Subordinate CA Obligations

Operate in accordance with EPCS CP

Issue Certificates to DEA registrants

Perform revocations as required; publish revocation information every four hours

Undergo annual audit for "approved" status

Audit performed by outside organization

Core Policy Provisions

3.0 Ident. & Authent.	▪3.1.9 Authent. of Individual Identity	[Gov. Photo ID, + DEA Registration, + Notary, DEA DB,]
	▪3.1.8 Authentication of Org. Identity	[Indiiv. + Empl. letter]
4.0 Operational Req.	▪4.4.4 Revocation Grace period	[6 hours]
	▪4.4.9 CRL Issuance Frequency	[4 hours]
	▪4.4.10 CRL Checking Requirements	[YES]
5.0 Physical …	Currently surveying locations for CA facility	
6.0 Technical Security Controls	▪6.2.1 Std. for cryptographic modules	[140-1,2 Level 1, HW]
	▪6.2.7 Method of Activating priv. key	[biometric]
	▪6.3.2 Usage Period for Private Key	[3 years]
7.0 Certificate Profile	Extensions for : [Name, business address, DEA registration #, auth. schedules]	

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 Remains the Same

❑ 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

FIPS 140-1,-2 approved crypto

Not a site specific audit !

Pharmacy Obligations

- Pharmacies/Pharmacist will not require EPCS certificates (will require a certificate for electronic orders)

- Prescription validity based upon validity of certificate at time of signing

- 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

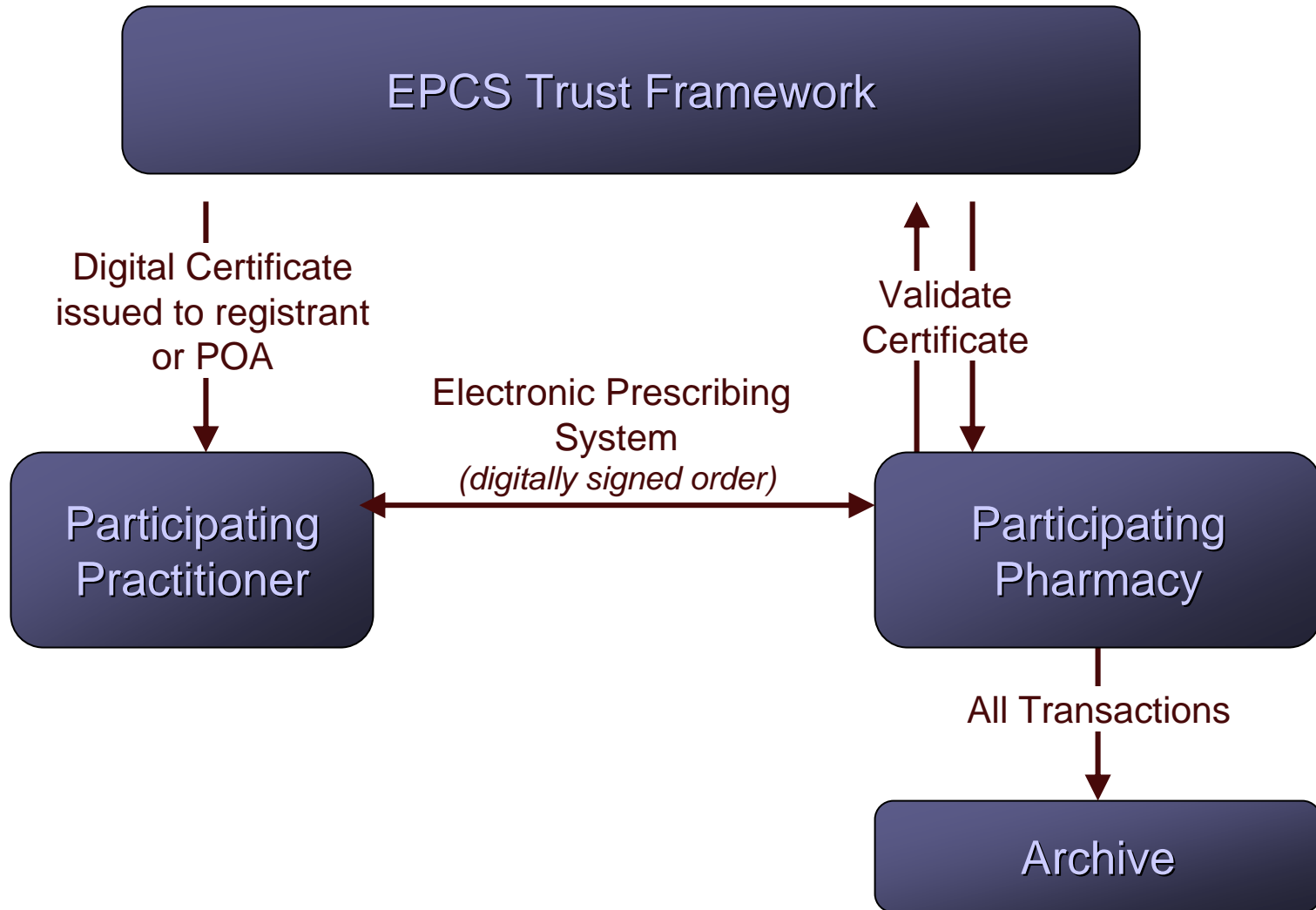Pharmacist must electronically sign the prescription

E-signature performed as a separate act

Access code/PIN is an acceptable solution

Maintain electronic archive for two years

Software audit for DEA compliance, NOT a site audit

EPCS Trust Framework

EPCS Trust Framework

Digital Certificate
issued to registrant
or POA

Validate
Certificate

Electronic Prescribing
System
(digitally signed order)

Participating
Practitioner

Participating
Pharmacy

All Transactions

Archive

DEA Efforts to Date

- Security Requirements Analysis

- Review of existing industry IT infrastructure

- Interop. testing & product review

- Concept of Operations

- System Architecture

- CP, CPS, Certificate Profile

Ongoing Efforts

- Current regulations do not permit electronic prescriptions for controlled substances…

- Developing new regulations and modifications to existing regulations

- Implementing EPCS Root CA

- Pilot Program conducted in concert with the Department of Veterans Affairs (Outpatient Pharmacies)

Stakeholder Coordination

Continued solicitation of industry input & comments

- Practitioner Working Group (2/2002)

- Pharmacy Working Group

- State Regulatory Working Group (NABP/NASCSA)

- Others…

Questions

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