DEA Presentation
Pharmacy Perspectives Panel

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Multi-SDO Digital Signature Project

- 2000-2001 NCPDP members and staff were very involved in the ANSI HISB “Multi-SDO Digital Signature Project”.
  - This project began with involvement from ASTM, HL7, IETF, NCPDP, and X12N.
  - NCPDP was very active in the paper that was being created and was one of the few submitters of use cases.
  - There were many open issues that did not appear to have proven industry experience to help close the gaps.
  - To our knowledge, the project is not active and the paper was never completed.
Industry Activities

• National Committee on Vital and Health Statistics (NCVHS) solicited industry testimony in 2004 and 2005

• NCVHS recommendation letter to HHS March 2005

• Recommendations of this presentation were submitted to NCVHS in 2004 and to DEA in 2006
Industry Concerns Cited during NCVHS Testimony

- Industry concerns were cited of the lack of healthcare experience and the costs involved in supporting the PKI, digital certification security that was being considered.
- No healthcare experience in multiple certification authorities demonstrated.
- Concerns in biometric pilots that NCVHS interviewed.
- Very limited pilot studies in healthcare, and in other industry segments to form a basis for healthcare.
Current business practices for authenticating prescriptions include

- User registration and verification processes provided by trusted partners,
- User sign-on authentication processes,
- Secure message transmission,
- Auditing processes,
- Pharmacist is responsible for using his or her professional judgment to assure the authenticity of the prescription before dispensing

*These are adequate for assuring the appropriate delivery of the prescriber’s intent to the dispensing pharmacy.*
Industry Perspectives

A recommendation of a minimum standard for assuring the secure delivery of prescriptions that include these basic processes for all prescriptions, including controlled substances (CII – CV).

Testifiers noted that there are laws and regulations for fraudulent behavior.
Electronic Signature Definition

An “electronic signature is an electronic sound, symbol, data string or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record”.

NCPDP recommended this definition of electronic signature be adopted so as to accept a variety of assurance solutions currently implemented in the industry and accepted by the state pharmacy boards.
Electronic Prescribing Security and eSignature Infrastructure

Authentication: POC and Router verify each other's static IP addresses, IDs and passwords before opening a secure channel for transporting eRxs.

Security: Prescriber initiates eRx being sent from the POC server to the Router server through the Router's https secure channel.

Use of PHI (protected health information) must be in accordance with HIPAA standards for the purpose of treatment, payment or healthcare operations.

Authentication: Pharmacy and Router verify each other's IP addresses, IDs, and passwords before opening a secure channel for transporting eRxs.

Authentication: Pharmacy and Router verify each other's IP addresses, IDs, and passwords before opening a secure communication channel.

Security: Router adheres to security policies which are consistent with HIPAA security guidelines.

Security: Router performs internal assessments using security scanning tools for network and system security.

Security: Router maintains only enough information to allow for routing, auditing and support.

Security: Router may not view or modify eRxs, except when translating from one messaging standard to another (e.g. HL7 to NCPDP).

Authentication: Pharmacy (Central Server) and each Pharmacy site verify each other's IP addresses, IDs, and passwords before opening a secure channel for transporting eRxs.
Secure Network

POC Network

Certified Point of Care Vendor (POC)

Desktop

Router

Secure Network

POC Server with Firewall

Pharmacy

Central Server

with Firewall

Secure Internal Pharmacy Network

Pharmacy

Central Server

with Firewall

Floor

Pharmacy #101

Pharmacy #102

Pharmacy #103

Pharmacy #104

Pharmacy #105

LTC Facility

LTC Facility

LTC Software Vendor

POC Server with Firewall (Optional)

Note: Security and authentication is the same as with the non-LTC model
Thank you