DEA Diversion Control
E-Commerce System

Controlled Substance Ordering System

Regulatory and Technical Working Group Meeting

November 8, 2000

Arlington, VA

Table of Contents

Section 1: Opening Remarks

On November 8, 2000, the Drug Enforcement Administration's (DEA) Office of Diversion Control met with representatives from the drug wholesale industry and their major national associations. Ms. Patricia Good welcomed those present to the first regulatory and technical working group meeting on the Controlled Substance Ordering System project. She emphasized this project is an evolving process, and meetings will be held throughout the project's various phases. Ms. Good encouraged participants to create a meeting of interactive discussion and feedback. Additionally, Ms. Good extended sincere thanks to McKesson, Walgreen's, the National Wholesale Druggist Association, and Abbott Laboratories for their participation in the electronic ordering system initiative.

Ms. Good informed the audience that both DEA and industry have a legal mandate to conduct Schedule II drug transactions pursuant to a form issued by the Attorney General. This form is known as a U.S. Official Order Form, DEA Form-222. Ms. Good described the function of the DEA Form-222 and related there is little diversion of the DEA Form-222. Furthermore, she acknowledged the form is antiquated, and requires business to step outside the normal flow of business, which creates a burden. The applicability of public key infrastructure (PKI) to the DEA Form-222, as well as to the ordering of Schedule III-V controlled substances, addresses DEA concerns of security and control issues and record keeping. DEA contracted with PEC Solutions, Inc. (PEC)

to create an electronic version of the DEA Form-222. The electronic system will be almost invisible to the customer and supplier. PEC is working as an agent of DEA throughout this project. Any developments PEC designs are property of the government. PEC will not market their products commercially. Ms. Good accentuated the PKI enabled version of the DEA Form-222 will not replace the paper DEA Form-222 Order Form. The Order Form will continue to exist under the same conditions as today. However, now industry has a choice: the electronic version of ordering controlled substances or the traditional paper Order Form.

The three options available in developing the Controlled Substance Ordering System are listed below.

1. DEA/PEC develops a generic order system utilizing PKI
2. PKI enabled commercially available software products currently used by industry
3. E-mail system which incorporates PKI

A final decision has not been made regarding any of the above-mentioned systems. However, the technology used in the ordering system must be FIPS (Federal Information Processing Standards) approved. The government is mandated to use FIPS approved products.

DEA wants the system to interface with ARCOS, conduct quota certifications, and address reverse distributor issues. This is an evolving, labor intensive process that will ultimately require a change in DEA regulations.

Section 2: Overview of CSOS project

2.1 Why PKI

PKI was chosen for the CSOS project because it provides many advantages. The following examples point out the benefits of using a CSOS PKI: reduction in the amount of paper used, increase speed of transaction times, lower costs per transaction, and introduce electronic security services into the process.

The electronic security services include authentication of sending party, integrity of communications and non-repudiation. Authentication of sending party allows the recipient to positively identify the sender of the communication and subsequently to demonstrate to a third party, if required, the sender was properly identified. Integrity of communication permits the recipient of a message to determine if the message content was altered in transit. Non-repudiation means the originator of the message can not convincingly deny to a third party that the originator sent it.

2.2 Survey/Interviews with Industry

Early in the project PEC spoke with DEA personnel, as well as industry representatives. PEC interviewed and conducted surveys of the top 30 members of industry. It was deemed that this group portrayed an accurate and adequate cross section of the

stakeholders in the controlled substance distribution environment. The industry group surveyed and interviewed included manufacturers, distributors, pharmacies, chain pharmacies, and other dispensing registrants. The survey and interviews with industry focused on the handling of DEA Official Order Forms, DEA Form-222 and industry's preference to use existing systems or develop a new system in the CSOS project. PEC learned industry is consistent in the process and manner in which they deal with DEA Form-222's. Furthermore, PEC discovered industry overwhelming wanted to use their existing systems in the CSOS project.

2.3 Policy

PEC wrote the Controlled Substances Ordering System Concept of Operations (CONOPS) documents. The CONOPS provides a conceptual overview of how the PKI will be implemented to bring the security services of authenticity, integrity and non-repudiation to the controlled substances ordering process. It defines how the system can be operated from both industry and DEA's perspective. It will be available on the DEA Diversion Web Site in the near future. The Web site address is www.deadiversion.usdoj.gov.

PEC will deliver the last remaining policy documents, the Certificate Practice Statement and Certificate Policy Statement, to DEA no later than January 2001.

2.4 Architecture Design

Mr. Sciora of PEC reviewed a flowchart depicting the architectural design of a controlled ordering system. This flowchart outlined the customer's responsibility, the supplier's responsibility, and PEC's responsibility. In addition, Keane Lee, also from PEC, conducted a demonstration of the PEC built PKI electronic controlled substance ordering system using laptop computers.

2.5 Phased Approach

1. Proof of Concept phase is anticipated to be completed by December 2000. Currently, PEC is testing the PKI system they designed and built with selected industry partners (Walgreens and McKesson).
2. Pre-production phase (i.e., testing) - this is the next phase, and it can be entered into once the rulemaking process has been finalized (regulations written, comments received, and final rule published). This phase proves the system does what it is intended to do and ensures there are no problems with the system.
3. Production phase – when and if this phase is entered is determined by industry. PEC will be available to help industry and offer solutions in the implementation of their CSOS.

Section 3: Project Factors

The PKI enabled software products must be FIPS approved. FIPS approval is a U.S. Federal Government mandate. Industry is not responsible for obtaining government approval; it is the product's responsibility to have FIPS approval.

The National Institute of Standards and Technology (NIST) Web site should be consulted to learn more about FIPS and FIPS approved products. The Web site address is http://csrc.ncsl.nist.gov.

Section 4: DEA Criteria

As previously mentioned, the technology used in the ordering system must be FIPS approved. FIPS is the defining criteria and the backbone of the U.S. Government mandate.

In addition, DEA requires the users digital certificates to have extension data capability. Certificates contain certain basic information, such as user name, issuing Certificate Authority, e-mail address of registrant, and validity date. However, in addition to the basic information, DEA requires certificates to contain additional information such as: the registrants DEA number, the validity period of the DEA registration, and the drug schedules that the registrant is authorized to handle. The product has to have the ability to extract the information provided from the certificate and ensure that it agrees with the information provided.

Section 5: Industry Criteria

Industry wants to use their existing systems.

Section 6: Product Evaluation

PEC selected products for testing that met both DEA and industry criteria. The products were required to support FIPS, certificate revocation management, posting of certificate revocation lists, and other aspects of product evaluation. PEC only found two products that performed the required functions well.

Section 7: Lessons Learned

In retrospect the McKesson project experience provided valuable insight to PEC. For instance, PEC learned industry is the driving force in this project. PEC attempted to determine which direction industry was interested in pursuing in this project. This still can be accomplished by gathering more information. For example, the survey phase should be revisited. Although more interactions with industry would have provided additional information, and more information in this circumstance is better, it should be noted that PEC would not necessarily modify the project solution.

PEC developed code to prove the concept. At this point in the project, PEC does not intend to modify the project solution, but does have the ability to go back and make a change, if required. The system developed by PEC saves time, money, effort, personnel, and provides faster transmission time.

PEC wants to assure and instill to members of industry there is not only one solution in designing an electronic controlled substance ordering system. The best solution is the one tailored for industry that industry would use. PEC is committed to helping industry implement an electronic controlled substance ordering system equipped with the proper security.

Section 8: Future Initiatives

PEC is reviewing JAVA and other PKI multi-platform code. At this point, PEC is recommending JAVA be pursued as a viable solution. Since JAVA has the capacity to work on IBM operating system AS-400, the need for a gateway is eliminated.

PEC is developing the signing and validating code only. It is DEA's intent to provide PEC developed digital signature validation and extraction modules to registrants. If any registrant requires help, PEC has documentation and will be available for assistance.

Before the project enters the full production code phase regulations have to be written, policy and registration issues need to be addressed, and pre-production testing conducted.

Section 9: Closing Remarks

Ms. Good thanked the conference participants and DEA staff for attending. She reiterated this was only the first of many meetings to be held regarding the Controlled Substance Ordering System project. She anticipates scheduling the next meeting in late January 2001.