

# Electronic Commerce Initiatives

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## Electronic Transmission of Prescriptions Electronic Order Forms

September 1999

### *Introduction*

This document describes two parallel projects being conducted by DEA in conjunction with Performance Engineering Corporation (PEC). The projects are intended to define acceptable standards that can be adopted to allow the electronic transmission of prescriptions for controlled substances from prescriber to dispenser, and the supplement of the DEA Schedule II order form (222) with an electronic version. Once the standards are clearly defined and tested, they will be the subject of a **Notice of Proposed Rule Making** intended to revise existing DEA regulations to allow for electronic transmission of controlled substance prescriptions and to define electronic record keeping requirements. Comments from all affected parties will be solicited and considered in the process of finalizing the rule.

DEA and PEC believe that the development of these new standards and regulations must be based on a clear understanding of industry practices, health care delivery issues, legal/regulatory requirements at both the state and Federal levels, and currently disclosed diversion techniques. Input is being solicited from representatives of the medical, pharmacy, industry, regulatory and law enforcement professions.

Following the description of each project are sets of questionnaires that are being used by PEC in their contacts with these groups. Although they will only be able to actively contact a limited number of people from each group, they are happy to accept responses to the questionnaires or any other feedback from anyone with an interest in these issues. The applicable points of contact are listed on the questionnaires.

### **Public Key Infrastructure (PKI)**

#### **PKI Technology can -**

- Reduce paper usage
- Speed transaction times
- Lower costs
- Introduce security measures including:

Message confidentiality  
Message originator authentication  
Message content integrity

Non-repudiation of involvement by parties to a transaction

**An e-Commerce Initiative by the Drug Enforcement Administration Office of Diversion Control**

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### ***Electronic Transmission of Prescriptions: Project Overview***

Physicians and pharmacists in many states are already using Electronic Data Interchange (EDI) technology to transmit prescriptions for non-controlled substances. However, this technology cannot be used for controlled substances. Current DEA regulations specifically require that a pharmacist must have the original physical prescription slip prior to dispensing schedule II controlled substances (with exceptions for long term care facilities and emergency dispensing). Prescriptions for substances on schedules III-V can be transmitted orally but must be reduced to writing by the pharmacist prior to filling. To ease the burden resulting from this paper-based method, the DEA is working to evaluate how an electronic system - one that provides stronger levels of security and assurance as compared to current methods - might work.

As a first step, the DEA is working with the Department of Veterans Affairs (VA) to evaluate the effectiveness of this concept in a controlled, VA hospital environment. The DEA is working with Performance Engineering Corporation (PEC) to develop the design for a pilot PKI-based electronic prescription system to automate the prescribing of controlled substances. After evaluating the results of the pilot, the DEA will develop and release revised regulations to allow for the electronic transmission of schedule II prescriptions. These regulations will be issued to provide an alternate mechanism by which controlled prescriptions can be sent to pharmacies. Use of an electronic system would not be mandated by the DEA.

### **Benefits to practitioners and pharmacists**

The project is expected to provide benefits in efficiency and accuracy to practitioners, pharmacies, and patients. As a result, pharmacists will acquire better methods for validating a prescriber's identity/credentials and for verifying the authenticity of a prescription - without the need for paper prescription slips. Replacing the pharmacy's controlled prescription archive with an electronic equivalent will also be possible.

This technology is expected to provide the following benefits to practitioners, pharmacists, and patients:

- Reduced paperwork burden.
- Improved patient confidentiality.
- Reduced forged or stolen prescriptions.
- Better tools to assist pharmacists with validating prescriber's identity.
- Electronic format reduces illegibility errors.
- Faster filling.

- Improved patient satisfaction with the prescription process.

### **PKI- The technology that makes this possible**

Public Key Infrastructure (PKI) technology will provide the essential mechanisms that support this electronic system. PKI takes advantage of strong cryptographic algorithms to make encryption and digital signature possible. PKI will provide the following services to electronic prescriptions:

#### Digital Signature

- Prescription Integrity - The content of a prescription has not been altered in transit.
- Non-Repudiation - The sender of a prescription cannot deny sending it.
- Authentication - The sender of a prescription is the person claimed and not an imposter.

#### Encryption

- Confidentiality - Only authorized parties can read a prescription.

### **Key Issues**

During the course of the design effort, PEC will be working to resolve a number of technological and policy issues. PEC will be soliciting Industry and government input as we continue to develop and refine the design of the pilot system. The following paragraphs identify some of these key issues relating to an electronic prescription system for controlled substances.

- **How should we define minimum security standards?** Strong safeguards, based on Public Key Cryptographic algorithms, are the first step to ensuring privacy and providing strong user authentication services. Equally important are the policies and procedures that guarantee that the system is managed in accordance with the best practices as defined for PKI.
- **What electronic prescription systems are in use today?** A number of existing Electronic Data Interchange (EDI) standards already exist for the transmission of prescription information over private networks. We are working to determine how these standards could be used to support encryption and digital signature.
- **How would an electronic system impact patient confidentiality?** Preserving patient confidentiality is a key concern. Strong encryption technology can provide the necessary safeguards to ensure that a prescription can only be read by the recipient. Encryption can be performed on the document itself or the communication link could be encrypted.

- **How does this impact the patient's ability to have a prescription filled at the pharmacy of their choice?** In most electronic systems in operation today, patients make a pharmacy decision at the point of care. This method is similar to facsimile techniques in use today. In an electronic system, a number of techniques could be used to allow a patient to visit the pharmacy of their choice. Providing this feature would require that the prescription be readable by an intermediate device.
  - **Can a practitioner easily adopt this technology?** The ultimate success of the project will be gauged by the extent to which doctors and pharmacies adopt this new technology. There should not be significant costs or complexity involved with deploying and using this approach.
  - **Will the States support such a method?** A few states currently prohibit electronic prescriptions between a pharmacist and the pharmacy. We are working to determine if these states are currently working to amend their regulations in this area.
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### ***Electronic Order Forms: Project Overview***

The Drug Enforcement Administration (DEA) currently requires that an Order Form 222 be executed for each distribution of a Schedule I or II controlled substance unless the distribution is exempted by law. Order Forms may only be obtained by those persons who are registered by DEA (Registrants) to handle Schedule II controlled substances. Further, these order forms may only be executed by Registrants or persons to whom the Registrants have granted Power of Attorney.

The current Order Form 222 is part of a paper-based process. While being relatively slow, paper-based processes have withstood the test of time. In an effort to improve performance, many manufacturers and distributors of Schedule II controlled substances have migrated to Electronic Data Interchange (EDI) systems to handle vital business processes. Electronic systems are relatively fast but are frequently difficult to make secure. One result of these efforts is that the paper regulatory process moves more slowly than the industry electronic workflow processes. This imbalance can cause inefficiency and delay.

Until the maturation of Public Key Infrastructure (PKI) technology, the practical means to accomplish both the industry goal of workflow speed and the statutory requirement of sufficient security was not available. Today, though, the legal and policy environments are favorable towards electronic commerce and PKI technology can provide acceptable, stable standards.

DEA is working with Performance Engineering Corporation (PEC) to design the Manufacturers and Distributors Initiative (MADI), which will bring to the ordering

process the benefits of PKI technology.

## **Benefits to Industry**

MADI will:

1. Introduce the four standard PKI security services into the Order Form process;
2. Reduce the amount of paper in the process;
3. Speed transaction times; and
4. Lower costs per transaction.

In short, MADI will improve DEA's ability to perform its regulatory responsibilities while at the same time reducing the burden of regulation on industry.

The four standard PKI security features are:

1. Confidentiality of communications - only authorized persons will be able to read encrypted Order Forms;
2. Authentication of sending party - the recipient will be able to positively identify the sender of an Order Form and subsequently to demonstrate to a third party, if required, that the sender was properly identified;
3. Integrity of communications - it will be possible for the recipient of an Order Form to determine if the Order Form content was altered in transit;
4. Non-repudiation - there will be convincing evidence that the private key of a particular person was used to sign an Order Form. This evidence will make it difficult for that particular person to convincingly deny, to an independent third party, signing the Order Form.

The alternative version of Order Form 222 will be a digital document. It will be possible to use this new digital order form in, or in conjunction with, EDI systems thus realizing the full advantage that electronic-based systems have over paper-based systems.

Participation in MADI will be voluntary. MADI will be an alternative to the existing Order Form 222 process which will continue. For Registrants who use only a limited number of these forms per year, the current paper based system may be entirely adequate and cost effective.

<b>Type A</b>	<b>Type B</b>
Retail Pharmacy	Manufacturer
Hospital / Clinic	Distributor
Practitioner	Researcher

Mid-Level Practitioner	Importer
	Exporter
	Narcotic Treatment Program

**Table 1-1 Registrant Categories**

## **Key Issues**

During the course of this project PEC will be working to resolve a number of technological and policy issues. PEC will be soliciting industry and DEA input as the design of MADi develops. The following are just some of the high level issues that must be resolved.

- **At what level of security must the PKI be operated?** The MADi PKI must operate at a sufficiently high level of security and assurance that the security and risk management requirements of industry and DEA are met.
- **To what extent can existing infrastructure, hardware, software, and procedures be leveraged?** Considerations of cost, time, and user acceptance of MADi will likely be arguments in favor of leveraging to the extent possible. The MADi PKI will be standards based. One of the standards could be X.12 (EDI) for the digital Order Form.
- **What are the design tradeoffs between DEA statutory responsibilities and industry desires for less regulatory burden?** PKI technology should permit both reduced regulatory burden and maintenance of statutory regulatory standards. An early design decision was that user acceptance was a priority goal.
- **To what extent can the current Order Form process be re-engineered to maximize the benefit of PKI technology?** This is only partially an engineering issue. It is also a matter of law and policy. Merely duplicating the current process in digital form would not capture all of the advantages of PKI technology.
- **Who will operate the PKI? DEA? Industry? A 3rd Party?** While the answer to this question will ultimately affect the engineering process, the crux of it is largely policy and legal in nature.
- **Should there be a decoupling of the DEA Registration process and the PKI certificate issuing process?** Many more persons than just registrants actually handle the Order Form 222 now. In a digital process this will continue to be the case and each person will need a PKI certificate.

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PEC is using questionnaires to gather data. If you are a member of the affected industry, you are invited to participate by answering the appropriate questionnaire and submitting it to PEC using the instructions included.

Click on the appropriate questionnaire.

<b>Electronic Prescriptions</b>	
Pharmacy Questionnaire	State Agency Questionnaire
Practitioner Questionnaire	DEA Staff Questionnaire

<b>Electronic Order Forms</b>	
DEA Certificate Policy Questionnaire	Industry Certificate Policy Questionnaire