Public Key Infrastructure Analysis

Controlled Substances Ordering System (CSOS)/ (MADI) PKI Existing Network Infrastructure Analysis

Prepared for

Drug Enforcement Administration
Office of Diversion Control
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600 Army Navy Drive
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in response to

Assist 5C-A-JMD-0072-DO-220

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Table of Contents

1. Introduction

1.1 Overview and Background

Under the authority of the Controlled Substances Act of 1970, the Drug Enforcement Administration, Office of Diversion Control (OD) regulates the manufacture and distribution of Controlled Substances in the United States. This regulatory control is designed to prevent the diversion of legitimate pharmaceutical drugs into illegal channels and also to ensure that there is a sufficient supply for legitimate medical uses. Title 21, Code of Federal Regulations, Parts 1300-1399 sets forth in detail the authority and responsibilities of DEA in this area. It is further intended that their systems prevent the introduction of contraband Controlled Substances into the legal distribution channels.

The Government Paperwork Elimination Act of 1999 (Title XXII of Public Law 105-277) mandates that Federal agencies allow for the option of electronic submission of required records and for the use of electronic signatures when practicable.

The Manufacturers and Distributors (MADI) Public Key Infrastructure (PKI) will be designed to bring to this regulatory process the advantages of PKI. The MADI PKI's goals will (1) reduce the amount of paper in the process (2) speed transaction times (3) lower costs per transaction and (4) introduce security services into the process.

The security services include those inherent in any PKI: (a) *confidentiality of communications*- only authorized persons will be able to read encrypted communications; (b) *authentication of sending party*- the recipient will be able to positively identify the sender of a communication and subsequently to demonstrate to a third party, if required, that the sender was properly identified; (c) *integrity of communications*- it will be possible for the recipient of a message to determine if the message content was altered in transit; (d) *non-repudiation*- the originator of a message can not deny to a third party that the originator sent it.

1.2 Mission of the Office of Diversion Control

The Federal Code of Regulations Title 21, Sections 1300 to Section 1399, defines the registration, record keeping, inventory, ordering processing, prescribing, and miscellaneous activities as they relate to Controlled Substances. Persons who wish to participate in a Controlled Substances business activity, i.e. manufacturing, distributing, dispensing, research, narcotic treatment programs, import, export, are required to register with the Office of Diversion Control unless otherwise exempted from registration described in §1301.22. Registrants fall into two categories, Type A registrants and Type B registrants as shown below.

The MADI Project focuses on both Type B registrants, Manufacturers and Distributors, and Type A registrants, Retail Pharmacies, Hospitals & HMOs. The MADI Project will

review the relationships and processes as they pertain to the DEA regulatory process and these two categories of registrants. The MADI Project will determine how the regulatory process can be enhanced through the use of a PKI.

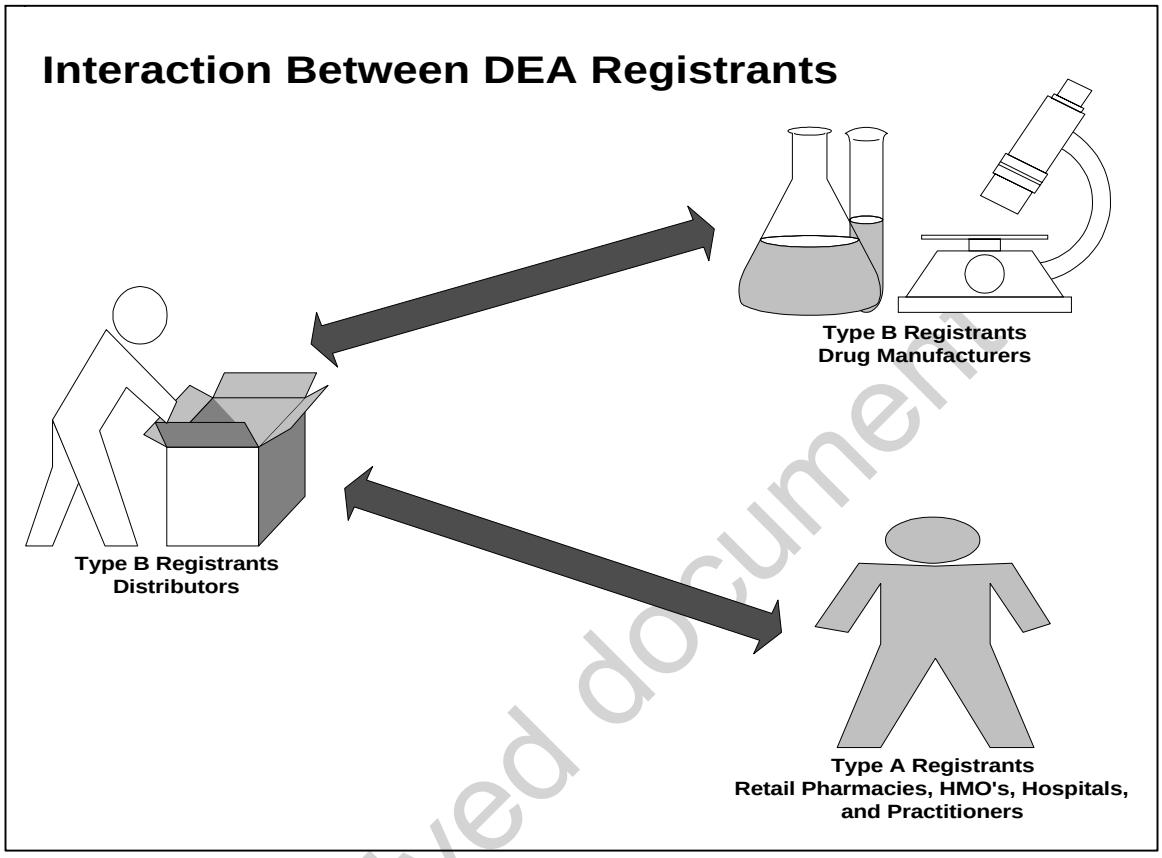

Figure 1. Interaction between DEA Registrants

1.3 Document Organization

The document is organized into the following sections:

Section 1– The introduction provides a description for this task and provides an overview of the goals and objectives of the task.

Section 2– Section 2 Provides detail and summary data and findings produced by the interviews, meetings, seminars, document reviews and site visits.

Section 3– Section 3 Provides Analysis of the data and findings to derive the requirements for the MADI PKI.

Appendix A– Listing of Interviews, Site Visits, Meetings and Conferences

Appendix B– Listing of Documents Reviewed

Appendix C– Requirements Detail

Appendix D– Listing of Acronyms

1.4 Description of Task 2.2.2

Existing Network Infrastructure Analysis Task 2.2.2

The purpose of this analysis is to identify and evaluate the existing facilities, hardware platforms, systems software, communications infrastructure, and software applications currently in use by both DEA and industry, which play a role in the registrants handling of Controlled Substances. The information gained through the analysis will provide direction for possible solutions that can incorporate existing networks and technologies and leverage existing investments in these networks and technologies.

The Existing Network Infrastructure Analysis will review representative Stakeholder's current information technology infrastructures from the following perspectives:

- Transaction Volume of DEA 222 Form and potential volume of transactions between the trading partners and DEA.
- Physical Security Infrastructure that surrounds their technology and data center operations.
- Network Architecture that describes the type of network communications protocols, and directory structures being used.
- Applications and Data Architecture- that describe the types of database, forms, workflows, and proprietary or COTS applications used.
- System Security Architecture- that describes the logical security products or methods used.
- Gain an understanding of potential new directions of information technology and possible implementations in the Stakeholders environment.

The Existing Network Infrastructure Analysis will also document input from both Industry and DEA concerning responsibility for management, support, administration, costs and impacts of improved processes for the Stakeholders.

ID	Task Name	Jul '99	Aug '99	Sep '99	Oct '99	Nov '99	Dec '99	Jan '00	Feb '00
1	Task 2.2.2 Network Analysis (KO + 29 Weeks)								

1.5 Analysis Methodology

Analysis Methodology

The methodology used for this analysis:

(1) Interviews with selected DEA and Industry representatives

(2) Review of documents recommended by DEA and industry

(3) Visits to sites recommended by DEA and industry

(4) Follow-up of leads and sources developed during (1)-(3) above and

(5) Questionnaires submitted to selected industry representatives.

Appendix A of this document contains the listing of all interviews conducted, site visits made, and conferences and meetings attended in the preparation of this analysis. Appendix B contains a listing of all documents read and reviewed in preparation for this analysis. Appendix C contains the detail level requirements table and Appendix D contains a list of acronyms used within the document.

1.6 Industry Stakeholder Groups Defined

Industry Stakeholder groups that are directly involved in the Controlled Substances handling process are organized and defined here into high level groups for the purposes of this project. A description of their position in the process flow and a description of the representative sample taken from that Stakeholder group is also provided.

Each of these groups of Stakeholders are distinct in terms of:

- Position in the regulatory process flow
- Impact of the process on their operations
- Motivation/Desire to Change
- Existing Technology Infrastructure
- Acceptance of Technology
- Sensitivity to IT Cost

Manufacturers

Representative drug manufacturers were chosen from those who manufacture Schedule 2 Controlled Substances, and process varying volumes of DEA 222 Forms: Three large volume manufacturers, a medium volume and two small volume manufacturers for a total of six interviews.

Distributors

Representative drug distributors were chosen from those who distribute Schedule 2 Controlled Substances and process varying volumes of DEA 222 Forms: Four large volume distributors, two medium and one small volume distributor for a total of seven interviews.

Chain Drug Stores/Grocery Chain Stores with In-house Pharmacies

Representative drug store chains and grocery stores that operate in-store pharmacies were chosen from those who either use an independent distributor to provide Controlled Substances to the stores or those that centrally warehouse and distribute Controlled Substances to their stores. Four large volume chain drug stores- two that centrally warehouse and distribute and two that do not, one medium chain grocery store with in-store pharmacies and one small chain grocery store with in-store pharmacies were interviewed.

Those that centrally warehouse and distribute Controlled Substances have similar volume and processing as a distributor. Those that utilize the services of an independent distributor have the same volume and process as an independent pharmacy.

Pharmacies

Representative pharmacy associations were chosen from those who represent the interests of both independent pharmacists and state boards of pharmacies. Three associations were interviewed.

HMOs and Others

Other representative groups who utilize the DEA 222 Forms were chosen from healthcare maintenance organizations (HMOs) and drug treatment clinics. Two HMOs and one methodone treatment clinic were interviewed.

DEA/ Pharmacy Boards/State Regulators

DEA Headquarters and Field Office personnel were designated by the Office of Diversion Control to participate in the interview process. DEA provided information on the regulatory issues of State Boards of Pharmacies and State regulators.

2. Existing Network Infrastructure Data and Findings

2.1 Controlled Substances Business Process

2.1.1 High Level Process Flow

The Controlled Substances business process varies by type of registrant and how the individual business is organized. These variances may be caused by state regulation and/or by organization internally developed processes. The Controlled Substances business processes described below are generic summaries of the responses received.

DEA uses the terms "supplier" and "customer" to describe the roles of Registrants that use DEA 222 Forms to order Controlled Substances. The customer fills out a DEA 222 Form and sends it to the supplier.

Industry uses the term "***inbound*** DEA 222 Form" to describe a DEA 222 Form coming in to a supplier. The term "***outbound*** DEA 222 Form" is used to describe a DEA 222 Form sent out by a customer. The terms inbound and outbound indicate a perspective on the flow of the process. Each DEA 222 Form is inbound to the supplier and outbound from the customer.

Manufacturers

Manufacturers are suppliers. They process ***inbound*** DEA 222 Forms that are received from their customers. Some manufacturers also transfer Controlled Substances internally using the DEA 222 Form. Manufacturers typically have 50 to 1000 trading partners. These trading partners are well established with long term relationships and do not change on a regular basis. Set forth below are the steps for processing these ***inbound*** DEA 222 Forms:

1. DEA 222 Form is sent by mail or courier service and received in Customer Service
2. DEA 222 Forms are quality checked
3. DEA 222 Forms are entered into the manufacturers computer order entry system and sent to C2 vault area
4. Picking/packing lists are created
5. Order is picked from the vault and cross checked with paper DEA 222 Form
6. DEA 222 Form is completed with order information and cross checked with the computer entry order

7. Order is shipped.

8. After it is annotated with the shipping information, one copy of the DEA 222 Form is retained at the manufacturer's site in a locked cabinet or safe; and one copy is forwarded to the local DEA office.

Distributors

Distributors are both customers and suppliers. In the customer role, they send DEA 222 Forms to the manufacturer and will typically have 50 to 500 trading partners. These trading partners are well established with long term relationships and do not change on a regular basis.

In the supplier role, they receive DEA 222 Forms from their customers (ie. Pharmacies, HMOs, Hospitals, Practitioners) and will typically have 500 to 25,000 customers. These customers are well established with long term relationships and do not change on a regular basis.

In the Distributor's role as a customer, DEA 222 Forms are filled out in the purchasing departments and may be quality checked prior to being mailed or sent by courier to a manufacturer.

In the Distributor's role as a supplier, set forth below are the steps for processing these ***inbound*** DEA 222 Forms:

1. The DEA 222 Form is sent by mail or picked up by the driver from the customer in a special envelope provided by the distributor.

2. The DEA 222 Forms are taken to Customer Service and quality checked.

3. The DEA 222 Forms are entered into the distributors computer order entry system and multiple checks are made by the system concerning the validity of the DEA registration, the State registration and other customer profile attributes (size of order, frequency of order).

4. The DEA 222 Forms are sent to C2 vault area and picking/packing lists are created.

5. Order is picked from the vault and the DEA 222 Form is completed with order information and cross-checked with the computer entry order.

6. The Order may be cross- checked again and the Order is shipped.

7. After it is annotated with the shipping information, one copy of the DEA 222 Form is retained at the distributor's site in a locked cabinet or safe; and one copy is forwarded to the local DEA office.

Chain Drug Stores/Grocery Chain Stores with In-house Pharmacies

Those that centrally warehouse and distribute Controlled Substances have a somewhat similar volume and processing procedure as a distributor, but with some differences. They act as suppliers and process ***inbound*** DEA 222 Forms from their own stores. They act as customers and process ***outbound*** DEA 222 Forms from their headquarters facility to manufacturers. Those Chain Drug Stores that ***do not*** centrally warehouse and distribute Controlled Substances, utilize the services of an independent distributor and have the same volume and process as an independent pharmacy.

Set forth below are the steps for processing these ***inbound*** DEA 222 Forms:

1. The blank DEA 222 Forms that come into the individual pharmacies are sent to the headquarters distribution facility.

2. The pharmacy places an order in their computer order entry system either through a Telxon unit (a handheld barcode scanner) or through the client application on the personal computer in their pharmacy.

3. The computer order is received in the Customer Service or vault area, a blank DEA 222 Form for that particular pharmacy is filled at the pharmacy chain headquarters distribution center from the information in the computer order entry system.

4. The DEA 222 Forms are sent to C2 vault area and picking/packing lists are created.

5. Order is picked from the vault and the DEA 222 Form is completed with order information and crosschecked with the computer entry order. The top copy of the DEA 222 Form (pharmacy copy) is separated and placed with the order to be shipped directly to the particular pharmacy.

6. The Order may be cross- checked again and the Order is shipped.

7. After it is annotated with the shipping information, one copy of the DEA 222 Form is retained at the pharmacy chain headquarters distribution center in a locked cabinet or safe; and one copy is forwarded to the local DEA office.

8. Upon receipt at the particular pharmacy, the Pharmacist in Charge or the Pharmacy Manager takes the original pharmacy copy and fills in the receiving information. Their copy of the original completed DEA 222 Form is stored in a locked cabinet or safe on site.

Independent Pharmacies

Pharmacies, acting as customers, send ***outbound*** DEA 222 Forms to a distributor to be filled. Pharmacies typically have one main distributor and, in a few cases, have a back up

distributor. These trading partners are well established with long term relationships and do not change on a regular basis.

Set forth below are the steps for processing these ***outbound*** DEA 222 Forms:

1. The owner, Pharmacy Manager, or Pharmacist in Charge will fill out a DEA 222 Form in their Pharmacy.

2. In some cases they will have a second staff Pharmacist quality check the order before it is mailed off or given to the distributor's driver.

3. Upon the order being delivered from the distributor, the Pharmacist in Charge or Pharmacy Manager will fill in the receiving portion of their original copy of the DEA 222 Form. Their copy of the original completed DEA 222 Form is stored in a locked cabinet or safe on site.

HMOs and Others

HMOs and others such as a drug treatment center, acting as customers, process ***outbound*** DEA 222 Forms to a distributor and in a few cases directly to a manufacturer to be filled. HMOs and Others typically have one main distributor and in a few cases, have a back up distributor. These trading partners are well established with long term relationships and do not change on a regular basis.

Set forth below are the steps for processing these ***outbound*** DEA 222 Forms:

1. The HMO or Treatment Center Pharmacy Manager or Pharmacist in Charge will fill out a DEA 222 Form in their HMO Pharmacy or Center.

2. In some cases they will have a second staff Pharmacist quality check the order before it is mailed off or given to the distributor's driver.

3. Upon the order being delivered from the distributor, either the HMO, Treatment Center Pharmacy Manager or Pharmacist in Charge will fill in the receiving portion of their original copy of the DEA 222 Form. The information is also entered into an internal inventory system. Their copy of the completed DEA 222 Form is stored in a locked cabinet or safe on site.

DEA Local Offices

Once the DEA 222 Forms are completed by the distributor or manufacturer when they are the suppliers, the green copies are forwarded periodically to the local DEA Office. The copies may be sorted into various groupings (by state, by board- dental, medical, veterinary) or simply filed away. Most local DEA offices make only limited use of these copies of the forms.

Import/Export

The DEA 222 Form ordering process does not include importing and exporting of Controlled Substances. Therefore the initial concern, that strong encryption technology that might be utilized in the MADI PKI could not be exported outside the continental United States, is no longer an issue.

2.1.2 Document Transaction Volume- Current and Future

The volume of DEA 222 Forms being generated and processed is directly related to the type of registrant and where in the document process flow the registrant is located. The volume varies significantly between registrant types as is illustrated in the chart below. The volume is exceptionally high for those registrants that both initiate ***outbound*** and accept ***inbound*** DEA 222 Forms.

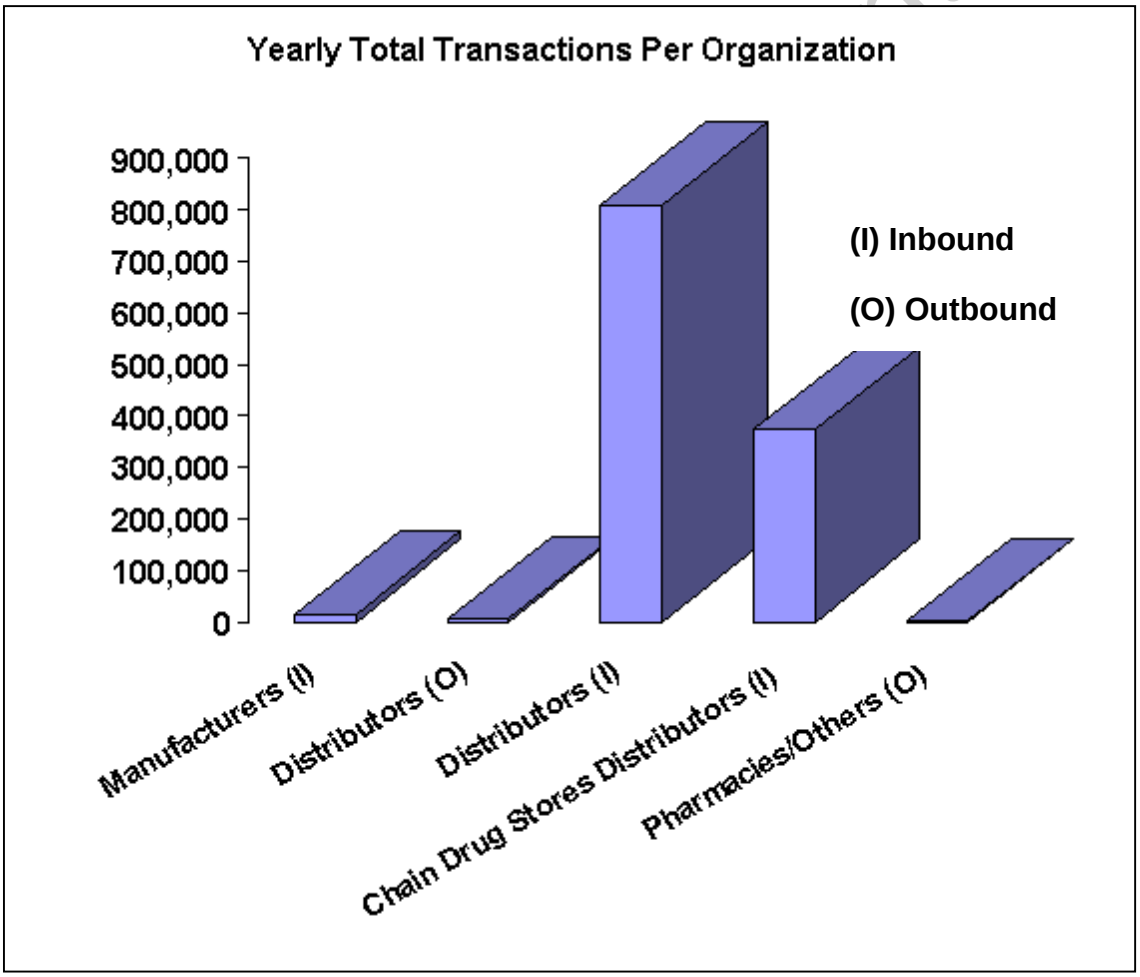

Figure 2. Yearly Total Transactions Per Organization

All registrant groups indicated that they believed that the volume of Controlled Substances transactions would increase due to the following factors:

- The aging population in the United States will create an increase in the general number of prescriptions.
- There is a greater focus on pain management.
- There are more drugs being researched and developed that will appear in the Schedule 2 Controlled Substances (C2) classification.

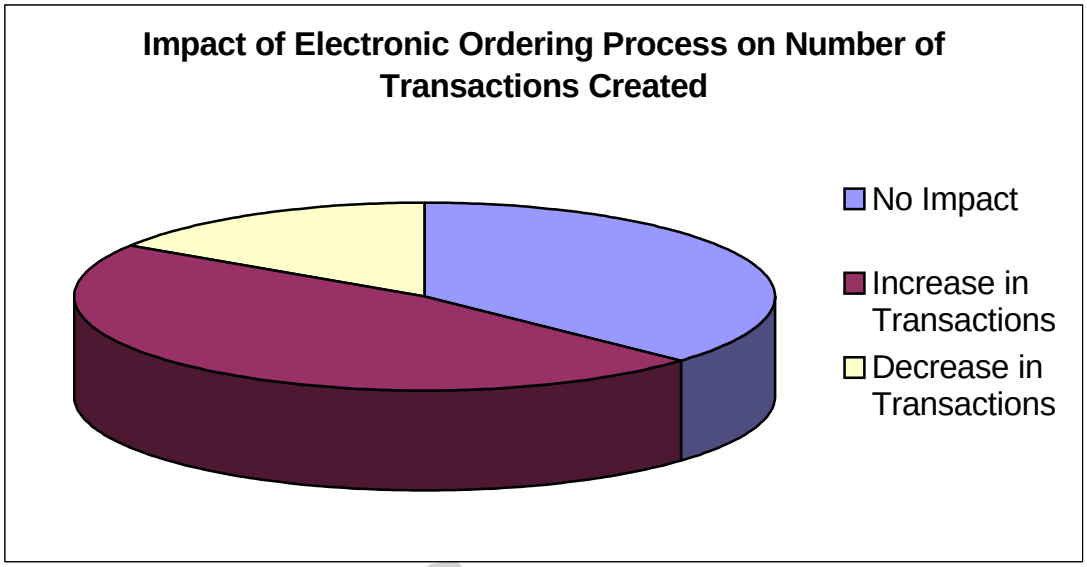

Figure 3. Impact of Electronic Ordering Process on Number of Transactions Created

All Stakeholder groups varied in their responses as to how the new electronic system would impact the number of transactions. Those that indicated that there might be ***decrease*** in the transaction level noted:

- The number of corrected forms would be less.
- The ability to create more line items on a single order.

Those that indicated that there would be an ***increase*** in the transaction level noted:

- With faster ordering there would be less consolidating of orders by Pharmacists, and orders would be placed more frequently for fewer items.
- With faster ordering there would be less reason to stockpile product and less waiting to fill up an order form.

- Less product would be kept on the shelf and smaller orders would be placed more frequently.

The Manufacturers indicated that there would be no impact or change to the volume of orders created.

2.1.3 DEA 222 Form Order Process Turnaround Time

The typical turnaround time for a DEA 222 Form order placed by a pharmacy to a distributor or distributor to manufacturer, is generally 1 to 3 days from the time the order is submitted until it is delivered. Factors that influence this are:

- Orders that were given directly to the distributor's drivers, or orders that were FedExed or couriered could be obtained more quickly.
- Orders that were placed in the regular mail tended to take longer- from 3 to 7 days.

Factors that significantly contributed to slower turnaround times:

- US Mail
- Getting the paper document from point A to B.
- Improperly filled out form
- Weather
- Quotas and Lack of Inventory

2.1.4 DEA 222 Form Document Error Rate

Stakeholder groups varied in their responses to the level of incidence of human errors with the paper DEA 222 Form. The following are the factors that contribute to the error rate:

- Corporate name changes, address changes due to Post Office redistricting, road construction changes that change addresses, mergers and acquisitions.
- Human errors such as National Drug Code (NDC) numbers that are transposed, forgetting to sign the DEA 222 Form and wrong number of line items indicated.

Factors that contribute to the lower error rates are:

- Corporate policy that only allows experienced employees to transact DEA 222 Forms.
- In-store training provided to those utilizing DEA 222 Forms.
- Training manuals and cheat sheets.
- Fear of fines from DEA audits.

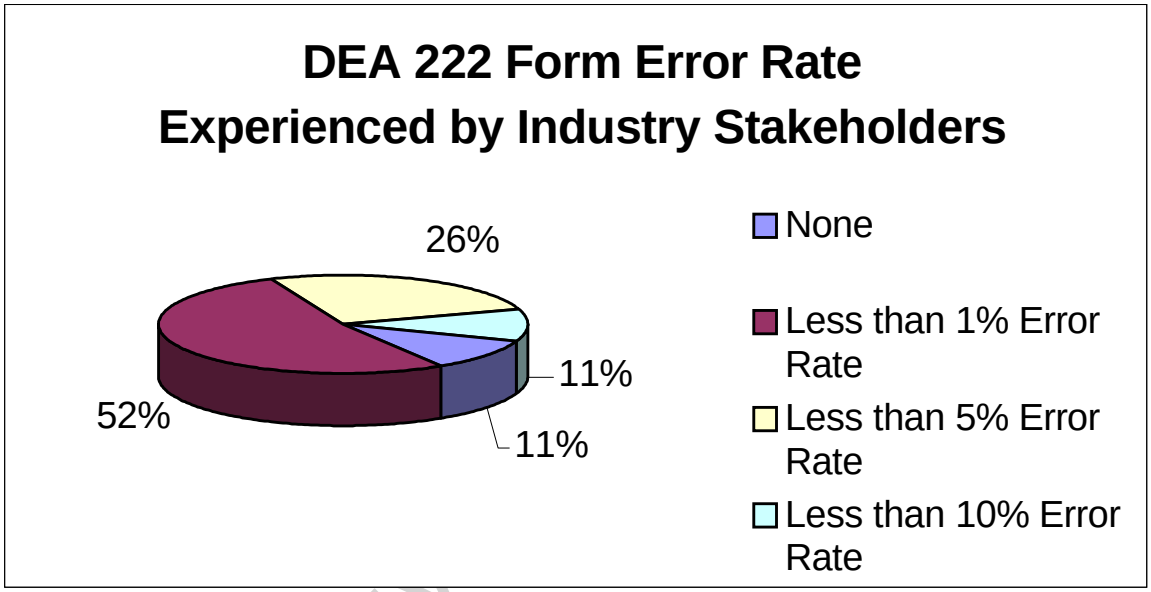

Figure 4. Incidence of Error Rate for Paper DEA 222 Form

2.1.5. Personnel Access to DEA 222 Form Process

The number and type of personnel that are involved in processing DEA 222 Forms varies by Stakeholder type and the size of an individual registrant. Each registrant has some number of persons holding power of attorney to sign ***outbound*** DEA 222 Forms. There are many more persons required to be involved that handle ***inbound*** DEA 222 Forms to review the order, fill the order, quality check the order, receive the order and file the orders that do not require power of attorney to fulfill those tasks. Access to DEA copies of completed DEA 222 Forms by state and local authorities are only used in a few isolated cases (e.g. Oklahoma).

Average Number of Personnel Handling DEA 222 Form Document

	Power of Attorney	Document Processors
Manufacturers	1-4 persons per registration	5-15 persons per location
Distributors	1-3 persons per registration	6-10 persons per distribution center
Chain Drug Stores	2-3 persons per registration	2-3 persons per store location
Pharmacies	1 person per registration	1-2 persons per store location
HMOs and Others	1-4 persons per registration	2- 3 persons per location
DEA Local Office	NA	1-2 persons per location

Table 1. Average Number of Personnel Handling DEA 222 Form Document

2.2 Existing Information Technology Infrastructure

The existing information technology infrastructures are varied by type, use of the network infrastructure and ownership of the network infrastructure.

2.2.1 Network Architecture

Manufacturers

Manufacturers are generally physically located in one or only a few locations; therefore having fewer wide area networks (WAN) and more local area networks (LAN) that connect to a single data center. Network technologies included frame relay, switched fast ethernet and token ring. Manufacturers make extensive use of value added networks (VAN) and generally have dedicated lines to those VAN providers. There is only very limited use of the Internet and Internet connections.

Distributors

Distributors are physically dispersed throughout the country, having multiple distribution centers. They typically have a WAN that connects all distribution centers to one or more data centers and/or LANs using frame relay, Asynchronous Transfer Mode (ATM) between some locations, TCP/IP and dial up connections for customers. Local area network technologies include fast ethernet and token ring and LANs with TCP/IP. Several distributors are considering the use of virtual private networking (VPN) technologies. Distributors also make extensive use of Value Added Networks (VAN) and generally have

dedicated lines to those VAN providers. There is only very limited use of the Internet and Internet connections.

Chain Drug Stores

Chain Drug Stores are physically dispersed throughout a region of the country, and may have multiple distribution centers for their operations. They typically have a WAN that connects all stores and distribution centers to one or more data centers using frame relay, TCP/IP, IP with systems network architecture (SNA) and VSAT (very small aperture terminal) satellite communications. Local area network technologies include fast ethernet, token ring and LANs with TCP/IP. Chain Drug Stores also make extensive use of VANs and generally have dedicated lines to those VAN providers. There is only very limited use of the Internet and Internet connections.

Pharmacies

Independent pharmacies generally reside in a single location. They may have a single personal computer with local applications and a dial-up connection to a distributor. Any technology present in their operation is generally provided by a distributor or maybe owned by the pharmacy. There is little or no evidence of Internet access or use in the independent pharmacy.

HMOs and Others

HMOs and other smaller clinics are physically dispersed throughout a region of the country. They typically have a WAN that connects all sites to a data center using frame relay. Local area network technologies include Microsoft NT and dial-up capabilities. There is only very limited use of the Internet and Internet connections.

DEA

DEA is physically dispersed and operates a wide area network (WAN) called “Firebird”. Firebird is a Microsoft NT network connected to all DEA Field Offices including Office of Diversion Control sites in the United States. Currently there is only very limited use of the Internet and Internet connections. DEA anticipates future changes to their network architecture in order to allow for secure remote access across the Internet.

Future Changes to Network Architecture

Stakeholders were divided with sixty percent responding that there were no future changes planned for their network architectures.

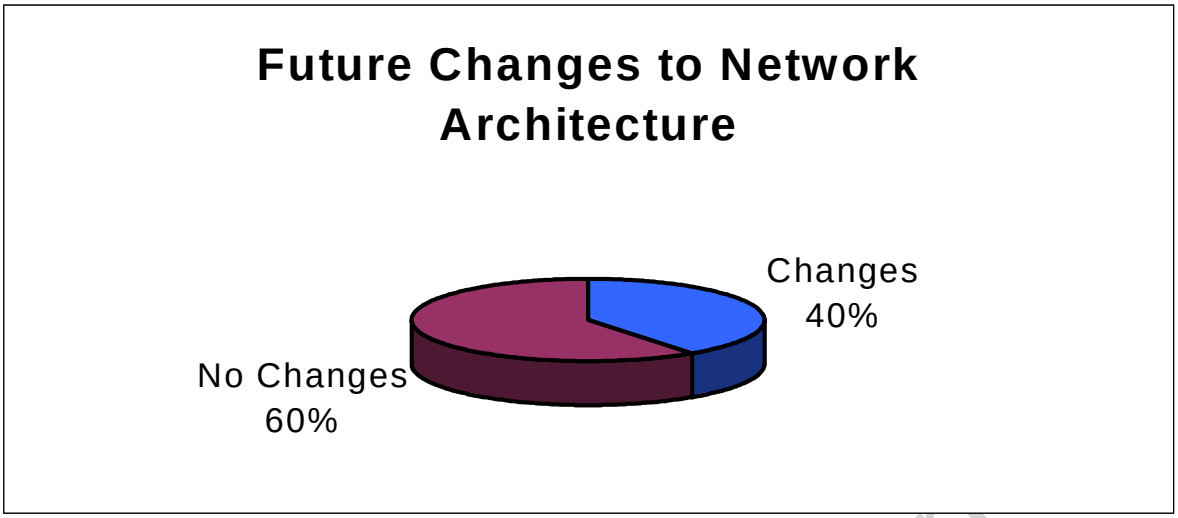

Figure 5. Future Changes to Network Architecture

2.2.2 Systems Architecture, Hardware and Software

Manufacturers

Manufacturers generally have a centralized data center operating with mainframes, midrange UNIX computers (IBM AS/400), and NT servers. End user devices include IBM compatible (Pentium level) desktop workstations, personal computers, portable computers and mainframe terminals. Although there is some evidence of use of large enterprise resource planning applications as JD Edwards and Peoplesoft, the majority of the enterprise applications are homegrown mainframe applications, operating both in real time and some batch applications.

Electronic Data Interchange (EDI) is the technology used most prevalently by Manufacturers to exchange business information between other trading partners. The types of transactions are purchase orders, invoices, order acknowledgments and charge backs. Most are using versions 3010 through 4010 of the X.12 standard. Most manufacturers are using VANs such as Sterling, General Electric Information Systems and IBM to provide private network access and transaction exchanges for their EDI transactions. Some also have a direct connections with trading partners to exchange EDI transactions.

Distributors

Distributors generally have one or more centralized data centers operating with mainframes, midrange UNIX computers (IBM AS/400), and NT servers. End user devices include IBM compatible (Pentium level) desktop workstations, personal computers, portable computers and mainframe terminals. Although there is some evidence of use of large enterprise resource planning applications as JD Edwards, Oracle and Peoplesoft, the

majority of the enterprise applications are homegrown mainframe applications or customized COTS applications operating both in real time and batch.

Electronic Data Interchange (EDI) is the technology used most often by Distributors to exchange business information with Manufacturers. Transactions included are purchase orders, invoices, order acknowledgments and charge backs. Most are using all versions, up to and including 4010 of the X.12 standard. Most Distributors are using VANs such as Sterling and General Electric Information Systems (GEIS) to provide private network access and EDI transaction exchanges. Some have purchased the Sterling Gentran product, which is the EDI translator and message processor, and have a direct connection with a trading partner to exchange EDI transactions.

To communicate with their customers, Distributors generally provide the proprietary ordering software and in some cases hardware, allowing their customers to create orders and send them to the Distributors system.

Chain Drug Stores

Chain Drug Stores generally have one centralized data center operating with mainframes, midrange UNIX computers (IBM AS 400 and SCO UNIX), and NT servers. End user devices in the individual pharmacies include IBM compatible (Pentium level) desktop workstations, personal computers, Telxons (hand held bar code scanner devices used inventory and ordering), electronic notebooks, portable computers and mainframe terminals. Although there is some evidence of use of large enterprise resource planning applications as Oracle and SAP, the majority of the enterprise applications are homegrown mainframe applications or customized COTS applications operating both in real time and batch. The pharmacy end user device may also have the proprietary ordering software of an independent distributor if their Pharmacy Chain does not do its own distribution.

Electronic Data Interchange (EDI) is only used to exchange business information with Manufacturers, some Distributors and other vendors. Transactions included are purchase orders, invoices, order acknowledgments and charge backs. Most are using all versions, up to and including 4010 of the X.12 standard and some use Uniform Communication Standard (UCS). Most Chain Drug Stores are using VANs such as Sterling and General Electric Information Systems (GEIS) to provide private network access and EDI transaction exchanges. Some have purchased the Sterling Gentran product which is the EDI translator and message processor and have a direct connection with a trading partner to exchange EDI transactions. Some also have arrangements where they dial-up the trading partner and do a request to receive with a password.

Pharmacies

Pharmacies will typically have a single personal computer (PC) or Telxon (hand held bar code scanner device). The PC will have local applications such as a COTS application for pharmacy management and inventory that may or may not be networked to their cash register. Resident on that PC will also be the proprietary ordering software of the specific

distributor and a dial-up connection to a distributor. Any technology present in their operation is generally provided by a distributor or maybe owned by the pharmacy. Pharmacies typically do not utilize EDI technology.

HMOs and Others

HMOs may have a smaller type of data center with midrange UNIX computers (IBM AS/400) and NT LANs running specific applications to manage clinics and benefits. End user devices are IBM compatible personal computers (PC) or Telxon devices. Also resident on that PC will be the proprietary ordering software of the specific distributor and a dial-up connection to the distributor. HMOs typically do not utilize EDI technology.

DEA

DEA has one centralized data center operating with mainframes (M204) that are accessed through the Firebird Network. End user devices in Headquarters and the local field offices include IBM compatible (Pentium level) desktop workstations, personal computers, portable computers and mainframe terminals. Legacy applications resident on the mainframes are the Registration (CSA) database and ARCOS reporting. Office automation applications are available through the Firebird Network. At this time, there is only very limited use of the Internet and Internet connections; more extensive use of the Internet is planned. DEA does not utilize EDI technology.

2.3 Information Technology Organization and Management Structure

Manufacturers, Distributors, Chain Drug Stores and HMOs have very large, sophisticated and centrally managed IT organizations. They have very large IT staffs and budgets that support both COTS and highly proprietary supply chain management systems. They do little or no outsourcing of IT functions or operations. Any outsourcing that is used, is limited to non-critical functions such as hardware break/fix, cabling and wiring and some application development.

Pharmacies have no specific or separate IT organization. They depend on Distributors to provide application software and support and in some cases hardware and devices (Telxons).

DEA has a large and centrally managed IT organization with substantial legacy systems.

2.3.1 Level of Technical Support and Administration

Manufacturers

The Manufacturers provide only minimum EDI implementation and help desk support to their trading partners (Distributors).

Distributors

The Distributors provide all support, training and administration for hardware and software provided to their customers. This generally includes a 24 hours a day and 7 days a week help desk, on site training and field support as necessary.

Chain Drug Stores

The Chain Drug Stores provide all support, training and administration for their stores. This generally includes a 24 hours a day and 7 days a week help desk, on site training and field support. If Distributor software is used for ordering, the Distributor provides support (training and help desk) for that software.

Pharmacies, HMOs and Others

The Distributors provide all support, training and administration for their Pharmacy customers. This generally includes a 24 hours a day and 7 days a week helpdesk, on site training and field support as necessary. Any other independently owned hardware or software is supported by other means.

2.4 Information Technology Security

2.4.1 Physical Security/Disaster Recovery

Manufacturers, Distributors, Chain Drug Stores and HMOs that have data centers or large IT organizations, utilize the following types of physical security measures:

- Access Control Badges/Security Stations
- Separate Buildings and Segregated Functional IT Areas
- Gated Areas and Security Guards
- Alarms/Key Pad Access

All groups interviewed had some type of disaster recovery plans and methods to insure business continuity:

- Redundant data centers
- Access to redundant data centers/communications provided by a vendor (Comdisco/Sunguard/Hewlett Packard)
- Offsite Tape/Medium Storage
- Business resumption policies/procedures

2.4.2 Logical Information Technology Security

All groups interviewed had some type of logical IT security within their systems. Larger organizations have multiple types of logical security for their information resources and systems. Different types included the following:

- Firewalls (Both front end and separate authentication servers)
- IBM AS/400 Mainframe Security
- RACF and ACF
- Secure ID, Siteminder (WEB) and Metaframe
- Application Level Role Based Access Security
- Profile for each User/Customer on the System
- Access Logging and Auditing
- Access Control Lists
- Log Offs for Inactivity

2.4.3 Information Technology Security Policy

Most groups interviewed had some type of policy for IT security within their organizations. Larger organizations had formalized written policies, written contracts with other trading partners and employee sign offs to ensure knowledge and compliance of the policies. Independent Pharmacies and small clinics tended to have more informal IT policies. These policies addressed such areas as:

- Password Care and Use
- Internet Use
- Use of Corporate Owned Hardware and Software
- Confidentiality of Proprietary Information

2.4.4 Information Technology System Auditing

All groups interviewed had IT system auditing schedules for internal and external audits. Some groups had, in addition to both internal and external audits, random audits of inventory and system inventory. Internal audits tended to be on a more frequent basis: quarterly, semi-annually or yearly. External audits performed by third party accounting

firms tended to be on a less frequent basis: yearly and bi-annually. Random audits were generally conducted several times a year and focused on specific areas.

2.5 Current Use of PKI and Encryption Technologies

There currently exists only very limited use of PKI and encryption technologies amongst the industry groups.

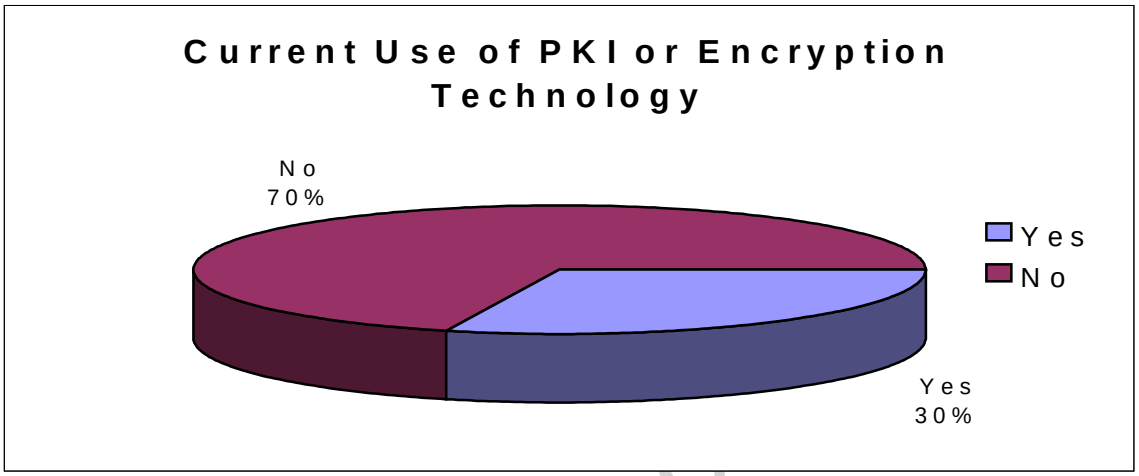

Figure 6. Current Use of PKI or Encryption Technology

For those groups that are utilizing some form of PKI or encryption technology, the following are the specific uses:

- Prescriptions that are encrypted and sent through the ***Scripts Network***.
- Encryption of patient information that is sent to ***Marketshare.***
- Consumer Web based ordering system uses ***Verisign*** server authentication.
- Bank transactions.
- Encryption of patient information that is sent to Medicaid.

2.6 Design Concepts

Several interview participants (3) took the opportunity to provide high level design concepts that they believed to be direction the resulting design should take. These are provided here without further comment and will be considered in the design phase.

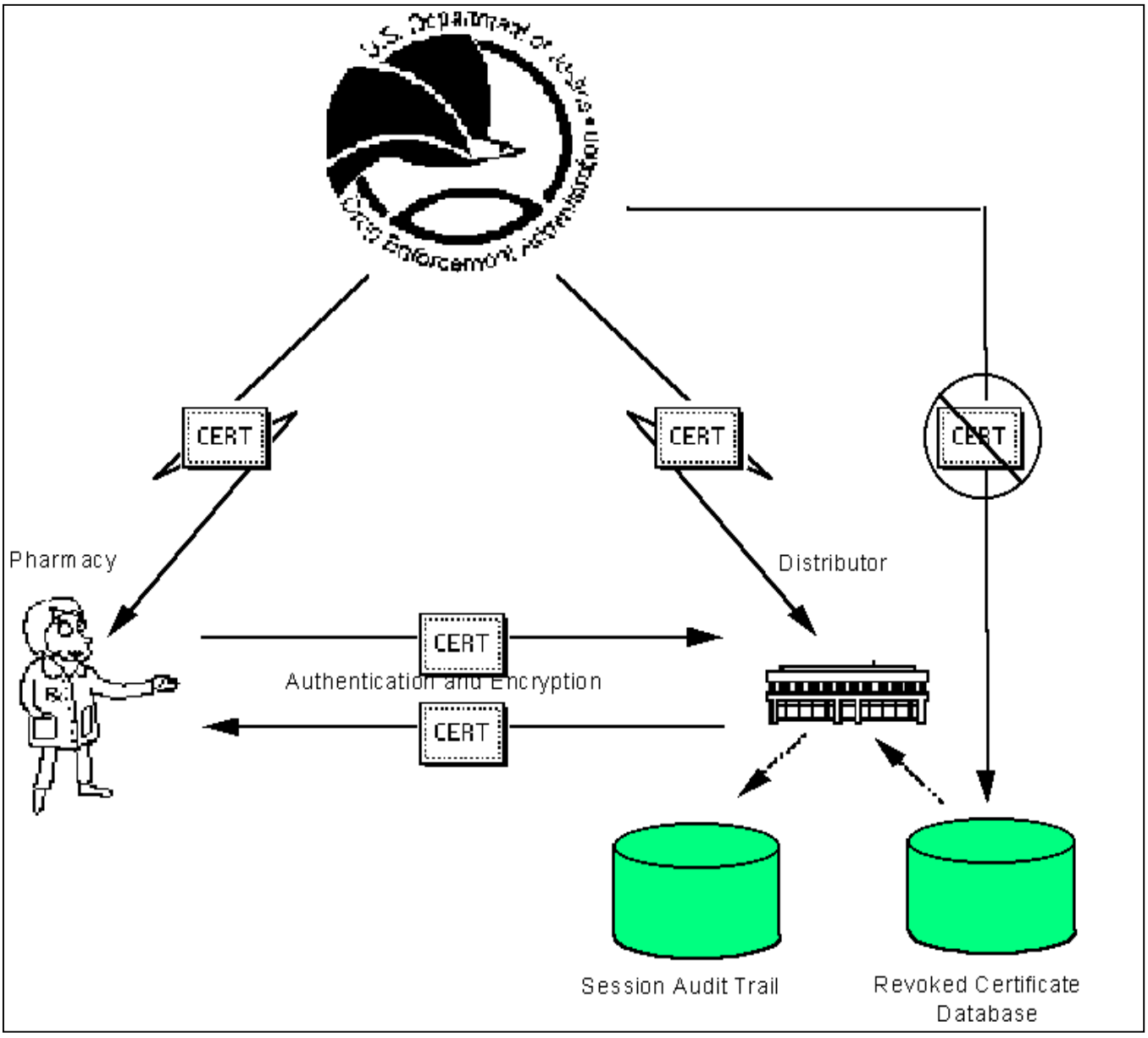

Figure 7. High Level Design Concept 1

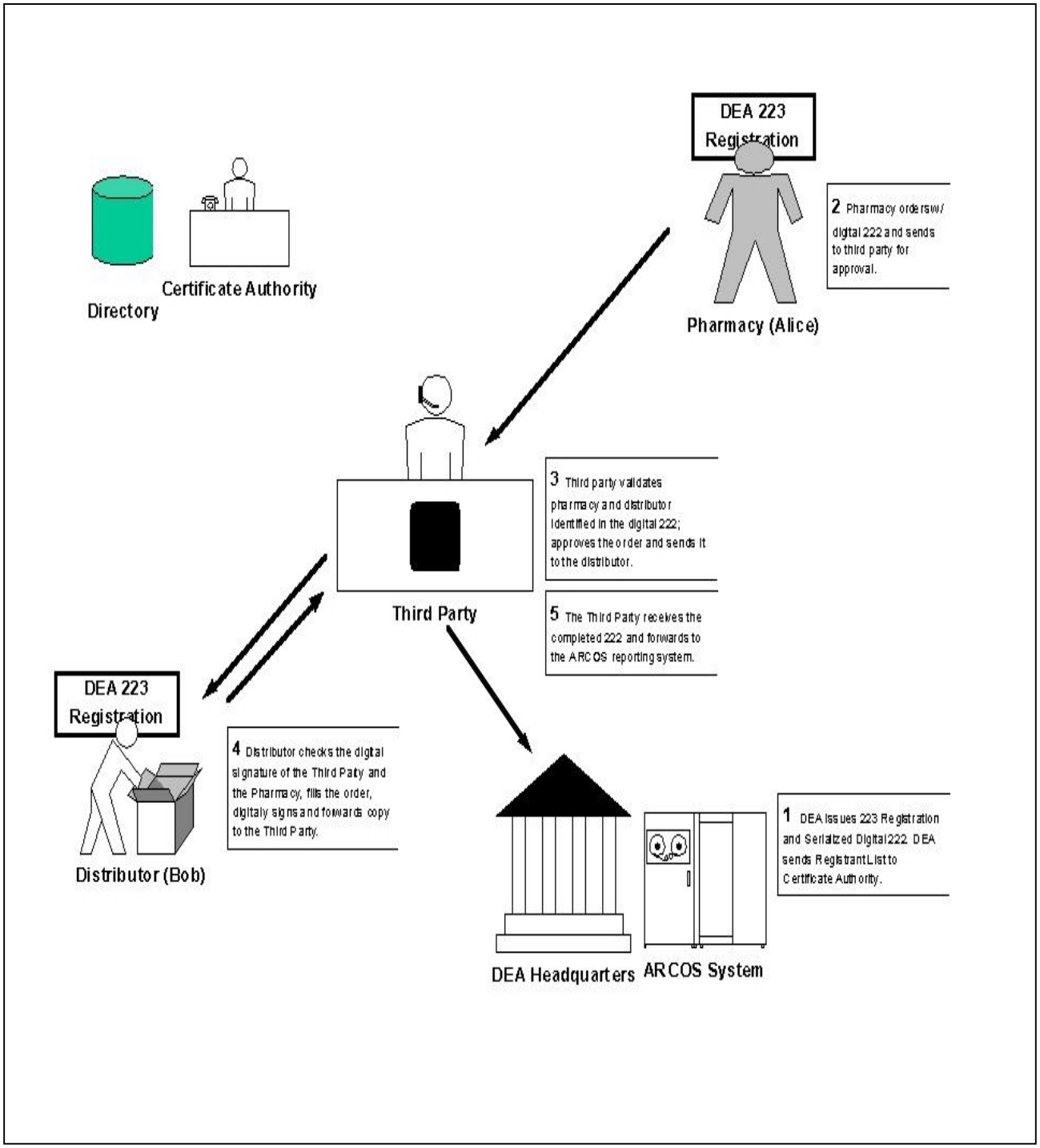

Figure 8. High Level Design Concept 2

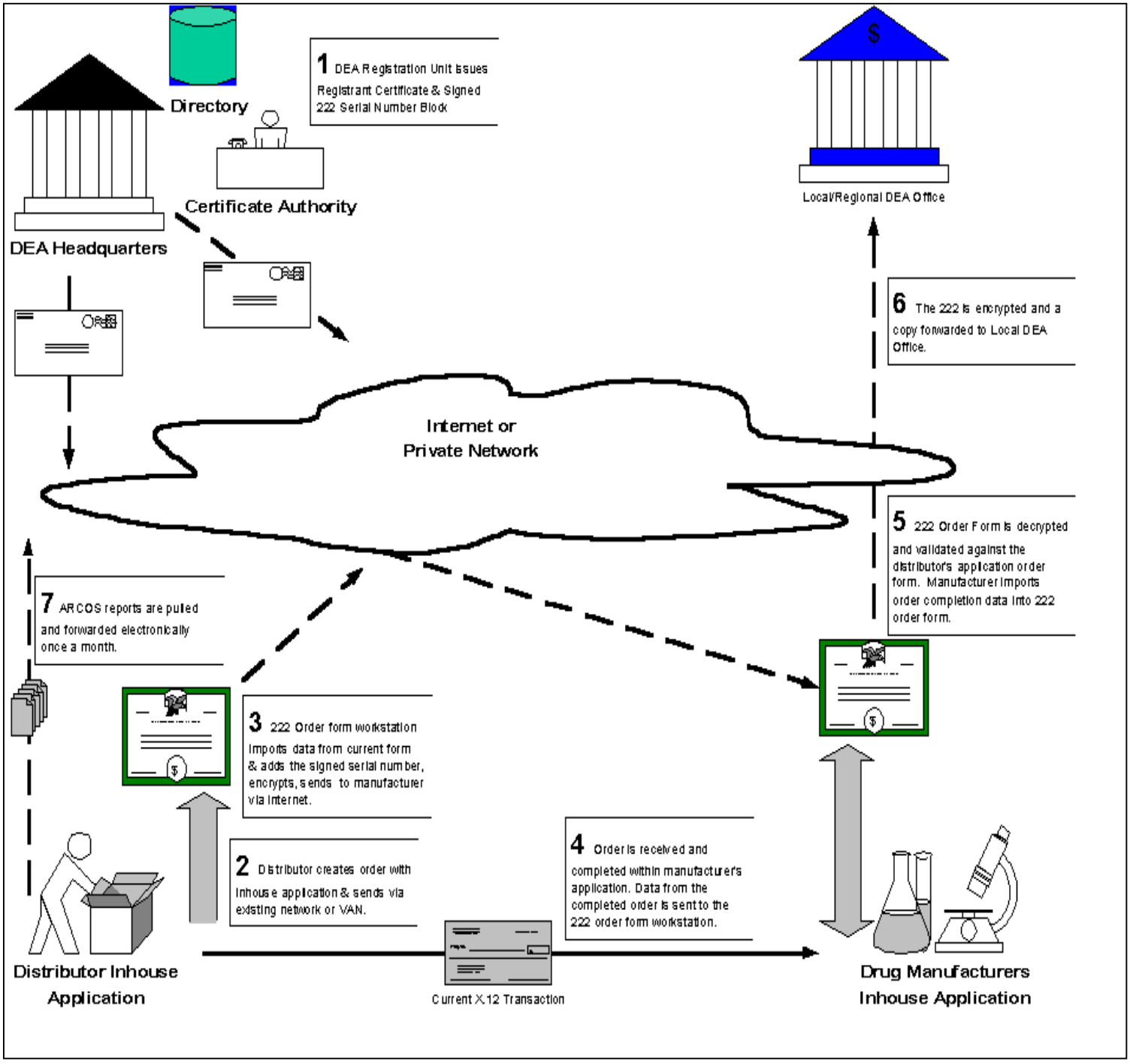

Figure 9. High Level Design Concept 3

2.7 Impact of Improved Regulatory Processes for Industry and DEA

The following are the collected responses from industry groups as to the impact of an improved regulatory process for their organization. These are provided in order of frequency of response.

Industry

- Time and Labor Savings
- Improved Customer Service
- Better Inventory Control
- Eliminate Human Errors
- Lower Potential for DEA Fines
- More Secure Process
- Less Product on the Shelf
- More accurate/timely Information for ARCOS
- More efficient use of Pharmacists' Time

DEA

The following are the collected responses from DEA representatives as to the impact of an improved regulatory process for the DEA. These are provided in order of frequency of response:

- Form DEA 222 Form information available more quickly
- More approval from Industry of DEA process
- Improved accuracy in record-keeping
- Less paper to inventory and store

3. Analysis and Derived Requirements for Existing Network Infrastructure

3.1 Prioritization of Stakeholder Requirements

Upon the completion of the interviews and review of the information gathered, it is evident that the impact of the current DEA 222 Form ordering process is felt most by two groups- the Distributors and the Chain Drug Stores. The volumes they experience, especially on the ***Supplier*** side (pharmacy customer to distributor) far exceed the volumes experienced by any other Stakeholder group. It is to be noted that these other Stakeholders- Manufacturers, Independent Pharmacies and HMOs did not feel the same level of paper burden and desire to change to a new system for Controlled Substances ordering. Manufacturers, Independent Pharmacies and HMOs exhibited much more of a "wait and see" attitude towards any new system.

These other Stakeholder groups- Manufacturers, Independent Pharmacies and HMOs- may have interest in an electronic option to the regulatory requirement, but do not have a situation where a change from the paper system is vital to commerce and corporate growth. Therefore it is suggested that a prioritization scheme be developed to help guide design requirements.

Creating this prioritization scheme will be very useful should conflicts arise among Stakeholder groups making it impossible to meet all Stakeholder groups requirements. Therefore, by placing those Stakeholder groups - Distributors and Chain Drug Stores- requirements at a higher level, those that are impacted the most by the current process will be considered first.

Below is a high level analysis of each Stakeholder group's general position towards important aspects of this project that may influence their acceptance of any particular design option. These designations are based upon comments and general impressions gained through our research.

This document uses the term ***"DEA Electronic Reporting Form"*** to generally describe the subset of data contained in an industry order that will be reported to DEA. This subset of data will approximate the data found in the paper DEA 222 Form.

Stakeholder Group's General Position Towards Project Aspects

	Manufacturers	Distributors	Chain Drug Stores	Pharmacies	HMOs and Others	DEA
Impact of Current Process on Operations	Medium	High	High	Low	Low	Medium
Acceptance of Technology	High	High	High	Low	Medium	Medium
Motivation/Desire to Change	Medium	High	High	Low	Low	Medium
Investment in Technology Infrastructure	High	High	High	Low	Medium	Medium
Sensitivity to IT Costs	Medium	Low	Low	High	Medium	Medium

Table 2. Stakeholder Group's General Position Towards Project Aspects

3.2 DEA High Level Design Requirements/Constraints

DEA provided PEC at the on set of this project with some initial high-level design requirements and constraints for this project:

- The MADI PKI will include the current order form process and provide for the potential inclusion of the quarterly reporting process.
- The MADI PKI will need to have the functionality of the current DEA 222 Form in a software application that will use the certificate generated by the CA. This application 1) may already exist in industry 2) may exist in a COTS solution or 3) may require an application development effort.
- Achieving industry consensus will be an important aspect of this project. DEA may consider creating a technical/focus group for this project consisting of industry representatives and DEA personnel.
- The DEA Firebird network will not be involved in the MADI PKI.
- The serial number and the DEA indicia are not legally required to be a part of the DEA 222 Form or the electronic DEA reporting form.
- The electronic DEA reporting form will only be an option; the current paper process will remain for those that choose to continue to use it.

3.3 Controlled Substances Business Process Requirements

For Industry, information technology is a vital part of the success of their organization. It is often the sole factor in their ability to distinguish themselves in the marketplace and gain competitive advantage over others in the marketplace. Industry registrants have substantial investments in their business processes and the technology infrastructures that support those processes.

The business process requirements for the electronic DEA reporting form fall into the following general categories, with the specific detail level requirements listed in a table at the end of this section. These requirements are not prioritized at this time.

REQUIREMENT: Ability to leverage existing processes and in-place systems to the fullest extent.

Industry Stakeholder groups currently use very sophisticated supply chain management software to manage the process of ordering, distributing, securing and accounting for Controlled Substances. Therefore, any new system must provide the features, business logic and efficiencies of their current supply chain management systems. Ability to leverage current ordering processes and have the same business logic as is now present is a key factor to acceptance of any new system.

REQUIREMENT: Ability to produce and process orders quickly, easily, efficiently and accurately.

Transaction volumes of DEA 222 Forms are very high and will continue to increase due to market factors such as the aging population and new products being brought to market. The ability to handle large and increasing transaction volumes is very important in providing improved customer service levels to all customers in the process- Manufacturer to Distributor to Pharmacy to Patient. The Stakeholders do not want additional obstacles or checks added to the process that do not add value to the process. The Stakeholders' measure of turnaround time is gauged against any other order placed in their current system. The electronic DEA reporting form must have substantially the same turnaround time.

The electronic DEA reporting form must be very easy to use and require little or no training. It must not place additional burdens of time or technical difficulty on users of the system.

REQUIREMENT: Ability to determine on a registrant-by-registrant basis if the new electronic DEA reporting form option is appropriate for their organization.

The Stakeholders want the ability to determine through individual cost benefit analysis if the electronic DEA reporting form process will be an improvement for their organization. As is discussed earlier in Section 3.1, several Stakeholder groups have no problem with the current system and believe that the new system may impose unnecessary costs and

changes to their organizations. Several Stakeholder groups expressed reservations with technology in general, and its inherent problems and costs.

3.4 Existing Information Technology Infrastructure Requirements

3.4.1 Network Architecture Requirements

REQUIREMENT: Ability to operate in a distributed network environment with such network architectures as Token Ring, SNA, and VANs.

REQUIREMENT: Ability to utilize multiple protocols (TCP/IP, EDI) and communication modes (Frame Relay and ATM).

The existing network architectures currently utilized by the Stakeholder groups within their organizations are varied and highly customized. All forms of network architectures, protocols and transmission methods are used. Electronic communication between the Stakeholder groups is generally accomplished through dial-up connections, direct line to trading partner or EDI over a VAN. The diagram below illustrates the general types of communication methods now employed between the major Stakeholder groups.

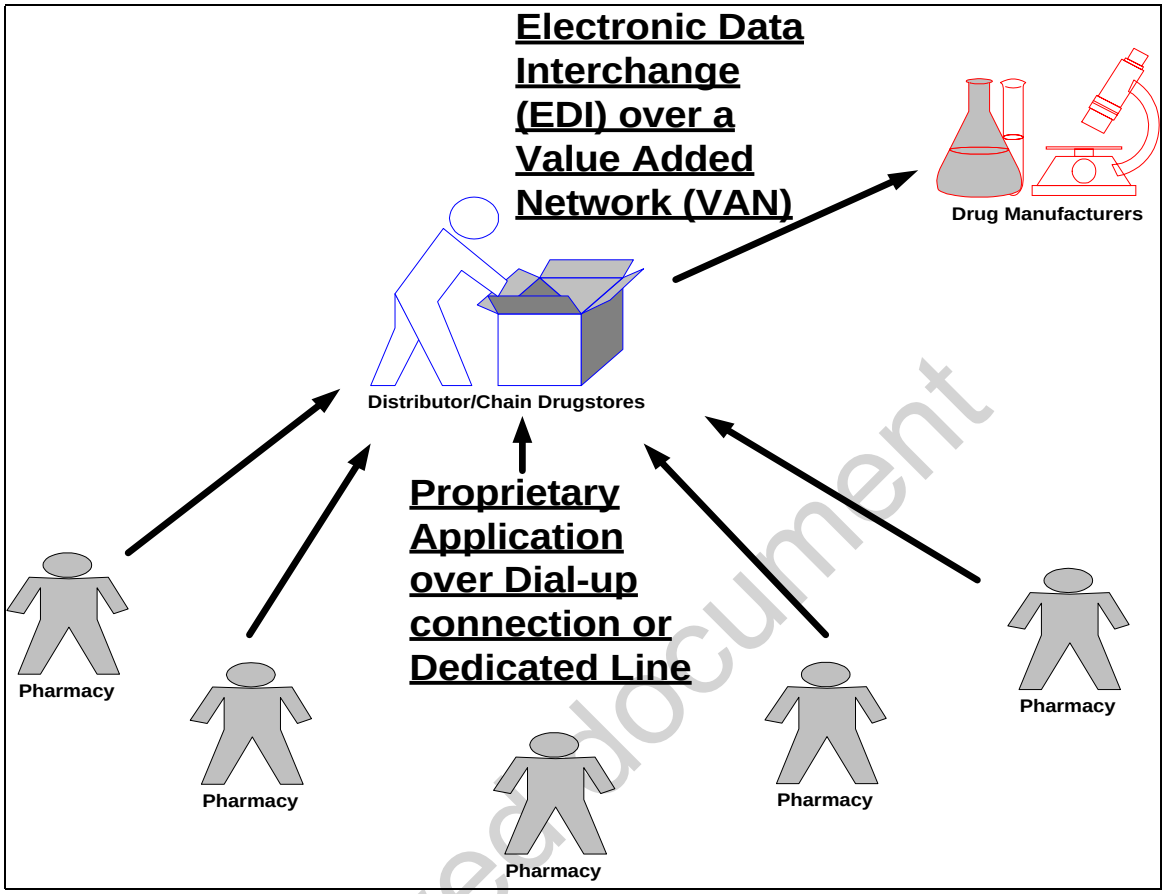

Figure 10. Existing Network Architectures Between Industry Trading Partners

There is at present essentially no business conducted between industry Stakeholder groups over the Internet. Conducting Internet business requires a substantial change to an organization's business processes and IT architecture. Therefore, at this time, there is no requirement for an Internet type solution. As Internet technologies and business processes mature, an Internet type solution will become more appropriate.

REQUIREMENT: Ability to move electronic DEA reporting form information from registrants to the ARCOS system.

At present DEA OD users utilize the Firebird Network to gain access to information in the CSA and ARCOS databases. Per an earlier design constraint, the MADI PKI will not be directly connected to the Firebird Network but will have the ability to move information from the MADI PKI to the Firebird Network. The content and form of that information is yet to be determined. Full exploitation of PKI technology and automation may require middleware for the current ARCOS system or a new type of ARCOS system.

3.4.2 Systems Architecture- Hardware and Software Requirements

REQUIREMENT: Ability to operate on existing central servers platforms such as IBM AS/400 with IBM compatible end user personal computers, workstations, terminals and laptops.

The Stakeholder groups (Manufacturers, Distributors and Chain Drug Stores) were very consistent in the use of central server technology and end user devices that access the central server. Pharmacies were divided in their use of Distributor provided personal computers and Telxon units. Several Distributors indicated that the Telxon units may be phased out.

REQUIREMENT: Ability to utilize existing in-house proprietary supply chain management software as the application to be PKI enabled.

The Stakeholder groups (Manufacturers, Distributors and Chain Drug Stores) were very consistent in the use of internally developed supply chain management software. These applications are very sophisticated and designed to the specific needs of individual Stakeholder's businesses.

These applications also have substantial business logic that is specific to the current DEA 222 Form ordering process:

- Ability to check status of DEA registration and renewal dates.
- Ability to check status of State registration and renewal dates.
- Ability to determine if the order to be placed is "normal" for that customer (checks against customer's profile of previous orders and other similar customers for suspicious order filing).
- Ability to check to customer's limitations to specific Controlled Substances schedules.
- Ability to produce on demand historical reporting for any customer.

Pharmacies are provided use of Distributor client software to place orders and benefit from the ability to use this software.

3.5 Information Technology Organization, Administration and Technical Support Requirements

Industry Stakeholders depend upon their IT assets and resources to operate their businesses. This requires that the internal IT groups responsible for the IT operations be fully accountable for those IT operations. Manufacturers, Distributors, Chain Drug Stores and HMOs have very large and sophisticated IT organizations that are centrally managed. This type of organization creates a single point of contact for problems and failures. This is

generally accomplished by a Help Desk that is available 24 hours a day 7 days a week that can either remotely diagnose and remedy the problem, or dispatch someone to the site.

REQUIREMENT: The MADI PKI will need to be centrally managed and provide a single point of contact for users on a 24 hour 7 day a week basis to manage all aspects of the system and any problems that may arise.

The MADI PKI will require a centrally managed organization that can manage all aspects of the system and process. It will need to provide a single point of contact for managing registration to the PKI, training issues, and hardware and software problems.

3.6 Information Technology Security Requirements

Both the DEA and Industry Stakeholder groups take information security very seriously and exercise prudent care and take measures to insure that information assets and resources are secure and available when needed.

3.6.1 Physical Security and Disaster Recovery Requirements

REQUIREMENT: The MADI PKI and any associated applications using the MADI PKI, must be available to registrants with certificates on a 24 hour 7 day a week basis.

DEA and Industry Stakeholder groups use substantial investments in on site physical security, backup measures and disaster recovery sites. As the DEA 222 Form ordering process is vital to conducting commerce, the physical measures to protect the MADI PKI must at a minimum, be the same measures used to protect current information assets and resources.

3.6.2 Logical Information Technology Security Requirements

DEA and Industry Stakeholder groups currently use very sophisticated logical system methods to control access, confidentially and integrity of information assets and resources.

REQUIREMENT: Ability to limit and restrict access based upon roles and functions down to the row level and log all actions taken on the system.

DEA and Industry Stakeholder groups utilize access control lists, authorization servers, firewalls, passwords, access to screens, information, application functions through role based security. They also require the ability to audit/archive all actions taken on an order down the authorized user level.

3.6.3 Information Technology Security Policy and Auditing Requirements

REQUIREMENT: Provide registrants with written Security Policy for MADI PKI users and scheduled system auditing procedures and timetable.

Stakeholder groups largely expect some type of formal policy for the MADI PKI from the DEA and will incorporate that into their existing IT Security Policies. All groups expect scheduled system audits and will want a schedule associated with that- yearly, bi-annually, etc.

3.7 Current Use of PKI and Encryption Technologies

REQUIREMENT: The MADI PKI will be designed for a single type of transaction, the electronic DEA reporting form that will be communicated between industry registrants and DEA. The MADI PKI need not be available for other uses.

There currently exists only very limited use of PKI and encryption technologies amongst the industry groups. Those applications involve consumer type transactions and most likely can not be utilized for a business-to-business type transaction. As use of PKI and encryption technologies are not prevalent in the industry Stakeholder groups, there are no standards, policies or infrastructure that can be leveraged for use in the MADI PKI.

4. Background and High Level Requirements Table

In addition to the requirements for the services provided in a PKI, there are requirements for business processes, both DEA and Industry, and system requirements. The requirements listed here represent a combination and compilation of high level existing network infrastructure elements gained through interviews, meetings and documentation of the Stakeholders both in Industry and DEA. These requirements are not exhaustive nor comprehensive, but represent a general view of the existing network infrastructure both now and in the near future.

These high level requirements will provide the guidance necessary to produce the Concept of Operations for the MADI PKI to leverage the existing business processes and systems to the maximum extent. It is recognized that it may not be possible to meet all requirements listed here in a single, universal design. As individual designs for the Concept of Operations are developed, the inclusion of these requirements will be measured against their ability to provide the maximum user acceptance. It should also be noted that these requirements will need to be reviewed periodically to maintain their validity.

In conclusion, there is commonality among the Stakeholders in the methods of operation surrounding the handling and documenting of Controlled Substances. There is a substantial variance though, in the types of networks, hardware, software and management of technology being used among the various Stakeholders. Therefore the design standards brought forward in the Concept of Operations will need to cover and extend to (ie. be elastic) a multitude of different technology choices. This design “elasticity” will help to promote the maximum degree of Stakeholder acceptance, and assure a faster implementation within the Stakeholder community.

At this stage of the project and with a better understanding of the complexities involved in solving the business problem for DEA, the entire system might better be represented as the "Controlled Substances Ordering System". The entire "Controlled Substances Ordering System" is composed of three major components- the PKI, the ordering application, and the ARCOS reporting system- each existing independent of the other but dependant on each other to provide all the necessary services. Recognizing that the PKI that will enable the business to occur is one component of the entire system, and that the ordering application and the ARCOS reporting systems together with the PKI comprise the complete system.

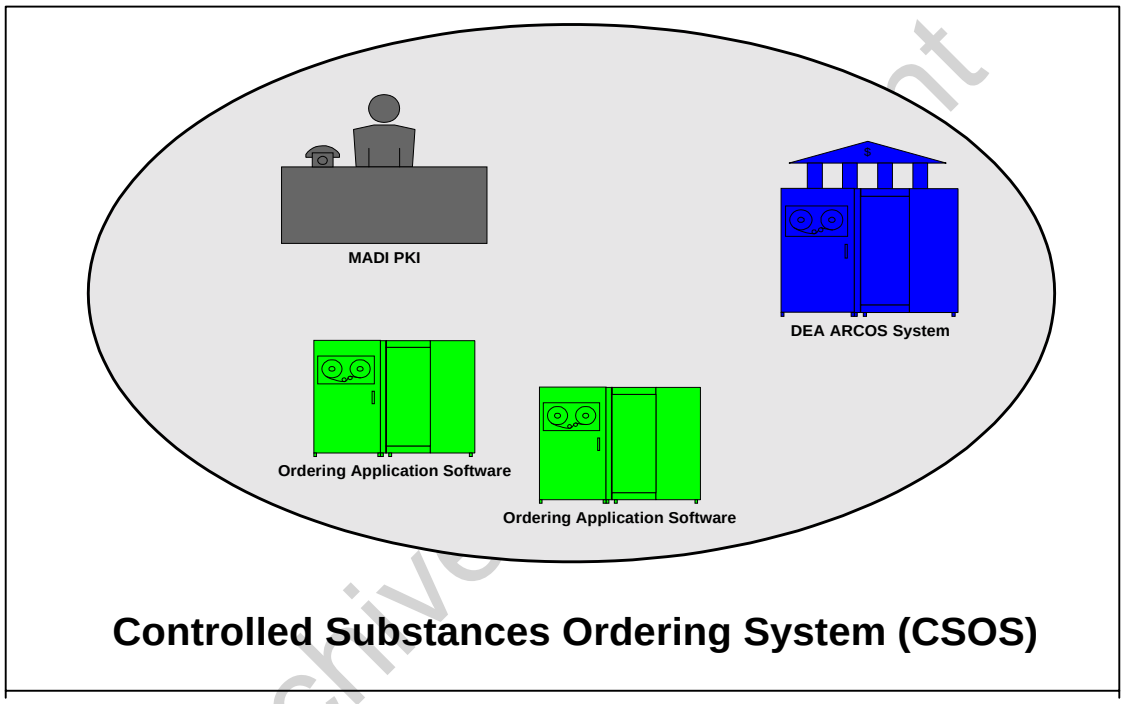

Figure 11. Controlled Substances Ordering System (CSOS)

	Business Process and System Requirements
REQUIREMENT	Ability to leverage existing processes and in-place systems to the fullest extent.
REQUIREMENT	Ability to produce and process orders quickly, easily, efficiently and accurately.
REQUIREMENT	Ability to determine on a registrant by registrant basis if the new electronic DEA reporting form option is appropriate for their organization.
REQUIREMENT	Ability to operate in a distributed network environment with such network architectures as Token Ring, SNA, and VAN.
REQUIREMENT	Ability to utilize multiple protocols (TCP/IP, EDI) and communication modes (Frame Relay and ATM).
REQUIREMENT	Ability to move electronic DEA reporting form information from registrants to the ARCOS system.
REQUIREMENT	Ability to operate on existing central servers platforms such as IBM AS 400 with IBM compatible end user personal computers, workstations, terminals and laptops.
REQUIREMENT	Ability to utilize existing in-house proprietary supply chain management software as the application to be PKI enabled.
REQUIREMENT	The MADI PKI will need to be centrally managed and provide a single point of contact for users on a 24 hour 7 day a week basis to manage all aspects of the system and any problems that may arise.
REQUIREMENT	The MADI PKI and any associated applications using the MADI PKI, must be available to registrants with certificates on a 24 hour 7 day a week basis.
REQUIREMENT	Ability to limit and restrict access to systems based upon roles and functions down to the field level and log all actions taken on the system.
REQUIREMENT	Provide registrants with written Security Policy for MADI PKI users and scheduled system auditing procedures and timetable.
REQUIREMENT	The MADI PKI will be designed for a single type of transaction, the electronic DEA reporting form that will be communicated between industry registrants and DEA. The MADI PKI need not be available for other uses.

Table 3. High Level Business and System Requirements Table

Appendix A- List of Interviews, Site Visits, Meetings and Conferences

Manufacturers

Abbot Laboratories Abbot Park, Illinois	• Marieta Neiss, Director Controlled Substance Corporate Regulatory Affairs
Mallinckrodt St. Louis, Illinois	• Karen Harper, DEA Compliance Coordinator • Ted Loucks, Information Services Group • Jack Frauenhoffer, Interim Compliance Manager • Joan Levy, Director of Administration for Dosage Products
Wyeth- Ayerst Cherry Hill, New Jersey	• Peaches Larro, Associate Director Controlled Substance Compliance
Noramco Wilmington, Delaware	• Ann Strusowski, Compliance Coordinator
Novartis East Hanover, New Jersey	• Tracey Hernandez, DEA Auditor • Earl Calloway, Systems Consultant IT • Dave Krozser, EDI Specialist • Lorretta Wolf, Manager EDI (Business Department) • John Renolds, Distribution Coordinator • Jan Hodge, Customer Service Representative
Barr Laboratories Northvale, New Jersey	• Dave Mendelsohn, Director of Security/DEA Affairs • Ralph Goldstein, IT Specialist

Distributors

Barnes Wholesale Drug Engelwood, California	• Robert Swartz, CEO • Angelo Grandi, Operations Manager

McKesson HBOC	• Donald Walker, Senior Vice President Distribution • Bruce Russell, Vice President Distribution and Operations • Gary Hilliard, Director of Regulatory Affairs • Tom McGill, IT Systems • Richard Wood, Distribution Center Manager
Cardinal Health	• Rodney Waller, Vice President Corporate Compliance • Steve Reardon, Director Corporate Compliance • Carol Verrastro, Manager Customer Service • Jill Flieman, Manager EDI
Bergen Brunswig Drug Company Orange, California	• Jim Snyder, Vice President Operations • Chris Zimmerman, Director Regulatory Compliance and Security Services • Leia Andrews, Manager EDI Technologies • David Tessman, Manager IT • Brian Jones, Manager IT • Katherine DeVera, Manager Customer Service • Jim McLaughlin, Research and Development • Tom Bergman, Project Systems Specialist • Danny Moore, Distribution Center Manager
The F. Dohman Company Minneapolis, Minnesota	• Francis Charland, Vice President Compliance • Steve Strobel, Manager Purchasing • Steve Deloat, Manager IT Group
Walsh Distribution Texarkana, Texas	• Randy Wilson, Vice President Purchasing • Tina Emilia, EDI Coordinator

Chain Drug Stores

Eckerd Corporation Largo, Florida	• Mickey Carter, Director of Loss Prevention and Regulatory Compliance • Ken Fisher, Manager IT
Giant Food Incorporated Landover, Maryland	• Sheldon Pelovitz, R.Ph., Director Pharmacy Professional Services • Mark Stachowski, Manager EDI Systems Development

Rite Aid Corporation Harrisburg, Pennsylvania	• Janet Getzey Hart, R.Ph., Manager Government Affairs • August J. Dobbish, R.Ph., Esquire, Manager Government Affairs
Publix Super Markets Lakeland, Florida	• Ron Miller, Director of Pharmacy Operations
CVS Corporation Woonsocket, Rhode Island	• Bill Masters, Vice President of Health Care Business • Carlos Ortiz, Government Affairs • Linda Cimpbron, Licensing Manager • Scott Jacobson, Operations Analyst • John Rinkas, Information Systems Security Audit Manager • Mike McGint, Director Internal Audit • Russ Pierce, Security Administrator
Walgreen Company Deerfield, Illinois	• Audrey H. Neely, R.Ph., Manager Professional Affairs Health Services • Dwyne Pinon, Attorney • Jim Ash, Pharmacy Marketing and Inventory Control • Trish Smith, Centralized Purchasing • John Martello, IT Group

Pharmacies

National Community Pharmacists Association Alexandria, Virginia	• B. Douglas Hoey, R.Ph., M.B.A., Associate Director Management, Professional, and Student Affairs
Academy of Managed Care Pharmacy Alexandria, Virginia	• Richard N. Fry, R.Ph., Senior Director of Pharmacy Affairs • Merle S. Fossen, Pharm. D., Pharmacy Affairs Manager
McArthur Drugstore Washington, DC	• Roy Goldstone, Pharmacist

Associations

National Association of Chain Drugstores Alexandria, Virginia	• Mary Ann Wagner, Director • Brian Gallagher, R.Ph., J.D., Director, Pharmacy Regulatory Affairs
National Wholesale Druggists' Association Reston, Virginia	• Diane P. Goyette, R.Ph., J.D., Director Regulatory Affairs • Robert Borger, Director, Standards and Guidelines
Food Marketing Institute Washington, D.C.	• Ty Kelley, Director Government Affairs
National Association of Boards of Pharmacy Park Ridge, Illinois	• Carmen Catizone, Executive Director

Other Registrant Types

American Methadone Treatment Association New York, New York **CODAC Treatment Center** Cranston, Rhode Island	• Michael Rizzi, Director
George Washington Health Plan (HMO) Bethesda, Maryland	• Dr. John Zatti, Pharmacy Operations Consultant
Merck Medco	• Robert Swartz, Compliance Manager

DEA Office of Diversion Control

Terrance W. Woodworth, Deputy Director
Patricia Good, Chief Liaison and Policy Section
Jim Pacella, Chief Regulatory and Program Support Section
Michael Moy, Chief Drug Operations Section
Michael Mapes, Deputy Chief Liaison and Policy Section
Elizabeth Willis, Deputy Chief Operations Section

Denise Curry, Chief Liason Unit
Sharon K. Partlo, Chief Policy Unit
Terrance Boyle, DPM DEA ODC, New Orleans, Louisiana
Larry Lockhard, Supervisor, DEA ODC Birmingham, Alabama

Site Visits, Meetings, Conferences and Seminars

May 10, 1999 DEA and Industry MADI PKI Project Kick Off Meeting
July 1-2, 1999 NWDA Productivity and Technology Conference
August 12, 1999 Midwest Controlled Substance Handlers Meeting
September 14, 1999 Bindley Western Distribution Center Site Visit
September 20, 1999 Rite Aid Corporation Site Visit
September 21, 1999 NWDA Technical Working Group Meeting
October 19, 1999 Bergen Brunswig Distribution Center Richmond Virginia
October 21, 1999 McKesson HBOC Distribution Center Landover Maryland
November 16, 1999 NWDA Compliance Working Group Meeting

Appendix B- List of Documents Reviewed

Author	Title	Date	Source
Adams, C. Farrell, S.	Internet X.509 Public Key Infrastructure; Certificate Management Protocols	March 1999	http://www.ietf.org/rfc/rfc2510.txt
American Management Systems, Inc. (AMS)	Analysis of Electronic Data Interchange	May 25, 1990	AMS Deliverable 3.1
Arsenault, A. Turner, S.	Internet X.509 Public Key Infrastructure PKIX; Roadmap	October 22, 1999	http://search.ietf.org/internet-drafts/draft-ietf-pkix-roadmap-04.txt
Baroni, Tracy	Changes to CFR Section 1300	January 8, 1998	National Associating of Chain Drug Stores (NACDS)
Bukar, Nancy	National Wholesale Druggists' Association's Comments	September 18, 1998	National Wholesale Druggists' Association (NWDA)
Chokhani, S. Ford, W.	Internet X.509 Public Key Infrastructure; Certificate Policy and Certificate Practices Framework	March 1999	http://www.ietf.org/rfc/rfc2527.txt
DEA's Office of Diversion Control	Pharmacist's Manual 8th Edition	March 12, 1999	Controlled Substances Act of 1970
DEA's Office of Diversion Control	Prescription Accountability Resource Guide	September 1998	Prescription Programs Resource Guide

DEA's Office of Diversion Control	Technological Advances to Enhance Diversion Programs	January 1995	DEA
Ford, W. Housley, R. Polk, W. Solo, D.	Certificate and CRL profile; Internet X.509 Public Key Infrastructure	October 22, 1999	http://www.ietf.org/internet-drafts/draft-ietf-pkix-new-part1-00.txt
Kocot, Lawrence S.	Testimony by NACDS	August 6, 1998	NACDS
Leibovich, Mark	Certified Mail Web-Style	Unknown	Washington Post
Management of Federal Information	Office of Management and Budget	March 5, 1999	Federal Register
Muirhea, Greg	New program reveals whether the patient filled the Rx	June 26, 1995	Drug Topics
Schultz, William B.	FDA rules and regulations	March 20, 1997	Federal Register Vol. 62, No. 54
Shirey, R.	Security Glossary	October 17, 1999	http://search.ietf.org/internet-drafts/draft-shirey-security-glossary-01.txt
Stieghorst, Tom	Prescriptions can be written on-line	July 31, 1995	Sun-Sentinel
Treasury Board of Canada Secretariat	Digital Signature and Confidentiality; Certificate Policies	April 1999	GOC PKI Certificate Policies Version 3.02
Unknown	Electronic Prescriptions	November 19, 1998	NACDS

Unknown	Supplementary issue in NACDS Proposal to change 1306	January 8, 1997	Unknown
Unknown	Capitalizing on an opportunity	November 1995	Health Data Management Vol. 3, No. 10
Unknown	ProxyMed Expands its Electronic Scripts Reach	Unknown	Health Data Network News
Wagner, Mary A.	Proposed Amendments to CFR 1306	October 31, 1997	Mary Ann Wagner

Appendix C- Detail Level Requirements Table

New system must be faster than current paper system.	Associations	Business Process
New system must cut costs of current paper system.	Associations	Other
New system must provide better service for the customer.	Associations	Other
New system must eliminate paper.	Associations	Technology
New system must be electronic.	Associations	Technology
A separate web based system would be an ideal solution.	Chain Drug Stores	Technology
Simultaneously capture transmissions in an acceptable format that satisfies all recordkeeping & reporting requirements.	DEA	Business Process
Maintain the integrity of the CSA's "closed system of distribution".	DEA	Business Process
The new application (software) does not have to be an absolute replacement for the paper 222.	DEA	Business Process
New system should not disrupt current legacy processes.	DEA	Business Process
DEA may or may not be a part of solution/system.	DEA	Business Process
DEA wants the 222 process to be seamless for industry.	DEA	Business Process
Ability to forward some completed 222s to state and local authorities.	DEA	Business Process
The MADI PKI must fulfill the current legal requirements.	DEA	Business Process
POC period should be short and solution should be taken live ASAP.	DEA	Other

Provide similar or even greater degrees of reliability & validity than the paper based system currently in use.	DEA	Security
The paper 222 will remain as the primary option for regulatory compliance.	DEA	Security
Easily adaptable system (adapts to industry environment).	DEA	Technology
Biometric devices & smart cards may be cost prohibitive, & only used for a subset of registrants.	DEA	Technology
X.12 EDI method has what is needed in an application.	DEA	Technology
MADI project will define a set of standards.	DEA	Technology
The MADI PKI will have no connection to Firebird; if any information is needed it will be air gapped over.	DEA	Technology
Schedule 2 records must be maintained separately from records of Schedule 3-5, and from other business records, and must be in a readily retrievable form.	DEA	Security
Improve turnaround time for controlled substance orders.	Distributors	Business Process
ARCOS reporting should be included in the new system.	Distributors	Business Process
Ability to provide generic drug substitutions on the 222.	Distributors	Business Process
Ability to respond to a controlled substance order upon receipt.	Distributors	Business Process
Automatically generate correct addresses.	Distributors	Business Process
Ability to make 222s more accurate with business rules.	Distributors	Business Process
New process should not be a clearinghouse.	Distributors	Business Process
Need ability to do next day orders for controlled substances.	Distributors	Business Process

Improve productivity surrounding the 222 process.	Distributors	Business Process
Ability to secure the document so that it can't be altered.	Distributors	Security
New system must accommodate 300+ transactions per day.	Distributors	Technology
No disruption to current legacy ordering/inventory systems.	Distributors	Technology
The 222 should have business logic incorporated in the form so that erroneous entries can't be made.	Industry	Business Process
The new system should be a Non Proprietary System.	Industry	Technology
Ability to use within the existing EDI transactions (X.12 standard).	Industry	Technology
New system should use commercial standards and not be a proprietary system.	Industry	Technology
Ability to use existing technical infrastructures (registrants).	Industry	Technology
Ability to have customer fill out just the NDC number versus the written drug name.	Manufacturers	Business Process
Consideration should be given to permitting partial/multiple shipments from the same order.	Manufacturers	Business Process
Consideration should be given to providing for partial/multiple receipts for an order.	Manufacturers	Business Process
Consideration should be given to allowing purchasers to use their present receiving systems.	Manufacturers	Business Process
Order, shipment and receipt information should be able to be maintained electronically.	Manufacturers	Business Process
Record retention time should be no longer than the current retention time.	Manufacturers	Business Process
New system needs to accommodate internal transfers (company to company).	Manufacturers	Business Process
Business rules need to be included in the software that would track DEA imposed drug quotas.	Manufacturers	Business Process

New system must accommodate internal transfers of controlled substances.	Manufacturers	Business Process
If notification to DEA of shipping information continues to be required with the electronic system, notification should be electronic and should only be required to be sent to one central DEA location.	Manufacturers	Business Process
Ability to edit or reject a line item.	Manufacturers	Business Process
The order system design must be flexible to allow alternate means of identifying the product ordered, e.g., NDC number, catalog number, written description of product.	Manufacturers	Business Process
Consideration should be given regarding endorsing an order to another supplier (this is permitted utilizing a paper DEA 222 order form).	Manufacturers	Business Process
Ordering process should provide for an electronic purchaser Certification of Available Procurement Quota for raw drug ordered by a manufacturer.	Manufacturers	Business Process
Orders must not be routed through the Certification Authority or DEA.	Manufacturers	Business Process
If ARCOS reporting is allowed along with the new electronic order system, traditional ARCOS reporting methods should be allowed for those companies that chose that form of reporting.	Manufacturers	Business Process
Requirements for records should be limited to current record retention time.	Manufacturers	Business Process
Registrants must not be required to use the electronic order system instead of a paper DEA 222 order form.	Manufacturers	Business Process
Ability to integrate registrant's current order systems (whether EDI or other) with 222 order system.	Manufacturers	Business Process
New system must accommodate bulk drug shipments for packaging by others.	Manufacturers	Business Process
Ability to do multiple shipments against a single 222.	Manufacturers	Business Process
Consideration should be given to allowing substitution, e.g., shipment of 5 x 100 when 1 x 500 is ordered. NOTE: This is currently allowed by DEA guidelines. This involves shipping a package size with a different NDC number than what was ordered.	Manufacturers	Business Process

Incorporate EDI into the new system.	Manufacturers	Business Process
Shorten the cycle time from order entry to time distribution center receives the order.	Manufacturers	Business Process
New system should eliminate separate ARCOS reporting.	Manufacturers	Business Process
Consideration should be given to permitting the record to be maintained at a central location.	Manufacturers	Business Process
Consideration should be given to voiding or cancellation of orders.	Manufacturers	Business Process
Allow pre-defined data sets to be used by both DEA and registrants for multiple purposes.	Manufacturers	Business Process
Order processing design should include a date/time identifier and unique number.	Manufacturers	Business Process
Consideration should be given to creating a complete order history record.	Manufacturers	Business Process
Consideration should be given to permitting order correction after the transmission has been made.	Manufacturers	Business Process
Ability to query against all 222s issued.	Manufacturers	Business Process
All system elements and implementation methods must be designed in with cost effectiveness in mind.	Manufacturers	Other
Ensure that transmission of data is secure since data contains proprietary information.	Manufacturers	Security
Ability to verify automatically current registration.	Manufacturers	Security
The DEA registrant information should be deemed valid for the supplier as a part of the incoming order in the new system.	Manufacturers	Security
Ability to do multiple endorsement for operations with multiple ship sites.	Manufacturers	Security
Ability to endorse the 222 over to another sister company.	Manufacturers	Security
Any encryption should be utilized for transmission only.	Manufacturers	Security

If software is provided by DEA- it must be validated by DEA.	Manufacturers	Security
If dedicated lines are utilized, encryption should not be required.	Manufacturers	Security
Certificate Authority should have redundant computer systems or the equivalent to protect against system unavailability.	Manufacturers	Technology
Certificate Authority should have a disaster recovery plan.	Manufacturers	Technology
Provide the flexibility to be able to use current existing closed (dedicated lines) systems and open (Internet) systems as well.	Manufacturers	Technology
Ability to move 222 info in the legacy ordering/inventory system.	Manufacturers	Technology

Appendix D– Document Acronyms

ACF	Access Control Facility
ARCOS	Automation of Reports and Consolidated Orders System
ATM	Asynchronous Transfer Mode
CA	Certification Authority
CN	Common Name
CONOPS	Concept of Operations
COTS	Commercial Off the Shelf
CP	Certificate Policy
CPS	Certification Practice Statement
CRL	Certificate Revocation List
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DN	Distinguished Name
EC	Electronic Commerce
EDI	Electronic Data Interchange
FIPS	Federal Information Processing Standard
FPKI	Federal Public Key Infrastructure
GEIS	General Electric Information Systems
GOC	Government of Canada
GPEA	Government Paperwork Elimination Act of 1999

HMO	Healthcare Maintenance Organizations
ID	Identification
IETF	Internet Engineering Task Force
IP	Internet Protocol
IT	Information Technology
LAN	Local Area Network
LDAP	Lightweight Directory Access Protocol
MADI	Manufacturers and Distributors
MOU	Memorandum of Understanding
NDC	National Drug Code
NTIS	National Technical Information Service
OD	Office of Diversion Control
OMA	Operations Management Authority
PKC	Public Key Certificate
PKI	Public Key Infrastructure
PMA	Policy Management Authority
POC	Proof of Concept
POP	Proof of Possession
RA	Registration Authority
RACF	Resource Access Control Facility
RFC	Request For Comment

RSA	Rivest Shamir Adleman
SNA	Systems Network Architecture
TCP/IP	Transmission Control Protocol / Internet Protocol
UID	Unique Identifier
VAN	Value Added Network
VPN	Virtual Private Network
WAN	Wide Area Network
X.500	The standard for directory services
X.509	The standard for PKI certificates
XML	Extensible Markup Language