INITIAL ECONOMIC IMPACT ANALYSIS
OF THE
PROPOSED ELECTRONIC ORDERS RULE

Drug Enforcement Administration
U.S. Department of Justice

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TABLE OF CONTENTS

EXECUTIVE SUMMARY 1
CHAPTER 1: INTRODUCTION 1
1.1 BACKGROUND 1
1.2 PROPOSED RULE 1
1.3 DIGITAL CERTIFICATES 1
1.4 PURPOSE AND ORGANIZATION OF THE ANALYSIS 2
CHAPTER 2: OPTIONS ANALYZED 5
CHAPTER 3: AFFECTED UNIVERSE 7
CHAPTER 4: UNIT COSTS 11
4.1 METHODOLOGY 11
4.2 UNIT COSTS FOR THE FORM 222 SYSTEM 12
4.2.1 Unit Costs for Purchasers 13
4.2.2 Unit Costs for Suppliers 14
4.2.3 Capital and O&M Costs 14
4.3 UNIT COSTS FOR THE ELECTRONIC ORDER SYSTEM 14
4.3.1 Initial Compliance 15
4.3.2 Annual Costs 17
4.4 TOTAL UNIT COSTS FOR EACH OPTION 19
CHAPTER 5: TOTAL COSTS 25
5.1 METHODOLOGY 25
5.2 ANNUAL COSTS OF THE PAPER-BASED SYSTEM 26
5.3 ANNUAL COSTS OF THE ELECTRONIC SYSTEM 27
5.3.1 Total Initial Compliance Costs 27
5.3.2 Annual Costs 29
5.4 TEN-YEAR AND ANNUALIZED COSTS 31
CHAPTER 6: BENEFITS OF THE ELECTRONIC ORDER SYSTEM 35
CHAPTER 7: SMALL ENTITY ANALYSIS 37
7.1 NUMBER OF SMALL BUSINESSES 37
7.1.1 Definition of Small Business 37
7.1.2 Estimate of Number of Small Businesses 38
7.2 INITIAL FACILITY COSTS 38
7.3 ANNUAL FACILITY COSTS 39
7.4 ANNUAL COSTS AS A PERCENTAGE OF SALES 39
7.5 CONCLUSIONS 40
7.6 UNFUNDED MANDATE REFORM ACT 40
CHAPTER 8: CONCLUSIONS 41
8.1 UNCERTAINTIES 41
8.2 COMPARISON OF COSTS AND BENEFITS 42
APPENDIX A: WAGE RATES AND SOURCES 45
APPENDIX B: PARTICIPANTS IN CSOS PILOT TEST 47
APPENDIX C: ECONOMIC ANALYSIS ASSUMPTIONS 49

LIST OF TABLES

Table 3-1: Suppliers and Purchasers of Controlled Substances
Table 4-1: Weighted Hourly Wage Rates
Table 4-2: Form 222 Unit Costs Per Purchaser
Table 4-3: Form 222 Unit Costs Per Supplier
Table 4-4: Unit Costs for Initial Compliance
Table 4-5: Unit Costs for Electronic Orders
Table 4-6: Annual Unit Cost Per Software Developer
Table 4-7: Estimated Annual Orders Issued and Filled by Registrant Group
Table 4-8: Estimated Annual Cost of the Form 222 System by Registrant Group
Table 4-9: Estimated Initial Cost of the Electronic System by Registrant Group
Table 4-10: Estimated Annual Cost of the Electronic System by Registrant Group
Table 5-1: Annual Total Labor Costs for the Form 222 System
Table 5-3: Total Annual Hours and Costs for the Form 222 System
Table 5-4: Total Initial Labor Costs for the Electronic Order System
Table 5-6: Total Annual Ongoing Labor Costs of the Electronic Order System
Table 5-7: Total Annual Compliance Hours and Costs for the
Electronic Order System
Table 5-8: Total Cost Over Ten Years
(Present Value – 7 Percent)
Table 5-9: Total Cost Over Ten Years
(Present Value – 3 Percent)
Table 6-1: Cost Savings Associated With the Electronic Order System
Table 7-1: SBA Definitions of Small Entities
Table 7-2: Initial Compliance Costs Per Firm
Table 7-3: Annual Costs Per Firm
Table 7-5: Annual Cost of Form 222 and Electronic Order Systems as Percentage of
Sales for the Smallest Entities

EXECUTIVE SUMMARY

The Controlled Substances Act (21 U.S.C. 801 et seq.) (CSA) provides that a Schedule I or II controlled substance may only be distributed to another person with a written order from that person on a form issued by the Attorney General. 21 U.S.C. 828(a). To date, the distributions have been accomplished using a paper form, the DEA Form 222 Official Order Form, that DEA issues. Now DEA is proposing regulations to allow registrants who order Schedule I and II controlled substances to issue orders electronically, using a digital certificate provided by DEA to sign the orders. Use of electronic orders would be voluntary.

DEA is proposing three criteria any electronic order would have to meet: authentication, nonrepudiation, and record integrity. At present, only digital signatures created using a digital certificate issued by a Certification Authority as part of a public key infrastructure meet the standards. To satisfy the CSA mandate that DEA issue the order forms, DEA will run the Certification Authority. The digital certificate will include the data currently pre-printed on the paper order forms. By signing the electronic order with a private key associated with the digital certificate, the registrant will irrevocably associate the DEA registration data included in the certificate with the order, thus, in effect, pre-printing the order with the registrant data in the same way that paper forms are pre-printed with the registrant data.

At this time, approximately 101,000 registrants currently issue more than 5 million orders annually. The number of orders is growing by 6 percent a year. Registrants include manufacturers, distributors, pharmacies, practitioners, exporters, researchers, chemical analysts, and narcotic treatment programs. Use of the paper-based system is limited to Schedule I and II controlled substances. For Schedule III – V controlled substances no such requirement exists and the majority of commerce is carried out electronically.

The paper-based system, while providing a high level of security and assurance against diversion, carries the inherent burdens and inefficiencies associated with paper, including the need to transcribe data from electronic systems to paper and back again, the resources that must be dedicated to physically handling and accounting for the paper documents, and the time required to transmit the paper document from the customer to the supplier. Against those burdens and inefficiencies, the proposed electronic orders system offers substantial benefits, despite the initial compliance costs.

The table below presents initial compliance costs for the electronic system, annual costs for the current year, ten-year cost (net present value) and annualized costs, assuming a 5 percent annual growth in orders. The electronic system costs assume that registrants take 5 years to adopt electronic orders, so electronic system costs include a mix of paper and electronic for the first four years. Initial compliances costs are distributed over 5 years.

	Paper	Electronic
Initial Compliance	N/A	$71 million
Annual Costs	$210 million	$32 million
10-Year (7% discount)	$2 billion	$629 million (5 year phase in)
Annualized	$285 million	$90 million (5 year phase in)
10-Year (3% discount)	$2.4 billion	$696 million (5 year phase in)
Annualized	$279 million	$82 million (5 year phase in)

Annual costs per registrant depend on the number of orders issued or processed. Costs range from $23 (a single order/year) to $115,000 for distributors for paper orders. Initial compliance costs range from $124 for a practitioner to $3,660 for distributors; initial costs are driven by the number of people who need a digital certificate and the cost of implementing the software system. Annual costs for the electronic system range from $6 to $32,000, depending on the number of orders issued. In addition, certain registrants are expected to spend approximately $150,000 to add digital signature capability to existing ordering systems.

Besides the cost-savings shown above unquantified benefits include the following:

- The ability to create single unified orders for all purchases from a supplier. The paper form is limited to Schedule I and II controlled substances and can list only 10 items. Electronic orders can include any controlled substance item sought from a supplier and can contain as many items as needed.
- Faster receipt of orders.
- The ability of suppliers to process orders centrally and fill them from multiple locations. Paper orders must be filled from one location.

DEA has shared the assumptions used in this analysis and early drafts of the analysis with the regulated community and revised its assumptions based on their comments.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

Under the Controlled Substances Act (CSA) and its implementing regulations, Schedule I and II controlled substances may be distributed only by DEA registrants through a controlled system of orders. DEA preprints the order form (DEA Form 222) with the registrant's name, address, DEA registration number, business activity, and schedules; each form is sequentially numbered. Purchasers must requisition these forms from DEA, which supplies them in books. Each form is in triplicate. The purchaser completes the form in triplicate, sends two copies to the supplier, and retains one copy, which it must annotate when the order is received. The supplier annotates its copies, retains one, and forwards the second to DEA on a monthly basis. Suppliers and purchasers must retain completed forms for two years.

Only persons registered as manufacturers, distributors, or importers may fill orders (suppliers). Any DEA registrant (except importers) eligible to handle Schedule I and II controlled substances may issue orders (purchasers). In practice, orders are issued mainly by pharmacies, distributors, exporters, institutional practitioners (hospitals, clinics), narcotic treatment programs (NTPs), and individual practitioners that maintain supplies of controlled substances for sale or administration. Teaching institutions, researchers, and chemical analysts use orders, but do not order frequently. Registrants involved in the order system are allowed to provide power of attorney (POA) to employees to sign orders.

1.2 PROPOSED RULE

DEA is proposing changes to its order rules to allow the creation and transmission of electronic orders for Schedule I and II controlled substances. These rule changes would be optional: registrants could continue to use Form 222 for orders. Under the proposed rule, registrants would be able to do the following:

- Create orders for Schedule I and II substances electronically if they include the information on Form 222 (except number of lines and supplier's address) and they are signed and validated using a digital certificate issued by the DEA Certification Authority. The digital certificate contains some of the information on the 222; the electronic order would not have to duplicate that data.
- File electronic copies or reports to DEA on electronic orders filled (suppliers only).
- Maintain electronic records of digitally signed orders.

1.3 DIGITAL CERTIFICATES

DEA is proposing that electronic orders for Schedule I and II controlled substances be signed using a digital certificate issued by a DEA Certification Authority (CA). The digital certificate is an element of a public key infrastructure (PKI) system. Under a PKI

system, the CA accepts applications for a digital certificate, verifies the identity of the applicant, and provides the applicant with the means to generate asymmetric public and private cryptographic keys. What one key encrypts, only the other key can decrypt. The two keys cannot be reasonably derived from each other (i.e., if you have the public key, you cannot determine what the private key is). Because only one person holds the private key, it cannot be compromised by other parties. Only signatures created using a PKI technology are referred to as digital signatures. The CA maintains a registry of all public keys issued and a Certificate Revocation List (CRL), which is updated on a daily basis.

When a key holder digitally signs an order, the PKI software creates a digital digest of the document and encrypts the digest using the private key. The recipient's software uses the public key to decrypt the message, checks the CA's CRL and the public directory of keys to ensure that the digital certificate is still valid, then generates a second digest of the message and compares the two digests. If the digests match, the recipient knows the record has not been altered. If the public key decrypts the message, the recipient knows who sent the order. The check of the CRL and the directory ensures that the sender is still authorized to order controlled substances. This process is considered validation of the order.

Despite the technical complexity of the PKI system, the signing and validating are both handled by the computer. For the persons signing an order, once they authenticate themselves to the system to access the signing key, little more than a single keystroke is needed to sign. The person validating the order also requires just a single keystroke. Both parties gain the speed of the transaction, which usually takes one to three days with paper forms. The suppliers also gain the rapid verification of the validity of the order.

Like any electronic signature system, digital signatures require new software modules. Both purchasers and suppliers will have to have their computers PKI-enabled. Various toolkits are available to add PKI functionality to existing systems. Most Internet browsers are PKI-enabled.

The digital certificate that DEA issues will serve as the electronic equivalent of a Form 222 because the certificate will contain, in its extension data, the information that is currently printed on a Form 222 (registrant name, address, DEA registration number, schedules the registrant is authorized to handle, business activity). The DEA CA will ensure that only DEA registrants or those who have power of attorney from a DEA registrant are issued digital certificates that are valid to sign orders for Schedule I and II substances. DEA will also issue digital certificates to registrants who are authorized to handle only Schedule III through V controlled substances although these registrants are not required to use digital signatures when issuing electronic orders.

1.4 PURPOSE AND ORGANIZATION OF THE ANALYSIS

This analysis provides estimates of compliance costs for the current, paper-based system and the electronic, PKI-based system. The analysis also presents the estimated benefits of implementing the electronic system. The remainder of this report is organized as follows:

- Chapter 2 outlines the regulatory options considered.

- Chapter 3 estimates the universe of entities potentially affected by the rule.
- Chapter 4 presents the unit costs and total costs for each item.
- Chapter 5 presents the total annual costs associated with both options.
- Chapter 6 estimates the benefits associated with the proposed rule.
- Chapter 7 estimates the impact on small entities.
- Chapter 8 presents conclusions.

CHAPTER 2: OPTIONS ANALYZED

Under Executive Order 12866, federal agencies are required to evaluate the cost of certain rules. An economically significant proposed rule that imposes costs of $100 million or more a year requires a cost-benefit analysis and a review of potentially effective and reasonably feasible alternatives. Other significant rules require an assessment of the potential costs and benefits of the action. The proposed rule for electronic orders would reduce costs of controlled substance orders to below the $100 million threshold for an economically significant rule. Nonetheless, because the proposed rule is a new program and one of the federal government's first regulations to incorporate requirements for the use of electronic signatures, DEA has conducted a cost-benefit analysis for the rule. This chapter discusses the options DEA analyzed and details the types of costs associated with each option.

Before developing its proposed rule, DEA evaluated existing electronic signature systems to determine which systems would provide the controls needed to ensure the integrity of the record and signature. Based on this evaluation, DEA determined that only digital certificates issued as part of a public key infrastructure (PKI) provided the level of authentication, nonrepudiation, and record integrity that DEA considers necessary to maintain the closed system of controls mandated by the CSA. Other electronic signature systems, such as those that use personal identification numbers (PINs) and biometric signatures, may provide for authentication, but do not ensure the integrity of the record. Because only a PKI-based system meets the criteria DEA has set, DEA did not analyze the costs of other electronic signature systems.

DEA also did not analyze variations in the possible cost of the PKI electronic system. In developing its proposed rule, DEA considered various options for implementing the rule and rejected some because the burden seemed unnecessary. For example, originally DEA assumed the certificates would have to be renewed annually, which is standard practice in the PKI industry. To reduce the burden, however, DEA decided to set the renewal period to coincide with the DEA registration period. For most registrants affected by this rule (pharmacies, hospitals, practitioners), this decision reduces costs because the renewal will be needed only once every three years. DEA also considered, but decided against, requiring biometric authentication instead of passwords or the use smart cards to store the private keys. Although these methods would have increased the security of the system DEA decided that the closed nature of the system for ordering Schedule I and II substances was sufficient to protect against diversion.

DEA has considered only two options, the current Form 222 system and a PKI-based electronic order system. The analysis considers the costs of implementing PKI technology for orders as well as the cost savings of being able to retain order records electronically.

- Option 1: The current paper ordering system (Form 222), the baseline system, consists of requisitioning orders using Form 222A via regular mail, completing orders, maintaining paper files of these orders for two years, and filing orders monthly with DEA (for suppliers).

- Option 2: A voluntary PKI-based electronic ordering system that would supplement and may eventually replace the current paper-based system.

The difference between Option 2 and Option 1 represents the benefits (cost-savings) of the electronic system. The PKI-based alternative would not be mandatory. If the costs of implementing the new system prove too high, a purchaser could continue to order controlled substances through paper forms. However, the analysis assumes that over a five-year time period all suppliers and purchasers will adopt the electronic ordering system.[1] There are three reasons for this assumption:

- If suppliers decide to switch to electronic ordering, purchasers will be encouraged to follow suit.
- Many suppliers and purchasers already generate orders electronically and complete the Form 222 solely to comply with DEA regulations.
- The assumption of full compliance allows the analysis to estimate the maximum costs associated with an electronic system.

[1] Specifically, the analysis assumes that 20 percent of registrants adopt the electronic order system in the first year, 40 percent adopt it in the second year, 20 percent in the third year, 10 percent in the fourth year, and 10 percent in the fifth year.

CHAPTER 3: AFFECTED UNIVERSE

This chapter discusses the number of entities affected by the proposed rule. Regardless of the system used for ordering controlled substances, there are two general types of affected entities based on DEA requirements: suppliers of controlled substances (manufacturers, distributors, and importers), and purchasers of controlled substances. Suppliers are required to annotate orders filled, send copies of all orders filled to DEA once a month, and maintain files of all orders for two years. Purchasers requisition order forms from DEA, fill in and submit orders to suppliers, annotate the order form when the substances are received, and maintain files of all orders for two years.

The number of affected registrants is based on the number of DEA registrants on October 7, 2002, minus the number of registrants in each group (except practitioners) that are not registered to handle Schedule I or II controlled substances (see Table 3-1). The number of practitioners is based on the number of practitioners who ordered Schedule II substances as reported in DEA's ARCOS records, which covers all orders from manufacturers and distributors. All DEA registrants, except importers, can be classified as purchasers of controlled substances. Only the registered manufacturers, distributors, and importers may supply Schedule I and II controlled substances.

Table 3-1: Suppliers and Purchasers of Controlled Substances

Registrant Type	Number of Registrants	Potential Certificate Holders	Number of Firms	CSOS Coordinators
		Suppliers		
Manufacturers	298	1,788	228	228
Distributors	455	2,730	15	15
Importers	38	N/A	38	N/A
		Purchasers		
Hospitals/Clinics	14,058	28,116	8,197	14,058
Pharmacies	60,765	101,742	25,890	35,196
Teaching Institutions	350	700	350	350
Exporters	144	288	144	144
Narcotic Treatment Programs	1,146	1,146	671	1,146
Researchers	6,322	6,322	6,322	6,322
Chemical Labs	1,437	1,437	122	1,437
Practitioners	15,860	15,860	15,860	15,860
TOTAL	**100,870**	**160,130**	**57,830**	**74,760**

The number of certificate holders is an estimate of the number of people at each type of registrant who either signed the registration application or who hold power of attorney (POA) to sign orders on behalf of a registrant. The estimate for each group is based on information that industry provided to DEA during discussions of the proposed rule. For pharmacies, the number has been adjusted to account for central ordering. Four pharmacy chains currently process all orders centrally; that is, each pharmacy in the chain communicates its needs to a central office, which then completes the Form 222 and submits it or, if the central office is a registered distributor, fills the order. The power of attorney for the almost 9,900 pharmacies in the four chains is held by a very small number of people. The estimate for pharmacy certificates was adjusted to assume that all other pharmacies have two people each with POA authority, but the four chains have six each. The number of certificate holders for practitioners may overstate the actual number. If practitioners ordering controlled substances are in a group practice, they may provide a single staff person with POA to submit orders for all individual practitioners in the practice, which could reduce the number of certificate holders.

The number of firms is also estimated because some costs, such as software implementation occurs at the firm level, particularly for hospitals, pharmacy chains, and practitioner offices; sixty percent of practitioners are in group practices.[2] The number of firms is conservative because it double counts some registrants who hold multiple DEA registrations. For example, some distributors hold a registration as a manufacturer for locations where they repackage controlled substances. Some chain pharmacies hold registrations as distributors.

Finally, registrants are required to appoint a Controlled Substance Ordering System (CSOS) coordinator, who is the point of contact between DEA and the registrants. The coordinator must have a digital certificate and is responsible for checking applications and submitting the application packages for all applicants from the registered location(s) which he or she coordinates. Only the coordinator application is notarized. If there is only one applicant, that person would be the CSOS coordinator. Firms may elect to have a coordinator per location or may have a coordinator for multiple locations. The analysis assumes that the distributors and 48 chain pharmacies that currently do batch renewals for their registrations would have a central CSOS coordinator, handling applications for all of their registered locations; other registrants are assumed to have coordinators for each location.

DEA will also provide digital certificates under this program registrants and their staff who are registered to order only Schedule III-V controlled substances.

Registrants authorized to order Schedule III-V substances can and do order these controlled substances electronically and would not be required to use a digital certificate on future electronic orders. If they want to use a digital certificate, they may apply and the DEA CA will issue them a certificate. DEA has not included these registrants and staff in the cost analysis for two reasons. First, they do not need a digital certificate to issue electronic orders for the controlled substances they are authorized to order. Second, DEA has no basis for estimating the percentage of these registrants or staff who would

[2] DEA requires separate registration of each location where controlled substances are handled or stored. Consequently, the number of registrants is not the equivalent of the number of firms.

choose to apply for a certificate or the number of staff who may currently be able to sign orders for Schedule III–V substances.

At present, many pharmacies, hospitals, and clinics obtain their electronic ordering systems from their distributors. DEA expects that the distributors will develop software to PKI-enable their systems. Because the 15 largest wholesale pharmacy distributors represent more facilities than DEA has registered distributor locations, DEA assumes that these 15 companies will PKI-enable their software and provide the updated software or necessary patch to their customers. In addition, DEA assumes that the 13 largest chain pharmacies, which own about 26,000 pharmacies, will PKI-enable their central systems and download (or migrate) the system to all of their pharmacies. All manufacturers (228 firms) are assumed to PKI-enable their systems. The analysis assumes that large manufacturers (78 firms) develop the systems themselves while smaller companies purchase the systems. Although the initial cost of the system would be the same, a company that purchases a system would not incur the ongoing costs estimated in the analysis.

DEA recognizes that some vendors will offer PKI-enabled ordering systems as part of larger information and business management systems. At present only two vendors appear to sell such systems to these sectors. It is not possible to determine what part of the costs of these larger ordering systems could be attributed to ordering Schedule I and II controlled substances. The business systems are presumably used for ordering all products that a registrant needs; the digital signature capability might be used only for ordering controlled substances or might be used more generally to ensure the integrity of the orders. Because DEA cannot estimate the portion of the costs that could reasonably be attributed to this rule, DEA has not included vendors in the universe.

Industry Classification

Sectors are classified using their North American Industrial Classification System (NAICS) codes (see Table 3-2). Manufacturers are most likely to be classified as part of the pharmaceutical manufacturing or the medicinal manufacturing industry. Distributors can be classified as part of the drugs and druggists' sundries wholesale trade industry.

Hospitals are classified in their own category in NAICS. Clinics are most likely to be classified as ambulatory health care services. Pharmacies are part of the pharmacy and drug store industry, but may also be covered by grocery stores, general merchandise stores (warehouse clubs and superstores), and electronic shopping and mail order houses. Teaching institutions are most likely part of general medical and surgical hospitals because they are usually hospitals associated with medical schools. Researchers are either associated with teaching institutions or manufacturers; chemical analysts are associated with research labs or medical labs although some are associated with law enforcement labs; exporters are most likely in the drugs and druggists' sundries wholesale industry or manufacturers. Narcotic treatment programs are part of outpatient mental health and substance abuse centers. Finally, practitioners are mostly physicians, dentists, and veterinarians.

Table 3-2: Industry Characterization

Affected Entity	Industry Description	NAICS Code
Manufacturer	Pharmaceutical Preparation Manufacturing	325412
	Medicinal and Botanical Manufacturing	325411
Distributor	Drugs and Druggists' Sundries – Wholesale	4222
Hospital/Clinic	Hospitals	622
	HMO Medical Centers	621491
	Freestanding Ambulatory Surgical and Emergency Centers	621493
Pharmacy	Pharmacies and Drug Stores	44611
	Supermarkets and Other Grocery Stores	44511
	General Merchandise Stores	45291
	Electronic Shopping and Mail Order Houses	454110
Teaching Institution	General Medical and Surgical Hospitals	6221
Researchers Chemical Analysts	Pharmaceutical Preparation Manufacturing	325412
	Medicinal and Botanical Manufacturing	325411
	Universities	6113
	Research and Development in the Life Sciences	54172
	Medical Laboratories	621511
Exporter	Drugs and Druggists' Sundries – Wholesale	4222
	Pharmaceutical Preparation Manufacturing	325412
Narcotic Treatment Programs	Outpatient Mental Health and Substance Abuse Centers	62142
Practitioners	Offices of Physicians, except Mental Health	621111
	Offices of Physicians, Mental Health Specialists	621112
	Offices of Dentists	621210
	Veterinary Services	541940

CHAPTER 4: UNIT COSTS

This chapter provides the estimated burden and unit costs of handling orders under the current regulations and of implementing a digital signature system. The regulated community currently incurs costs to complete order forms and fill orders, ship order forms, submit records to DEA, and maintain records. As it adopts digital signatures, the regulated community is expected to incur costs to install software, apply for digital certificates, learn to use digital signatures, and digitally sign and validate orders.

Section 4.1 presents the general methodology and wage rates. Section 4.2 presents the unit cost estimates for the baseline scenario. Section 4.3 presents the unit costs for PKI-based option.

4.1 METHODOLOGY

Costs are divided into three categories: labor costs, capital costs, and operations and maintenance (O&M) costs. Unit labor costs are presented in terms of the time required for each action and the type of personnel performing the action.

To monetize time spent on various activities in either the baseline or electronic system, weighted wage rates were constructed based on the 2000 industry-specific information from the Bureau of Labor Statistics; see Appendix A for the source of wage rates for each industry sector and category of employee. Wage rates for suppliers (distributors, manufacturers, and importers) and for purchasers (all registrant categories) are weighted based on the number of orders estimated for each industry category. Wage rates were developed separately for suppliers and purchasers because they perform different tasks and because using a single set of weighted wage rates for all registrants would overstate the costs to suppliers. Suppliers represent less than one percent of the regulated universe and are estimated to issue less than two percent of all orders. They also have generally lower wage rates than pharmacies and practitioners do. Despite their low percentage of the orders issued, they handle all orders and spend almost half the total hours for the baseline system and more than half of the total hours for ongoing costs in the electronic system. Therefore, separate wage rates based on wages in the pharmaceutical industry and drug wholesale industry are used for suppliers.

The wage rates applied also vary with the type of activity performed. In the case of purchasers and suppliers, the wage rate depends on whether documents require completion by an authorized individual (i.e., a person with power of attorney) or are handled by clerks who process and file orders. In the electronic order system, certain tasks are performed by computer technicians. The wage rate depends on whether expertise is needed in software and hardware development or in computer support and maintenance. All wages were inflated to 2002 dollars using BLS employment cost index data. Wages were then loaded with fringe benefits (36 percent for medical professionals, 38 percent for all others) based on 2002 BLS data and with overhead based on a survey of overhead rates for government contractors (59 percent of wages plus fringe). The

weighted wage rates are summarized in Table 4-1. Appendix A provides details of the wages and sources used.

Table 4-1: Weighted Hourly Wage Rates

Type	Basic Activity	Hourly Rate
Supplier	Signing, Verifying	$62.97
	Mailing	$35.21
Purchaser	Signing, Verifying	$75.10
	Mailing	$24.22
Computer	Development	$76.66
	Maintenance	$41.31

As part of the process of developing this analysis and the rule, DEA has sought stakeholder input on the existing system and on unit time estimates in early versions of this document. In addition, DEA is conducting a pilot test of the electronic system to determine whether it works with various stakeholder systems and to develop estimates of how much time various elements of the electronic system take. Comments and data collected from stakeholders have been used wherever available in this analysis. Appendix B provides a list of the stakeholders who are participating in the pilot test.

Costs that occur under each option and do not change are not included in the unit time or cost estimates. For example, purchasers will create the actual order electronically under the electronic system. In the paper system, purchasers complete the Form 222 and then enter the data into their electronic systems to maintain a centralized record of all their orders. Because purchasers enter the order data into electronic systems under both options, the costs of entering the data are not ascribed to either system. In contrast, under the paper system, the suppliers told DEA that they enter the data from the Form 222 into their systems; with electronic orders, this data entry will no longer be needed so the cost of data entry for suppliers is included in the baseline option.

4.2 UNIT COSTS FOR THE FORM 222 SYSTEM

The costs of the current paper-based order system are divided into the following activities:

- The time required to requisition order forms (Purchasers).
- The time to log and track forms (Purchasers).
- The time required to complete the order form (Purchasers).
- The time required to annotate and file the order forms (Purchasers and Suppliers).
- The time required to enter the information into the system (Suppliers).
- The time required to log and track order forms and prepare them for mailing to DEA (Suppliers).
- The cost of mailing requisitions to DEA and the order forms to suppliers (Purchasers) and the cost of mailing order forms to DEA (Suppliers).

- The cost of file cabinets to store the order forms and the cost of space occupied by the file cabinets (Purchasers and Suppliers).

Most of these costs are estimated on a per order basis. The cost of logging, tracking, compiling, and mailing Form 222s to DEA is on a per registrant per month basis.

4.2.1 Unit Costs for Purchasers

Purchasers of Schedule I and II controlled substances must requisition books of Form 222s from DEA. They must also complete an order in triplicate, either on a typewriter or by hand, mail it to the supplier, annotate the order form when the order is received, and file it. Although it is a necessary part of business, the time required to complete the order is included in the baseline, for two reasons:

- Most purchasers generate orders electronically; the triplicate Form 222 is time-consuming paperwork. To maintain centralized records in their systems, purchasers enter the order information from the Form 222 into their computer system as well. As discussed above, that cost is not included in the estimate.

- The Form 222 process requires purchasers to generate orders that are limited to ten items and specific substances; instead of being able to submit a single order to their supplier for all their needs, purchasers may have to submit multiple orders to a single supplier, with one limited to Schedule I and II controlled substances. If they need to order more than ten Schedule I or II substances, they must complete multiple Form 222s because the form has space for only ten line items.

Table 4-2 presents the unit costs for purchasers.

Table 4-2: Form 222 Unit Costs Per Purchaser

Activity	Hours	Hourly Wage	O&M Cost	Unit Cost
Requisition forms	0.05	$75.10	$0.37	$4.13
Complete and ship orders	0.25	$75.10	$11.25	$30.03
Complete and mail orders	0.25	$75.10	$0.37	$19.15
Complete and send with truck	0.25	$75.10		$18.78
Annotate form	0.05	$75.10		$3.76
Log and file forms	0.033	$24.22		$0.81

4.2.2 Unit Costs for Suppliers

Suppliers of controlled substances must enter the orders they receive into their system, annotate the orders as they are filled, track and log orders, file them, and compile and transmit a copy of each form to DEA once a month. Based on industry comments, DEA has included the time required for suppliers to enter the orders into their computer system because most, if not all, companies use computers to manage their sales and distribution. In addition, DEA requires suppliers to track Form 222s they receive so they can notify DEA if a Form is lost. Industry commenters stated that this cost should be included because the tracking will no longer be needed with electronic orders. DEA requires that the completed Form 222s be kept separately from all other files. Table 4-3 presents the unit costs for suppliers. Estimates of the unit time are based on comments from suppliers. Suppliers are assumed to ship their monthly submissions to the DEA area office using an express service; the average monthly submission is estimated to weigh five pounds.

Table 4-3: Form 222 Unit Costs Per Supplier

Activity	Hours	O&M Cost	Hourly Wage	Unit Cost
Annotate forms	0.083		$62.97	$5.25
Enter and file forms	0.25		$35.21	$8.80
Log and track forms, prepare for mailing to DEA	9	$17.25	$35.21	$334

4.2.3 Capital and O&M Costs

Both suppliers and purchasers are required to retain a copy of each order for two years. The Form 222s must be retained on paper. A four-drawer file cabinet that holds 12,500 pages currently costs approximately $100; depreciated over 15 years, the annualized cost per file cabinet is $10.98. In addition, the file cabinets take space (about 2.75 square feet for a letter-sized file cabinet); the average cost per square foot is $43.47 for warehouse space and $120.18 for retail space (National Real Estate Index).

4.3 UNIT COSTS FOR THE ELECTRONIC ORDER SYSTEM

The costs of the electronic order system are divided into two categories: the costs of initial compliance (acquiring a digital certificate, installing and learning to use the digital signature system) and the annual costs of using the electronic system to submit and fill orders. In addition to purchasers and suppliers, registrants who develop PKI-enabling software also incur costs under the electronic system. The DEA Certification Authority will also incur costs to implement the system and register applicants; these federal costs are not included in this analysis.

4.3.1 Initial Compliance

The one-time start-up costs of an electronic order system stem primarily from the cost of the following activities:

- Reading the subscriber manual and agreement and completing and mailing an initial application for a digital certificate.
- Implementing the PKI-enabling software.
- Generating private and public keys and completing the process of obtaining a digital certificate.
- Learning how to use the system.

No capital costs are assumed because all of the certificate holders are likely to have and use computers as part of their regular activities. The software will be added to these existing systems.

4.3.1.1 Unit Costs for Purchasers and Suppliers

Only people who have signed the DEA registration form for a registrant or have been granted power of attorney (POAs) by a registrant are eligible to obtain and use a digital signature for Schedule I and II orders. Thus, the costs of submitting an application to obtain a digital certificate from DEA, generating the public and private keys, and learning how to use the new system apply to these individuals. In addition, CSOS coordinators have to compile the applications for which they are responsible and verify the identity of the applicants.

Based on information collected during discussions with registrants, DEA assumes that a manufacturer or distributor has 6 POAs, a hospital/clinic has 2 POAs, a pharmacy has 2 POAs (other than the four chains with centralized processing systems which are assumed to have six POAs each), and a teaching institution or exporter has 2 POAs. For other registrant categories, only the registrant or a single POA is assumed to have a digital certificate.

Except for manufacturers, distributors, and chain pharmacies, one of the POA applicants is assumed to serve as the CSOS coordinator. For manufacturers and distributors, each firm is assumed to have a single coordinator. The 48 chain pharmacies that currently submit batch registration renewals to DEA are assumed to have CSOS coordinators in addition to their POAs; other chain pharmacies are assumed to have a POA serve as coordinator.

Suppliers are also purchasers, so all registrants except importers listed in Table 3-1 and their POAs are assumed to submit an application to the DEA Certification Authority (CA), generate keys, and complete the process of obtaining a digital certificate. The cost of implementing the PKI software accrues to each firm, however, rather than each certificate holder. Because the cost of implementing the software at individual locations includes the cost of training staff, only registrants whose software is installed at the firm level (manufacturers, distributors, hospital/clinics, and chain pharmacies) are assumed to incur additional costs for certificate holders to learn how to use the system. The only O&M cost attributable to initial compliance is the cost of notarizing the application

package ($2.00) and the cost of mailing it to the DEA CA ($0.37 for first class mail; $8.05 for express shipping); distributors, manufacturers, and chain pharmacies where the CSOS coordinator is submitting applications on behalf of a number of applicants are assumed to express ship the package at the least expensive rate (based on FedEx Express saver). Table 4-4 presents the unit costs for initial compliance.

Table 4-4: Unit Costs for Initial Compliance

Task	Entity	Hours/Person	Hourly Wage	Unit Cost
Complete certificate application	Supplier	0.72	$62.97	$45.36
	Purchaser		$75.10	$54.10
Complete certificate application – CSOS coordinator	Supplier	1.24	$62.97	$77.89
	Purchaser		$75.10	$92.90
Generate keys	Supplier	0.10	$62.97	$6.30
	Purchaser		$75.10	$7.51
Implement software	Supplier	40	$76.66	$3,066
	Purchaser	8.00	$41.31	$330
	Practitioner	0.50	$41.31	$21
Learn to use system	Supplier	0.417	$62.97	$26.26
	Purchaser		$75.10	$31.32
Notarize and mail application				$2.37 (mail) $10.05 (express)

The cost of implementing the software (installing, training staff, updating policies and procedures) varies based on how the analysis assumes the registrant will obtain the software. To be conservative, the analysis assumes that all firms except practitioners will have to devote time to loading the software and testing it with its existing ordering system. Manufacturers and distributors are assumed to spend 40 hours implementing the system. Most purchasers are assumed to obtain the system from their suppliers and spend far less time. For practitioners, the analysis assumes that they will receive the system as a separate piece of software that will be ready to be loaded to their computer system without linking to any other software on their computer.

4.3.1.2 Unit Costs for Software Development

Most registrants covered by this rule use EDI systems to transmit orders. These systems will need to be modified to accept digital signatures and to validate digitally signed orders. The cost of modifying a system is assessed on a system basis. As discussed above, a limited number of chain pharmacies and distributors would modify their systems; the modification would be downloaded to all registrants of the same firm. Because distributors have often provided ordering systems to their customers, they are expected to provide the modification to their customers as well. In addition, all manufacturers are assumed to either develop or purchase PKI-enabling software. Larger

manufacturers (78 firms) are assumed to develop their own software with the smaller companies purchasing the software at the same cost.

The development of a PKI-enabling modification to an electronic order system is estimated to take 2,000 hours. This estimate includes management oversight, programming, debugging and testing of the system, documentation, and administration. PKI-tool kits are available. DEA assumes the registrants developing software would use these toolkits to add PKI capabilities to their systems. In addition to PKI-enabling their systems, suppliers are expected to add a program that will extract the information on Schedule I and II orders and create a file to be transmitted to DEA every two business days. DEA intends to provide standard formats and data field parameters for this file. DEA notes that manufacturers may have to conduct additional validation of their systems to meet requirements of the Food and Drug Administration. Because this validation is not required by DEA, it is not included in the costs of this proposed rule.

The cost of developing a system is equal to the average wage for an information technology systems developer of $76.66 multiplied by 2,000 hours, or $153,320. DEA recognizes that some registrants may not perform this work in house, but will contract the development out. DEA expects the total cost will be similar for contracted work. Because DEA has no basis for estimating the number of firms that will contract the cost, the analysis includes the cost as a labor rather than an O&M cost.

4.3.2 Annual Costs

4.3.2.1 Unit Costs for Purchasers and Suppliers

For registrants that adopt the electronic ordering system, the purchaser will digitally sign and archive each order. The supplier will validate the order before filling it; validation is handled by the computer, with the only registrant action being a keystroke. Both suppliers and purchasers have to annotate the order electronically; because the digitally signed order cannot be altered, "annotation" requires the creation of a file that includes the data required (quantity shipped, date shipped or quantity received, date received) and that is linked to the digitally signed original. Once every second business day, the suppliers' computers will extract data on Schedule I and II orders from orders filled and transmit a computer-generated report on the orders to DEA. There is no cost to maintaining electronic records outside of routine maintenance of the computer system, which is accounted for elsewhere. Because most, if not all, firms maintain order information in their computers at present (in addition to the paper files), no new server space would be required for storing electronic orders.

In addition to the costs of processing orders, certificate holders will have to renew their digital certificates whenever their DEA registrations expire. For suppliers, exporters, researchers, chemical analysts, and NTPs, annual renewals will be required. Pharmacies, hospitals, teaching institutions, and practitioners will have to renew every three years. Most renewals will occur on line and require little time. Every third renewal would require a new application, which is assumed to take half the time of the original because the basic documents would not need to be reread. Table 4-5 presents the unit costs for annual activities.

Table 4-5: Unit Costs for Electronic Orders

Activity	Entity	Unit Hours	Wage Rate	Unit Cost
Signing orders	Purchaser	0.006/order	$75.10	$0.42
Validating orders	Supplier	0.004/order	$62.97	$0.26
Annotating orders	Purchaser	0.025/order	$75.10	$1.88
	Supplier	0.042/order	$62.97	$2.62
Sending orders to DEA	Supplier	0.05/submission	$62.97	$3.15
Renewing certificate	Purchaser	0.083/person	$75.10	$6.26 $2.09*
	Supplier		$62.97	$5.25
Renewing certificate (every third renewal)	Purchaser	0.36 hour/person	$75.10	$27.05
	Supplier		$62.97	$22.68

* For certificate holders who renew every three years.

4.3.2.2 Unit Costs for Software Maintenance

Registrants who develop the PKI systems in-house are expected to incur ongoing costs for the following activities:

- System maintenance and help desks.
- Software upgrades.
- Third-party audits.

DEA assumes that registrants who develop software will upgrade their software every three years; upgrades are estimated to take 15 percent of the time required for the initial development or 300 hours every three years. To ensure that the electronic order system is functioning properly, the developer will be required to have a third-party audit of the software whenever the PKI functions of the software are changed. The consulting fee for an independent auditor to review a system's software is estimated to be $10,000 per audit. In addition, it is estimated that each developer will have a computer technician spend 40 hours assisting the auditor with his or her inspection. Finally, each developer is assumed to spend 500 hours a year to provide system support. Table 4-6 presents the annual costs.

Table 4-6: Annual Unit Cost Per Software Developer

	O&M Cost	Hours/year	Hourly Wage	Unit Cost
System maintenance		500	$41.31	$20,655
Upgrades		100	$76.66	$7,666
Cost of Audit	$10,000	--	--	$3,333
Assisting Auditor	--	13.30	$41.31	$551

4.4 TOTAL UNIT COSTS FOR EACH OPTION

Because the major costs are incurred on a per order basis, it is not possible to develop accurate estimates for per firm costs. It is reasonable to expect that there will be considerable variation based on the volume of business and populations served. For example, hospitals that specialize in cancer treatment are likely to order more Schedule II drugs than general hospitals of the same size. To estimate average costs, the analysis made assumptions for the number of orders issued by different groups based on information from the ARCOS database[3] about the quantity of Schedule II substances ordered by pharmacies, hospitals, practitioners, and teaching institutions and on the percentages of all prescription drugs sold to various categories of dispensers.[4] Table 4-7 presents the assumptions for the number of orders issued and filled by each registrant group. Importers are not included in the table because there are only 38 and some of those are likely to be covered because they hold registrations as manufacturers or distributors as well as importers.

Table 4-7: Estimated Annual Orders Issued and Filled by Registrant Group

	Number	% order issued	% orders filled	Average orders issued	Total orders issued	Average orders filled	Total orders filled
Manufacturer							
Large	147	0.07%	8%	26	3,822	2,905	427,087
Small	151	0.03%	2%	12	1,812	707	106,772
Distributor							
Large	455	1.77%	90%	208	94,640	10,560	4,804,733
Pharmacies							
Chain	35,248	59.2%		90	3,160,914		
Independent	25,517	18.0%		38	960,226		
Hospital							
Large	4,434	4.32%		52	230,568		
Small	2,156	1.58%		39	84,084		
Clinic							
Large	3259	3.17%		52	169,468		
Small	4209	3.07%		39	164,151		
Teaching	350	0.01%		1	350		
Chem Analyst	1437	0.03%		1	1,437		
Research	6322	0.12%		1	6,322		
NTP	1146	0.84%		39	44,694		
Export	144	0.07%		26	3,744		
Practitioner	15860	7.72%		26	412,360		

[3] DEA, ARCOS 2 – Report 7, U.S. Summary of Retail Drug Purchases.
[4] NACDS, *The Chain Pharmacy Industry Profile 2002*, Figure 1: 2001 Manufacturer Sales of Prescription Drugs.

Based on the assumptions in Table 4-7 and the unit costs presented in this chapter, the analysis developed average costs for the paper-based and electronic system for each registrant group. Note that only distributors and chain pharmacies are estimated to submit requisitions more than once a year. The annual costs do not include the cost of developing and maintaining software, which occur at the firm rather than registrant level. For a manufacturer with a single location the costs would add $153,000 in initial costs and $52,900 in annual costs to the costs of the electronic system. Tables 4-8 through 4-10 present the average annual costs for each registrant group.

Table 4-8: Estimated Annual Cost of the Form 222 System by Registrant Group

	Order	Requisition	Log/Track/ Mail to DEA	Enter Data	Annotate	Mailing Costs	File Cabinet	Annual Cost
Manufacturer								
Large	$488	$1.27	$3,804	$25,567	$15,390	$9.62	$61.43	$45,321
Small	$225	$0.59	$3,804	$6,222	$3,775	$4.44	$15.07	$14,047
Distributor	$3,905	$10.16	$3,804	$92,927	$11,306	$2,340	$225.65	$114,518
Pharmacies								
Chain	$1,684	$4.38	$7.26		$337.20	$33.18	$5.92	$2,072
Independent	$707	$1.84	$3.05		$141.50	$13.92	$5.78	$873
Hospital								
Large	$976	$2.54	$4.21		$195.52	$19.24	$5.47	$1,203
Small	$732	$1.90	$3.16		$146.64	$14.43	$2.14	$900
Clinic								
Large	$976	$2.54	$4.21		$195.52	$19.24	$5.30	$1,203
Small	$732	$1.90	$3.16		$146.64	$14.43	$2.14	$900
Teaching	$19	$0.05	$0.08		$3.76	$0.37	$0.05	$23
Chemical Analyst	$19	$0.05	$0.08		$3.76	$0.37	$0.05	$23
Research	$19	$0.05	$0.08		$3.76	$0.37	$0.05	$23
NTP	$732	$1.90	$3.16		$146.64	$14.43	$2.14	$900
Export	$488	$1.27	$2.11		$97.76	$9.62	$0.54	$599
Practitioner	$488	$1.27	$2.11		$97.76	$9.62	$1.43	$600

Table 4-9: Estimated Initial Cost of the Electronic System by Registrant Group

	Apply For Certificate	Generate Keys	Learn System	Implement Software	Notarize/Mail Application	Total Initial Cost
Manufacturer						
Large	$305	$37.80	$187.90	$3,066	$31.50	$3,660
Small	$305	$37.80	$187.90	$3,066	$31.50	$3,660
Distributor	$305	$37.80	$187.90	$3,066	$31.50	$3,660
Pharmacies						
Chain	$147	$15.02	$62.63	$330	$21.00	$578
Independent	$147	$15.02		$330	$4.74	$497
Hospital						
Large	$147	$15.02	$62.63	$330	$4.74	$560
Small	$147	$15.02		$330	$4.74	$497
Clinic						
Large	$147	$15.02	$62.63	$330	$4.74	$560
Small	$147	$15.02		$330	$4.74	$497
Teaching	$147	$15.02		$330	$4.74	$497
Chemical Analyst	$93	$7.51		$330	$2.37	$433
Research	$93	$7.51		$330	$2.37	$433
NTP	$93	$7.51		$330	$2.37	$433
Export	$93	$7.51		$330	$2.37	$433
Practitioner	$93	$7.51		$21	$2.37	$124

Table 4-10: Estimated Annual Cost of the Electronic System by Registrant Group

	Sign Orders	Validate	Annotate	Send to DEA	Renew Certificate	Total Annual Cost
Manufacturer						
Large	$10.92	$755	$7,680	$479	$31.50	$8,957
Small	$5.04	$184	$1,884	$479	$31.50	$2,583
Distributor	$87.36	$2,746	$28,212	$479	$31.50	$31,555
Pharmacies						
Chain	$37.66		$169		$4.18	$210
Independent	$15.80		$71		$4.18	$91
Hospital						
Large	$21.84		$98		$4.18	$124
Small	$16.38		$73		$4.18	$94
Clinic						
Large	$21.84		$98		$4.18	$124
Small	$16.38		$73		$4.18	$94
Teaching	$0.42		$2		$4.18	$6
Chemical Analyst	$0.42		$2		$6.26	$9

	Sign Orders	Validate	Annotate	Send to DEA	Renew Certificate	Total Annual Cost
Research	$0.42		$2		$6.26	$9
NTP	$16.38		$73		$6.26	$96
Export	$10.92		$49		$6.26	$66
Practitioner	$10.92		$49		$2.09	$62

CHAPTER 5: TOTAL COSTS

This chapter provides the estimated total costs of compliance with the current paper-based system and the PKI-based electronic order system. The chapter presents the annual costs of current compliance with the paper-based system, then presents the costs of initial compliance and ongoing compliance for the electronic system. Because it is probable that adoption of the electronic system will take place over time, the actual annual costs of the electronic system are not accurately reflected by the initial or ongoing costs. To account for the phase-in of the system, DEA estimates the rate of adoption over five years and estimates costs over that period to include some initial and ongoing costs for each of the first five years. In years six to ten, only ongoing costs occur. The annualized costs for each system and the combined systems as the phase-in occurs are presented.

In addition to phasing in the electronic order system, the analysis estimates growth rates for orders based on DEA order data from 1997 to 2002. The inclusion of the growth rate provides a more accurate estimate of the total cost of issuing and processing Schedule I and II controlled substance orders over time. Nonetheless, the accuracy of the growth rate, which is based on growth rates over recent years, is uncertain. The ability to combine orders for Schedule I and II controlled substances with other substances in a single electronic order may result in more individual orders for Schedule I and II substances; the ability to order more than 10 substances at a time (the limit on a Form 222) may result in fewer orders being issued. The growth rate used, therefore, may be reasonably accurate for the paper-based system, but may understate or overstate the number of orders for the electronic system.

Section 5.1 presents the methodology used to estimate total costs. Section 5.2 provides the annual costs for the paper-based system. Section 5.3 presents the annual costs of the electronic system for both initial and ongoing costs, if these costs were to occur in a single year. Section 5.4 provides the ten-year and annualized costs and the assumptions on the phase-in.

5.1 METHODOLOGY

Costs are divided into three categories: labor costs, capital costs, and operations and maintenance (O&M) costs. Labor costs are generally calculated by multiplying the unit time by the wage rate of the person carrying out the activities by the number of activities performed. O&M costs, such as the cost of a third-party audit, are presented separately. These costs are multiplied by the number of such activities expected to occur each year. Capital costs for file cabinets are depreciated over 15 years.

As discussed above, costs of the electronic system are phased in over time. The phase-in occurs because purchasers and suppliers are likely to take time to adopt the system. The costs that are estimated on a per order basis are similarly calculated on the assumption that the number of electronic orders is proportionate to the number of purchasers issuing

electronic orders. This assumption may understate the phase-in rate if the larger purchasers, who issue most of the orders, adopt the system quickly.

5.2 ANNUAL COSTS OF THE PAPER-BASED SYSTEM

Tables 5-1 and 5-2 demonstrate how the unit costs associated with the continuation of the paper-based system for Form 222s are translated into total annual costs. For example, the unit cost to prepare a Form 222 is $18.78 per order. To obtain the annual total cost, this unit cost is simply multiplied by the 5,338,592 orders (the total number of Form 222s printed in FY 2002). The result is that it costs approximately $106 million per year to prepare orders under the paper-based system.

The number of requisitions is based on the number of Form 222s divided by 77, the average number of Form 222s that DEA provides at one time based on the number of paper requisitions received in the most recent year. The actual number of requisitions is likely to be different because some distributors have standing orders for requisitions and others phone in orders. The cost of the orders compiled and shipped to DEA monthly is the total number of suppliers multiplied by 12.

Note that both the unit costs and the total costs have been rounded, unit costs to two decimal places. Total costs are based on multiplying unrounded unit costs by the number in column 4.

Table 5-1: Annual Total Labor Costs for the Form 222 System

Activity	Entity	Unit Cost	Number	Total Cost
Requisition Form 222s	Purchaser	$4.13	69,332	$260,000
Complete and submit order	Purchaser	$18.78	5,338,592	$100 million
Annotate/file order	Purchaser	$4.56	5,338,592	$24 million
Enter data, annotate, file order	Supplier	$14.05	5,338,592	$75 million
Log and track forms, compile and mail orders to DEA	Supplier	$317	9,444	$3 million

Based on comments from distributors and manufacturers to an earlier draft of this analysis, DEA assumes all distributor orders (four per week), all manufacturer orders, and half of hospital orders are express shipped as are five percent of all other orders. Of the remaining orders, 45 percent are assumed to be mailed; the rest are sent via the delivery truck (no charge). DEA assumes that requisitions are mailed to DEA. Express shipped orders are assumed to be within the closest zone and to weigh no more than eight ounces. There are no O&M costs attached to orders that are sent with the delivery truck. The number of file cabinets is based on the number of 4-drawer, 12,500-page file

cabinets needed nationally to store the orders, multiplied by the annualized cost of the cabinets.

The paper-based system for orders requires 3.6 million hours per year (see Table 5-3). The total annual cost of the paper-based system is about $209 million, 97 percent of which is due to the cost of labor.

Table 5-3: Total Annual Hours and Costs for the Form 222 System

Activity	Total Hours	Total Labor Cost	Total Capital and O&M Cost	Total
Completing and mailing orders	1,334,648	$100,232,000	$5,853,000	$106,085,000
Requisitioning Form 222s	3,467	$260,000	$26,000	$286,000
Annotating and filing	2,224,413	$99,364,000	$405,000	$99,768,000
Sending orders to DEA	85,428	$3,008,000	$164,000	$3,172,000
Total	**3,647,956**	**$202,864,000**	**$6,447,000**	**$209,311,000**

5.3 ANNUAL COSTS OF THE ELECTRONIC SYSTEM

5.3.1 Total Initial Compliance Costs

The initial costs of the electronic order system are divided between the cost of developing a PKI system, which relatively few registrants are expected to do, and all other initial compliance costs, which include the cost of the initial application, installing the system, learning how to use a digital signature, and generating public and private keys. Software installation is on a per firm basis, but the analysis assumes that the chain pharmacies that do not develop software will install the software centrally and download it to their stores. The 28 chain pharmacies and distributors as well as the manufacturers assumed to develop software do not incur additional installation costs for their facilities. Completing applications and generating keys occur on a per certificate holder basis. As discussed in Chapter 4, the cost of learning to use the system is incorporated in the implementation costs where implementation occurs at each registered location. Where implementation occurs at the firm level (manufacturers, distributors, chain pharmacies, hospitals), the cost of learning to use the digital signature is additional and estimated on a per certificate basis.

The estimate for the cost of applying and learning the system is conservative. DEA anticipates that many chain pharmacies will adopt centralized processing systems similar to those already used by four chains. These centralized systems would reduce the number of certificate holders substantially (from two per registrant to perhaps six per chain or from about 51,000 for chain pharmacies to about 2,200 for chains). The lower number of affected certificate holders would reduce all total costs associated with applying for and learning to use a digital certificate. DEA is developing a software utility

that will allow chain POAs to generate location-specific certificates automatically, without having to enter codes and generate keys for each location. This process will also reduce the costs of generating keys and obtaining certificates.

As explained in Chapter 4, there are no capital costs associated with compliance. The only O&M cost is the cost of having the application for a digital certificate notarized and mailed, which is estimated to cost $254,000. Small manufacturers may purchase rather than develop the needed software, but those costs are assumed to be the same as the costs of developing software and are included in the labor costs.

If chain pharmacies and other registrants with multiple locations move to centralized ordering, the cost for mailing and notarization will also fall because it is likely that the entire set of applications for a firm would be mailed together and notarized once. The total initial compliance cost of the electronic order system is about $71 million. Table 5-4 presents labor costs for initial compliance.

Table 5-4: Total Initial Labor Costs for the Electronic Order System

Activity	Entity	Unit Cost	Number of Entities	Total Cost
Complete certificate application	Supplier	$54/$93*	4,518	$11.5 million
	Purchaser	$45/$78*	155,607	
Implement software	Supplier	$3,066	243	$15 million
	Purchaser	$330	43,500	
	Purchaser – Practitioner	$21	15,860	
Generate keys	Supplier	$6.30	4,518	$1.2 million
	Purchaser	$7.51	155,607	
Learn system	Supplier	$26.26	4,518	$2.6 million
	Purchaser	$31.32	78,824	
Develop software	Software developers	$153,000	256	$39 million

* Higher figure is for the CSOS coordinator.

Table 5-5 presents the total initial compliance costs, if those costs were incurred in a single year.

Table 5-5: Total Initial Compliance Hours and Costs for the Electronic Order System

	Total Hours	Total Labor Cost	Total Capital and O&M Cost	Total Cost
Supplier				
Complete Application	3,649	$224,000	$2,400	$226,000
Implement software	304	$758,000		$758,000
Generate keys	452	$28,000		$28,000
Learn to use system	1,884	$119,000		$119,000
Purchaser				
Complete Application	150,424	$11,312,000	$252,000	$11,564,000
Implement software	400,307	$15,113,000		$15,113,000
Generate keys	15,561	$1,169,000		$1,169,000
Learn to use system	32,870	$2,469,000		$2,469,000
Software Developers	512,000	$39,250,000		$39,250,000
Total	**1,127,000**	**$70,440,000**	**$254,000**	**$70,694,000**

5.3.2 Annual Costs

The ongoing costs of the electronic order system are costs that are incurred on an annual basis, including the year in which the system is implemented. One exception is software upgrades, which are assumed to occur only after initial compliance. The estimate for application renewal assumes that one third of the hospitals, clinics, pharmacies, teaching institutions, and individual practitioners, who have three-year certificates, renew each year; other certificate holders renew annually. Unit costs are multiplied by the appropriate units - the number of firms, number of certificate holders, or number of orders - to obtain total annual costs for each task associated with an electronic order system. For the transmission of orders to DEA, the analysis assumes that distributors and manufacturers do this 152 times a year and importers 125 times a year; neither transmit on holidays. Table 5-6 presents the annual labor costs.

Table 5-6: Total Annual Ongoing Labor Costs of the Electronic Order System

Activity	Entity	Unit Cost	Number	Total Cost
Transmit orders to DEA	Supplier	$3.15	119,206	$375,000
Use digital signature	Purchaser	$0.42	5,338,592	$2.2 million
Validate orders	Supplier	$0.26	5,338,592	$1.4 million
Annotating orders	Purchaser	$1.88	5,338,592	$24 million
	Supplier	$2.62	5,338,592	
Application renewal	Purchaser	$6.26	155,607	$387,000
	Supplier	$5.25	2,259	
Audit	Software Developer	$551	106	$58,000
Software Upgrades	Software Developer	$7,666	106	$813,000
System Maintenance	Software Developer	$20,655	106	$2.2 million

The only O&M cost associated with the ongoing compliance is the cost of the third party audit, which is estimated to cost $353,000 a year (assuming one third occur in each year). Small manufacturers who purchase rather than develop software are also likely to incur some costs from their vendors in the form of fees for support contracts. Because the PKI-capability will probably be added to an existing system, it is not possible to estimate what those costs will be. Table 5-7 presents the total ongoing hours and costs of the electronic system.

Table 5-7: Total Annual Compliance Hours and Costs for the Electronic Order System

	Total Hours	Total Labor Cost	Total Capital and O&M Cost	Total Cost
Supplier/Purchaser				
Sign orders	29,659	$2,227,000		$2,227,000
Supplier				
Validate orders	22,244	$1,401,000		$1,401,000
Collect and send to DEA	5,960	$375,000		$375,000

	Total Hours	Total Labor Cost	Total Capital and O&M Cost	Total Cost
Annotate	222,411	$14,007,131		$14,007,131
Renew certificate	377	$24,000		$24,000
Purchaser				
Annotate	133,465	$10,023,000		$10,023,000
Renew certificate	4,833	$363,000		$363,000
Software Developer	157,012	$3,060,000	$353,000	$3,414,000
Total	**575,992**	**$31,481,000**	**$353,000**	**$31,834,000**

The electronic order system requires 576,00 hours per year. The total annual ongoing cost of the electronic order system is about $32 million.

5.4 TEN-YEAR AND ANNUALIZED COSTS

The yearly, total, and annualized costs of the baseline and electronic ordering system are estimated over ten years using a seven percent discount rate (see Table 5-8) and a three percent discount rate (see Table 5-9). The number of orders is assumed to increase by 6 percent a year, based on the average growth rate in orders from 1997 to 2002. In addition, the analysis assumes that registrants will adopt the electronic system over the first five years: 20 percent of registrants switch to an electronic order system in the first year, 40 percent in the second year, 20 percent in the third year, 10 percent in the fourth year, and 10 percent in the fifth year. To estimate costs, initial costs are multiplied by the initial implementation rate for the applicable year. To estimate ongoing costs, those costs are multiplied by the cumulative rate for the year. Because every third renewal requires a new application, every three years suppliers and some purchasers will have higher costs for renewal; most certificate holders will have to file new application only every nine years. These higher renewal costs are accounted for in the ten-year estimates, based on the percentage of each group that would be subject to higher costs in each year.

The total cost of the paper system is estimated to be $2 billion over ten years (7 percent discount; $2.4 billion at 3 percent discount). The cost of electronic orders over that period is estimated to be $317 million ($375 million at 3 percent). Because the two systems are assumed to co-exist as electronic orders are adopted over five years, the analysis also estimates the cost of the combined system as electronic orders are phased in and paper orders are phased out; over ten years, the combined system is estimated to cost $629 million ($696 million at 3 percent).

The annualized cost of a paper-based system is $285 million ($279 million at 3 percent). The annualized cost of an electronic order system is $45 million ($44 million at 3

percent). The annualized cost of the combined systems, as electronic orders are phased in is $90 million ($82 million at 3 percent). In years six through ten, when the electronic system is fully implemented, the annualized costs of the electronic system would be $38 million ($42 million at 3 percent) for processing all orders versus the annualized cost of $247 million ($279 million at 3 percent) for the paper system over that period. The cost of both systems is driven by the time required to complete and handle orders.

Table 5-8: Total Cost Over Ten Years
(Present Value – 7 Percent)

Year	Paper System	Combined Phase-In	Electronic System
1	$209,309,378	$190,624,769	$23,175,616
2	$207,553,519	$129,336,435	$46,314,210
3	$205,405,142	$78,583,875	$37,502,441
4	$203,290,492	$50,805,508	$30,476,258
5	$201,208,360	$35,104,573	$35,104,573
6	$199,157,608	$29,317,358	$29,317,358
7	$197,137,163	$28,983,870	$28,983,870
8	$195,146,013	$28,406,985	$28,406,985
9	$193,183,203	$28,646,700	$28,646,700
10	$191,247,832	$28,857,626	$28,857,626
Total	**$2,002,634,000**	**$628,668,000**	**$316,786,000**
Annualized	**$285,131,000**	**$89,508,000**	**$45,103,000**

Table 5-9: Total Cost Over Ten Years
(Present Value – 3 Percent)

Year	Paper System	Combined Phase-In	Electronic System
1	$209,309,378	$190,624,769	$23,175,616
2	$215,613,850	$134,359,209	$48,112,820
3	$221,668,722	$84,805,993	$40,471,812
4	$227,906,507	$56,957,439	$34,166,563
5	$234,332,342	$40,883,673	$40,883,673
6	$240,951,518	$35,469,707	$35,469,707
7	$247,769,486	$36,428,030	$36,428,030

Year	Paper System	Combined Phase-In	Electronic System
8	$254,791,863	$37,089,503	$37,089,503
9	$262,024,431	$38,855,010	$38,855,010
10	$269,473,149	$40,661,142	$40,661,142
Total	**$2,383,841,000**	**$696,134,000**	**$375,314,000**
Annualized	**$279,450,000**	**$81,608,000**	**$43,998,000**

CHAPTER 6: BENEFITS OF THE ELECTRONIC ORDER SYSTEM

This chapter discusses the benefits that adoption of the electronic ordering system will provide. The basic benefit this proposed rule will provide to DEA registrants is the reduction in time required to handle orders for Schedule I and II controlled substances and the elimination of the costs of mailing orders, requisitions, and compilations of orders.

Although the electronic order system has additional types of costs associated with it, over a ten-year period the electronic order system is considerably less costly than the paper-based order system (see Table 6-1). The primary reason for such substantial savings is that ordering and verifying controlled substances from suppliers take substantially less time when the orders are electronic. Because most purchasers already generate orders electronically, for drugs and other purchases, the only new cost that the electronic system imposes is the cost of using the digital signature. In contrast, with Form 222s, all of the costs for creating and submitting the paper order are in excess of normal business practice.

Table 6-1: Cost Savings Associated With the Electronic Order System

Ten Year Total Cost (Present Value – 7 percent)	
Paper-Based System	$2,003,000,000
Electronic System Phased In	$629,000,000
Difference	**$1,374,000,000**
Annualized Costs After Phase-In (years 6-10)	
Paper-Based System	$247,000,000
Electronic System	$38,000,000
Difference	**$209,000,000**

Another way to look at this cost savings is to consider the costs of filling out a Form 222 versus creating the order electronically and digitally signing it. Although purchasers need to complete an order as a part of doing business, DEA has estimated that it takes a purchaser 15 minutes to complete the Form 222, in triplicate, by hand or with a typewriter. The Form 222 may contain only Schedule I and II controlled substances. Consequently, purchasers must complete it separately from other orders being sent to the same supplier. Some purchasers report that they now routinely transmit all of their orders electronically, including their orders for Schedule I and II controlled substances, and complete the Form 222 to document the order for DEA. In comparison, applying a digital signature to an order, which may contain non-controlled substances, is estimated to take 20 seconds. Leaving aside all other costs, purchasers will be saving more than 14 minutes per order. In addition, suppliers must enter the orders into their systems. Both

suppliers and purchasers must annotate and file the orders. Over ten years, if all orders were electronic versus paper, the time saved in completing, validating, annotating, and filing orders is estimated to be approximately 42 million hours, a 89 percent reduction. The electronic system will have time associated with initial compliance and renewing certificates that will offset some of the hours savings, but DEA registrants should benefit from a far more efficient ordering system.

Electronic orders will also provide a number of other benefits that cannot be quantified. Purchasers will be able to create single unified controlled substance orders to their suppliers. With Form 222s, purchasers must create the separate Form 222 for the Schedule I and II controlled substances and complete other orders for all other controlled substance purchases from a particular supplier. If a purchaser needs more than 10 Schedule I or II substances, multiple Form 222s must be completed because the form is limited to ten items. With the electronic orders, they will be able to submit a single order covering all controlled substance and other prescription drugs being purchased from the supplier. The combined orders should reduce the orders that need to be logged, tracked, and handled by both purchasers and suppliers.

Electronic orders should also bring faster receipt of controlled substances. Under the present system, the purchaser has the choice of sending the order by overnight service at considerable cost, mailing it and waiting several days, or sending the order back with the delivery truck, which may not be returning directly to the distributor. In most cases, the purchaser is likely to have to wait at least two days and possibly four or five days when the order is mailed or is shipped back by truck. If the distributor that receives the order cannot fill it, the distributor may endorse it to another distributor and ship it on to another distribution point, further delaying the final shipment. Electronic orders will be received almost instantly and can be shipped the same day. This speed may allow purchasers to order only when they need an item and limit the quantity of controlled substances that they stock. Limiting the quantity of Schedule I and II controlled substances in stock reduces the possibility of diversion and the cost of security.

With the Form 222, if a supplier cannot fill all of an order, the supplier may endorse the entire order over to another supplier. The order cannot be divided and filled in part by one supplier and in part by a second, even if both suppliers belong to the same company. Because each location holds a separate registration, a distributor with multiple locations must maintain stocks of all Schedule I and II controlled substances at each location to be able to fill orders for these substances from that location. Some distributors have created centralized systems where all orders are processed through the central distribution office, which then transmits parts of the orders to the warehouses that hold specific items. The Form 222 system cannot take advantage of this system because the paper must accompany the order. With electronic orders, DEA will allow a distributor with a central distribution system to divide an order and ship parts of the order from different distribution points. New orders will not need to be generated because the central computer system can track each item in the order and ensure that it is shipped to the appropriate registrant only once. DEA and the supplier will have the records necessary to maintain the closed system of control while allowing the supplier to take advantage of its own system of distribution.

CHAPTER 7: SMALL ENTITY ANALYSIS

The Regulatory Flexibility Act requires federal agencies to determine whether proposed regulations will have a significant economic impact on a substantial number of small entities. This chapter discusses the number of small entities potentially affected by the proposed electronic prescription rule and the potential impacts.

7.1 NUMBER OF SMALL BUSINESSES

7.1.1 Definition of Small Business

Based on an evaluation of U.S. Census data, a certain percentage of manufacturers, hospitals, clinics, and pharmacies that are registrants with DEA are likely to be small, as defined by the Small Business Administration (see Table 7-1). All distributors, teaching institutions, and exporters are likely to be large. Only large universities and research centers typically have medical teaching institutions. All exporters are likely to be large since they are usually also distributors or manufacturers, and only large manufacturers and distributors are likely to be involved in exporting.[5]

Table 7-1: SBA Definitions of Small Entities

Affected Entity	Industry Description	NAICS Code	Small Business Definition
Manufacturer	Pharmaceutical Preparation Manufacturing	325412	750 employees
	Medicinal and Botanical Manufacturing	325411	750 employees
Distributor	Drugs and Druggists' Sundries – Wholesale	4222	100 employees
Hospital	Hospitals	622	$29,000,000
	Outpatient Mental Health and Substance Abuse Centers	62142	$8,500,000
Clinic	HMO Medical Centers	621491	$8,500,000
	Freestanding Ambulatory Surgical and Emergency Centers	621493	$8,500,000
Pharmacy	Pharmacies and Drug Stores	4461101	$6,000,000
Teaching Institution	General Medical and Surgical Hospitals	6221	$29,000,000
Exporter	Drugs and Druggists' Sundries – Wholesale	4222	100 employees

[5] DEA requires facilities to maintain separate registration for manufacturing and distribution, and for exporting.

Affected Entity	Industry Description	NAICS Code	Small Business Definition
	Pharmaceutical Preparation Manufacturing	325412	750 employees

7.1.2 Estimate of Number of Small Businesses

Manufacturers fall into one of two industry classifications; pharmaceutical preparation, or medicinal and botanical manufacturing. Based on DEA data on registered manufacturers and assuming that any manufacturer that has multiple locations or is a major company is large, the analysis estimated that 151 of the 298 of DEA registrants classified as manufacturers are small. It is also assumed that only companies with 20 or more employees are involved in the manufacturing of controlled substances since the costs of meeting Schedule II security requirements are generally high enough to prevent entry of smaller firms. Distributors are assumed to be large based on Census data that indicate that the 10 largest distributors (25 or more establishments) have more establishments than are registered with DEA.

There are 14,058 hospitals and clinics registered with DEA to handle Schedule I and II substances. According to the U.S. Census, there were 6,590 hospitals in the United States in 1997. It is assumed that all hospitals are registered with DEA. The remaining 7,468 registrants are assumed to be clinics. Census data indicates that there are 4,434 large hospitals. Thus, 2,156 hospitals registered with DEA are assumed to be small. There are about 3,260 clinics that can be defined as large. Assuming that all large clinics are DEA registrants, the remaining 4,209 clinics that are DEA registrants are small.

There are 60,765 pharmacies registered with DEA and eligible to order Schedule I and II substances. According to National Association of Chain Drug Stores (NACDS) and Census data on mail order prescription firms, there were 35,428 chain pharmacies, mass merchant pharmacies, supermarket pharmacies, and mail order pharmacies in 2001. It is assumed that the remaining 25,517 DEA registrants are independent pharmacies and that these independent pharmacies are small businesses that will be affected by the rule. The chain drug, mass merchant, supermarket, and mail order pharmacies are assumed to be large establishments.

Researchers, teaching institutions, and analytical labs are assumed to be associated with large institutions or governmental entities. Practitioners and narcotic treatment programs are assumed to be small entities.

7.2 INITIAL FACILITY COSTS

The paper-based system has no initial compliance costs because it is already in existence. For the electronic system, initial costs include the cost of obtaining and installing the software and the cost of having POAs complete the application process for a digital certificate, generate the keys, and learn to use the system. In addition, manufacturers are incur costs equal to development costs to purchase software systems. The average cost per small business per sector is shown in Table 7-2.

Table 7-2: Initial Compliance Costs Per Firm

	Total Cost
Manufacturer	$3,660 $153,000 (software)
Pharmacy, Hospital, Clinic	$497
NTP	$433
Practitioners	$124

7.3 ANNUAL FACILITY COSTS

Because the ongoing cost of both the paper and electronic systems are driven by the number of orders issued, to develop an estimate of average cost per small business, the analysis made assumptions about the number of orders issued per type of small business (see Chapter 4). Manufacturers costs include both ordering and filling orders and also cover the cost of transmitting the orders to DEA. No costs for on-going support of software are included although contracts with vendors may include fees; the analysis has no basis for estimating these costs. In the paper system, purchasers incur additional per firm costs for requisitioning Forms 222, a cost that does not accrue to suppliers; the cost of requisitioning is minimal because most small firms will submit only one requisition a year. These requisitions can now be submitted electronically.

Table 7-3: Annual Costs Per Firm

	Number of Orders Issued	Number of Orders Filled	Total Cost Form 222	Total Cost Electronic
Manufacturer	12	707 (filled)	$14,047	$2,583
Pharmacy	38		$873	$91
Hospital	39		$900	$94
Clinic	39		$900	$94
NTP	39		$900	$96
Practitioners	26		$600	$62

7.4 ANNUAL COSTS AS A PERCENTAGE OF SALES

Table 7-4 demonstrates the impact that a paper-based and an electronic order system will have on small businesses by comparing the annualized costs for each order system (per facility) to average annual receipts, sales, or value of shipments to the smallest entity firms in each relevant NAICS code. The costs of the electronic system to all affected entities are less than 0.15 percent of the average value of shipments or sales. Except for the smallest clinics and NTPs, the cost of the Form 222 system is also under one percent of revenues.

Table 7-5: Annual Cost of Form 222 and Electronic Order Systems as Percentage of Sales for the Smallest Entities

NAICS Code	Type	Establishment Size (Number of Employees or revenues)	Average Annual Value of Shipments (2002)	Paper-Based Annual Cost as a Percentage of Annual Sales	Electronic Annual Cost as a Percentage of Annual Sales
325412	Manufacturer	20-49	$9,726,865	0.14%	0.03%
44611	Pharmacy	$250,000-$499,999	$429,853	0.20%	0.02%
622	Hospitals	$1m-$2.5m	$2,078,107	0.04%	0.00%
62142	Clinics, NTPs	<$100,000	$61,909	1.45%	0.15%
62111	Practitioners	<$100,000	$63,688	0.94%	0.10%

7.5 CONCLUSIONS

The proposed rule will affect a substantial number of small entities. The impact, however, will be minimal when evaluated as percentage of average annual sales, receipts, or shipments. Consequently, the proposed rule does not create a significant adverse effect on a substantial number of small entities. In addition, the rule reduces the cost of the closed system of controls mandated by the Controlled Substances Act. Those registrants who issue more orders (and, therefore, incur greater costs) gain more benefits.

7.6 UNFUNDED MANDATE REFORM ACT

DEA expects that both the paper-based and the electronic order system will have no impact on state and local regulatory agencies. DEA will monitor registrants' compliance and will verify the validity of registrants' certificates. DEA will not require assistance from state and local agencies in monitoring the paper or electronic order system. Therefore, state and local regulatory agencies will not incur any costs due to the rule. In addition, the total cost of the proposed rule is less than the $113 million standard for a major rule under UMRA and, therefore, does not require an analysis under the statute.

CHAPTER 8: CONCLUSIONS

This chapter discusses the limitations of the analysis and presents the overall conclusions. Section 8.1 discusses the uncertainties involved in the analysis and the potential effect on the conclusions. Section 8.2 compares the costs and the benefits of the electronic ordering system.

8.1 UNCERTAINTIES

Any analysis of costs involves assumptions about the unit time required for tasks and the level of professional who will be performing the tasks. For this analysis, the person performing the task is often, but not always, dictated by law. Only a registrant or a person granted power of attorney by a registrant may sign orders, but other employees of registrants may process orders, annotate and file them, and send them to DEA. The analysis assumes that only more senior staff (managers), pharmacists, and practitioners would be signing orders, but that other (less expensive) employees would handle most of the other activities related to processing orders. If all work related to orders is handled by senior staff, the costs of both systems would be higher.

The analysis also made assumptions about the number of people at each location who would hold power of attorney to sign orders. These numbers are intended to be high average numbers, but may overstate the actual numbers. Under the present system, four chain pharmacies process all orders through a central location. If that practice spreads, the number of certificate holders from pharmacies will be lower, which will lower overall costs. Centralized processing has been limited because of the need for the central office to hold paper forms for each registered location. When paper is no longer needed, industry has indicated that it is likely that more chains will move to centralized processing. Such processing allows the chain to track what is being ordered much more efficiently and identify problems. It will also reduce substantially the number of digital certificates that must be issued and tracked. For example, if all chain pharmacies shifted to centralized processing, the number of certificate holders for this group would drop from the approximately 51,000 estimated for this analysis to 1,300.

Another issue related to the number of people in the system is the problem of turnover. The analysis assumes that once a person with power of attorney obtains a digital certificate, the person stays in the system and is not replaced. Although it is generally true that there is limited turnover among registrants who submit and fill orders, it may not be the case that turnover is limited among the employees who hold power of attorney. To the extent that there is turnover among the POAs, the costs of the electronic system would be higher because more initial certification applications would be needed.

The actual time required for each of the tasks, in both the baseline and electronic system, had to be estimated. Where data existed, the analysis used the data, but in most cases, the time required per task is an estimate because no studies were identified that measured the time spent on these discrete tasks. To gain additional information, DEA provided

stakeholders with a summary of this analysis and key assumptions to seek their input. The initial estimates were then adjusted using information from industry. For example, the time estimated for compiling the monthly reports to DEA was increased based on stakeholder comments. The number of orders submitted by mail and express shipping was similarly adjusted. Cost of storage space was added in response to industry comments. For the electronic system, the time required had to be estimated where information was not available from DEA's pilot project. The analysis attempts to develop unit time estimates that reflect likely average times, recognizing that there will be considerable individual variation.

In general, DEA attempted to make conservative assumptions about the electronic system so that the costs of the system would not be understated. A major cost of the electronic system is the cost of developing and maintaining the PKI-enabling software. This cost depends on the time required to develop software that can be easily added to existing electronic ordering systems. Depending on the number of existing ordering systems, either more time could be required to develop compatible software or more time could be required for installation. The analysis assumes a standard time for installation, but this time is likely to vary. In some cases, where all locations will share a server (e.g., a major chain pharmacy), the costs will be much lower, because the software, once developed and tested, will automatically be downloaded onto each machine linked to the server.

Another uncertainty is the number of companies that elect to develop the software. The analysis assumes 261 developers, but this number may be high. Currently, distributors tend to develop ordering systems that they provide to their customers to ensure that the systems are compatible. Some chain pharmacies provide a single-company system and process all orders through central facilities. The analysis assumes that all manufacturing firms develop or purchase (for the same cost) software. Only large firms are assumed to maintain and support the systems themselves. The actual cost to smaller manufacturers may be lower if they are able to purchase a system from a vendor that sells its product to multiple manufacturers. The analysis does not include costs that smaller manufacturers will incur for annual service contracts or fees associated with purchased systems because it is not possible to estimate what these charges will be or what percentage of the charges could be associated with the PKI part of the systems.

A final major uncertainty associated with the electronic system is the speed with which the system will be adopted. Electronic transmission is an option, not a requirement. As explained in Chapter 5, the analysis assumes that adoption would occur over five years, but the actual time will depend on the speed with which software is developed and the ease of use of that software.

8.2 COMPARISON OF COSTS AND BENEFITS

The electronic system produces significant cost savings. The paper-based system imposes substantial costs, primarily because of the time required to complete a Form 222 and the cost of sending it to a distributor or manufacturer. In contrast, most of the costs of the electronic system are the result of applying for a certificate and of developing the software. The actual cost of completing and processing an electronic order is very low. In addition, as discussed in Chapter 6, the electronic system will allow purchasers to

submit single orders, combining Schedule I and II controlled substances with other controlled and non-controlled substances. Overall, adoption of electronic ordering is likely to reduce the cost of ordering substantially and increase the efficiency of the ordering process for both suppliers and purchasers.

APPENDIX A: WAGE RATES AND SOURCES

	Salary*	Fringe Rate (BLS)	Overhead Rate	Total	Wage Source	Wage
Purchasing managers	25.15	0.36	0.59	$54.39	OES	weighted rate/median
Medical Assistants	11.26	0.38	0.59	$24.70	OES	median
Pharmacy Technicians	10.66	0.38	0.59	$23.40	OES	median
Pharmacists	36.63	0.36	0.59	$79.22	OES	median
Physicians Assistants	31.96	0.36	0.59	$69.12	OES	median
Physicians	82.62	0.36	0.59	$178.65	OOH	median
Dentists	66.63	0.36	0.59	$144.08	OES	median
Podiatrist	55.54	0.36	0.59	$120.09	OES	median
Vets	31.45	0.36	0.59	$68.00	OES	median
Optometrists	42.79	0.36	0.59	$92.53	OES	median
Nurse Practitioners	33.23	0.36	0.59	$71.86	OOH	top 10% of nurses
All Practitioners				$157		weighted average
Purchasing managers	28.70	0.38	0.59	$62.97	OES	median/drug wholesale
Software develop/install	34.94	0.38	0.59	$76.66	OES	median
Computer support	18.83	0.38	0.59	$41.31	OES	median
Expediting clerks – manufacturer	29.74	0.38	0.59	$65.25	OES	median/drug wholesale
Expediting clerks-distributor	12.33	0.38	0.59	$27.05	OES	median/hospital
Licensing clerk	18.41	0.38	0.59	$40.39	OES	median/ licensing clerk national
Order clerk	15.83	0.38	0.59	$34.74	OES/State	Median
Expediting clerks – hospital	13.50	0.38	0.59	$29.62		Median

2000 wages inflated to 2002 using an inflator of 7.4%, based on BLS Employment Cost Index for wages and salaries
OES = 2000 National Occupational Employment and Wage Estimates
OOH= Occupational Outlook Handbook 2000
BLS = Employer Costs for Employee Compensation, June 19, 2002
Overhead = weighted average of overhead rates for government contractors, from the 2001 Grant Thornton Survey, based on overhead as a percentage of wages plus fringe.

APPENDIX B: PARTICIPANTS IN CSOS PILOT TEST

DEA has been conducting a pilot test of the electronic ordering system. A total of 12 test plans were received back from participants. Participants that submitted test plans included:

Abbott Laboratories
AmerisourceBergen
Anda, Inc.
Baxter Healthcare Corporation
Baxter Healthcare Corporation
Baxter Healthcare Corporation
Brooks Pharmacy
Cardinal Health
Endo Pharmaceuticals Inc.
Grove Pharmacy
Kaiser Permanente California Division
Longs Drug Stores
Mallinckrodt
Massachusetts General Hospital
McKesson Corporation
McQueary Brothers Drug Company
North Carolina Mutual Drug Wholesale Drug Company
Osborn Pharmacy
Purdue Pharma L.P.
Rite Aid Drug Stores
Southern Anesthesia & Surgical, Inc.
The Butler Company
Wal Mart Stores East, LP
Walsh HealthCare Solutions, Inc.

APPENDIX C: ECONOMIC ANALYSIS ASSUMPTIONS

	Element	Assumptions	Source
1	Average number of potential certificate holders (POAs)	Manufacturers/Distributors – 6 Hospitals/clinics – 2 Teaching institutions, exporters – 2 Pharmacies – 2 Practitioners, NTPs, Researchers, Chemical Analysts – 1 Central processing chains – 5	Industry information
2	Percent of orders transmitted by express, mail, or sent with delivery truck	All distributor and manufacturer orders, half of hospital orders, and 5 % of other orders are express shipped. Of remaining orders, 45% mailed, rest sent by truck.	Industry comments
3	Time to fill out a Form 222	0.25 hours	DEA estimate; industry comments
4	Time to compile monthly package of orders to submit to DEA	9 hours – includes logging and tracking Form 222s	Industry comments
5	Time to enter data from Form 222 into system and file	0.25 hours	Industry comments
6	Time to annotate a Form 222	5 minutes for suppliers 3 minutes for purchasers	Industry comments
7	Frequency with which orders are submitted	Pharmacies – 3 orders/2 weeks Hospitals, clinics – 1/week to 1/1.5 weeks Distributors – 4/week Manufacturers – 1/month to biweekly Practitioners, exporters – 1 every 2 weeks NTPs – 1 every 1.5 weeks Teaching institutions, researchers, chemical analysts – once a year	Industry comments Estimates based on ARCOS data
8	Number of practitioners issuing orders	15,860	ARCOS data
9	Number of orders	Assume number will continue to increase as in the past.	FY 2002 orders printed 6% growth rate based on average annual growth rate from FY 1997 to FY 2002
10	Time to implement software	40 hours for manufacturers, distributors, chain pharmacies 8 hours for other registrants. 0.5 hours for practitioner.	Industry comments; includes cost of installing, training, and revising policies and procedures

11	Time to Complete certificate application	0.72 hours	Pilot test results
12	Time to complete CSOS coordinator application	1.24 hours	Pilot test results
13	Time to generate keys	0.10 hours	Pilot test results
14	Time to learn to use	0.417 hours	Applies only to registrants who implement the software at the firm rather than location level. Other registrant's training cost are part of the implementation costs.
15	Time to digitally sign	20 seconds	
16	Time to validate e-order	15 seconds	
17	Time to annotate e-order	2.5 minutes for suppliers 1.5 minutes for purchasers	Half the time needed to annotate 222 and electronic records created in the 222 system

DATA FOR DISTRIBUTION OF ORDERS AMONG REGISTRANT GROUPS:

DEA ARCOS 2- Report 7, U.S. Summary of Retail Drug Purchases, 1999.

Registrant Group	Quantity (grams)	Percent of Total
Pharmacies	61,234,418	77%
Hospitals	9,893,749	12%
Practitioners	6,184,737	8%
Teach	28,867	0%
Midlevel	1,855,013	2%
	79,196,784	

Note that these are purchases by groups classified by DEA as retail; they do not include purchases by manufacturers, distributors, exporters, researchers, or chemical analysts. Covers only Schedule I and II substances.

2001 Sales of Prescription Drugs by Group

Registrant Group	Percent of Total
Chain Drug, Mass Market, Supermarkets, Mail Order	59%
Independent Drug Stores	17%
Hospitals	11.6%
Clinics	7.6%
HMOs	0.8%
Long Term Care	3.3%
Home Health	1.1%
Other	0.4%

The Chain Pharmacy Industry Profile 2002, NACDS, based on IMS data.
Note that these numbers are based on dollar sales, not units of prescription drugs sold.