INITIAL ECONOMIC IMPACT ANALYSIS
OF THE
PROPOSED ELECTRONIC PRESCRIPTION RULE

Drug Enforcement Administration
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EXECUTIVE SUMMARY

Under the Controlled Substances Act (CSA), DEA is required to maintain a closed system of controls on controlled substances. For Schedule II controlled substances, which have the highest potential for abuse and dependence of those drugs with an accepted medical use in treatment in the United States, the CSA mandates that, with very limited exceptions, a pharmacist may only dispense a Schedule II controlled substance if there is an original written prescription from a practitioner. For Schedule III through IV controlled substances, the pharmacist may dispense if there is a written (original or fax) or oral prescription from a practitioner. DEA is proposing to give practitioners the option of signing and transmitting controlled substance prescriptions electronically; pharmacies would maintain records of these prescriptions electronically. The proposed rules for electronic prescriptions for controlled substances are an addition to, not a replacement of, the existing rules for controlled substance prescriptions. Practitioners will continue to be able to issue controlled substance prescriptions on paper or, for Schedule III-V substances, fax or call in prescriptions.

DEA is proposing to allow, but not require, electronic prescriptions for controlled substances if the systems used to create, transmit, and process controlled substance prescriptions meet certain requirements that DEA has identified as being necessary to prevent the misuse of the systems for diversion and to ensure that the records will be usable in legal actions if needed. DEA examined four options. Under the Base Case, service providers would conduct in-person identity proofing and verify the DEA registration and State licenses of each practitioner allowed to sign an electronic controlled substance prescription. Before signing such a prescription, the practitioner would authenticate to the system using two-factor authentication that meets the standards of NIST Special Publication 800-63 Level 4. The systems would also have to meet requirements for the information contained in a controlled substance prescription. The electronic controlled substance prescription would have to be digitally signed by the service provider or first intermediary and archived. Practitioners would have to review a monthly log of controlled substance prescriptions issued under the practitioner's name. Pharmacies would also have to digitally sign the controlled substance prescription on receipt and archive that record. Pharmacy systems would have to maintain an internal audit trail. All service providers would have to obtain a third-party audit annually that meets the requirements of a SysTrust, WebTrust, or SAS 70 audit for physical security and processing integrity.

Option 1 differs from the Base Case only in that a DEA-registered hospital, a state licensing board, or a law enforcement agency would conduct the initial in-person identity proofing. The service provider would verify the DEA registration and State license and contact the applicant to verify that the practitioner had submitted the application. Option 2 is a modified public key infrastructure approach. The practitioner would obtain a digital certificate from a recognized Certification Authority and use that to digitally sign the controlled substances prescriptions. The monthly log check would be eliminated, and the audit would address only processing integrity. Option 3 would impose no requirements on the service providers.

Pharmacies would be required to phone the practitioner to verify each controlled substance prescription received.

COSTS

DEA estimates that the costs of the options range from $19 million for Option 2 to $1.3 billion for Option 3, both annualized over 15 years at 7 percent discount rate. The Base Case is estimated to cost $33 million annualized and Option 1 $38 million. Table ES-1 presents the estimated annualized costs of all options.

Table ES-1: Total Costs ($)

	7.0 percent	3.0 percent
Base Case	$32,561,000	$33,392,000
Option 1	$38,256,000	$39,221,000
Option 2	$18,595,000	$18,928,000
Option 3	$1,280,000,000	$1,404,000,000

Most of the direct practitioner cost in the Base Case and Option 1 is driven by the requirement to check a computer-generated log of controlled substance prescriptions once a month. The service provider costs over time are primarily the costs of the annual audit, which accounts for all but about $1.2 million a year of the annualized service provider costs in the first three options.

BENEFITS

The benefits of the rule that can be quantified – reductions in callbacks ($316 million) and reduced public wait time (up to $589 million) (at 7 percent) – far exceed the cost of the three of the four options considered. DEA has not attempted to quantify any reduction in medical errors. DEA expects that there will be reduced medication errors linked to more readable prescriptions, but decided that it did not have a reasonable basis for quantifying the benefits. Another benefit of electronic prescriptions for controlled substances that is ascribable to the proposed rule, but not easily quantified and monetized, would come from reductions in controlled substance prescription forgery and alteration.

SMALL ENTITY IMPACTS

The proposed rule will have an impact on a substantial number of small entities. The economic impact on those directly regulated by this rule would not be significant under the first three options. DEA estimates that the direct first-year costs to practitioners for in-person identity proofing, training, and log review will range from about $150 to $350, which represents less than 0.2 percent of the net income of the lowest paid physician. DEA cannot accurately estimate the incremental cost to the systems that will be passed on to practitioners and pharmacies because that cost will depend on how many customers each service provider has and how they finance their costs, but these costs are unlikely to be higher than the first-year costs and should decline over time as the industry consolidates and costs can be

recovered from a larger practitioner base. For pharmacies, the incremental cost that their service providers may pass on would be less than $100 in the first year and about $35 a year in the out years, which represents about 0.003 percent of the average independent pharmacy's annual sales. DEA, therefore, has determined that the proposed rule would not impose a significant economic impact on small entities directly regulated by DEA.

Service providers are not directly regulated by DEA. The proposed rule indirectly affects them because DEA would require that its registrants use only systems and service providers that meet its requirements. DEA recognizes that the requirements may impose a significant impact on service providers, many of which are small entities, but the costs are not so great that a service provider would not be able to recover them from customers or that the incremental price increase would discourage customers from purchasing a system. DEA expects that some service providers may drop out of the market if they cannot meet the security standards that an auditor would demand, but given other government requirements for security under the Health Insurance Portability and Accountability Act and the public's expectations for secure medical records, DEA believes that these service providers would not be able to meet the other standards and public expectations. The market for healthcare information technology (IT) is evolving rapidly. DEA anticipates that most of the current service providers will not be in this market by the time most practitioners have adopted electronic medical record (EMR) systems. As the history of other IT applications has shown, over time, for reasons unrelated to DEA, a few systems will dominate the market; for the remaining service providers, DEA's requirements will not be a burden.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND

Under the Controlled Substances Act (CSA)[1], DEA is required to maintain a closed system of distribution for controlled substances. DEA publishes the implementing regulations in Title 21 of the Code of Federal Regulations.[2] These regulations are designed to ensure an adequate supply of controlled substances for legitimate medical and other purposes, and to deter the diversion of controlled substances to illegal purposes.

Controlled substances include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a potential for abuse and psychological and physical dependence. DEA divides controlled substances into Schedules I through V. Schedule I substances have a high potential for abuse and no accepted medical use in treatment in the United States and, therefore, may not be dispensed. Schedule II through V substances have accepted medical uses and also have potential for abuse and dependence. They may be dispensed; except for Schedule V substances, controlled substances cannot generally be dispensed except in response to a prescription.

For Schedule II controlled substances, which have the highest potential for abuse and dependence of the medications with accepted medical uses in treatment in the United States, the CSA mandates that, except in emergency circumstances, a pharmacist may only dispense a Schedule II controlled substance if there is a written prescription from a practitioner. For patients in long term care facilities or hospices, prescriptions for Schedule II substances may be written and manually signed and faxed with the fax serving as the original prescription. Most Schedule II prescriptions, however, are written with the original prescription presented to the pharmacy before dispensing. Schedule II prescriptions may not be refilled; a new prescription must be issued. For Schedule III and IV controlled substances, the pharmacist may dispense if there is a written or oral prescription from a practitioner; faxed prescriptions may serve as the original prescription, but must be written and signed prior to being faxed. Regulations implementing the prescription requirements are found in 21 CFR part 1306.

Under the regulations, a prescription for a controlled substance may be issued only by an individual practitioner who is authorized to prescribe by the State in which he or she is licensed to practice and is registered with DEA, or exempted from registration. To be valid, the prescription must be written for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. Every controlled substance prescription must contain the name and address of the patient, the drug name, strength, dosage form and quantity, directions for use, and the name, address, and DEA registration number of the practitioner. Every prescription that is written must be dated as of, and signed on, the day it is issued.

[1] 21 U.S.C. 801 *et seq.*
[2] 21 CFR parts 1300-1399.

A prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a registered pharmacy. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by DEA regulations.

With respect to records, the pharmacy must maintain a paper file of all prescriptions, consisting of the original prescriptions, or, where allowed, the facsimiles of the original written prescriptions, or written documentation of oral prescriptions. The pharmacy must also maintain records of when the prescription was filled and by whom, for both original prescriptions and any partial fillings or refillings. Practitioners are not required to maintain copies of prescriptions written or other records of prescriptions (unless issued for maintenance or detoxification treatment). Consequently, although practitioners create the record, pharmacies maintain it. This division between the person who creates the record and the person who retains it makes the integrity of the record particularly important.

Diversion of controlled substances may occur in a number of ways. With prescriptions, diversion may take place if a practitioner knowingly or otherwise writes a prescription for a person who does not have a legitimate need for it. Prescriptions may also be altered (e.g., changing a "10" to "40" or "100") or forged. Prescription pads may be stolen to create forgeries or prescriptions may be used to create fake prescription forms. Pharmacy records can be altered to hide illegal dispensing or theft by pharmacy employees. Practitioners and pharmacists may illegally dispense substances.

DEA's recordkeeping requirements and its concern about its ability to determine the integrity of the prescription record are directed toward preventing diversion and having a legally defensible record to prove that diversion has occurred. With paper prescriptions, the signed prescription provides a provable link to the prescribing practitioner. Forgeries can usually be detected by handwriting experts. As a result, a practitioner whose prescriptions are altered or forged can prove that he or she did not issue the suspect prescriptions, but a practitioner who issues invalid prescriptions cannot deny them and can be subject to administrative, civil, and criminal penalties. Similarly, paper records held at pharmacies can be compared with pharmacy inventories to determine if all drugs dispensed were dispensed legally.

1.2 ELECTRONIC PRESCRIPTIONS

Industry has asked DEA to develop regulations that will allow the creation and transmission of electronic prescriptions for controlled substances. Many parties in the healthcare industry are encouraging the adoption of electronic prescriptions because such prescriptions have the potential to improve patient safety by reducing medical errors that arise from misread or misunderstood prescriptions. From DEA's perspective, electronic prescriptions have distinct advantages, if created in a way that reduces the possibility of forgery or alteration. The reality of the speed of electronic communications, however, is that electronic prescriptions could also open a new avenue for rapid diversion, which could leave no trail that DEA could use to act against those diverting controlled substances. A recent study conducted for the Department of Health and Human Services (HHS) by the American Health Information

Management Association, "Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities," noted that "e-prescribing presents a new vulnerability because of the increased velocity of authenticated automated transactions."[3] Electronic records are easy to create and relatively easy to alter without the alteration being detectable. Without proper protections, a criminal could open an account, use a practitioner's DEA number to generate a fake prescription, send it to multiple pharmacies over a wide area, have confederates pick up the drugs, and close the account within a few hours. Because DEA registration numbers are publicly available, criminals could do this repeatedly without using any one DEA registration number more than once, making it unlikely that pharmacists would notice a pattern. Without proper controls, electronic prescriptions could create the potential for organized, widespread, and undetected diversion of controlled substances.

To the extent that electronic prescriptions for noncontrolled substances are being issued at present, they are signed electronically, with personal identification numbers (PINs) or using some combination of passwords and user IDs and transmitted over closed networks or the Internet through three to five intermediaries who may open the prescription files to reformat them and add information, such as routing and payer data. Reformatting is often required if the pharmacy system is not compatible with the practitioner's prescribing system. The service providers authorize the practitioners to use the system. Some systems allow practitioners to enroll online, without any assurance that the person is who he or she claims to be. Some systems authorize anyone in the practice to use the system so that the system cannot link a specific practitioner to a prescription. At the pharmacy, the prescription translates directly into the pharmacy computer system, and the records are maintained electronically.

This existing electronic prescription system is not sufficient to protect the transactions as the CSA requires. From DEA's perspective, the existing system has several fundamental flaws.

- The system relies on service providers to authenticate practitioners and control the integrity of the transaction without ensuring that the service providers check the identity of the practitioner, limit access for prescription signing, or use authentication protocols that allow only authorized practitioners to sign a prescription. In addition, the service providers are not subject to security requirements for their own systems. DEA would have to prove that the third party was not at fault before it could successfully take action against a registrant who had been a party to diversion. For example, if a practitioner denied issuing prescriptions and claimed they had been forged, DEA would have to prove that the third party had not issued authorization to someone else to use the practitioner's name and DEA registration number and that none of the third party's employees or outside hackers had used the system to generate false prescriptions in the practitioner's name.

[3] Foundation of Research and Education, American Health Information Management Association. "*Report on the Use of Health Information Technology to Enhance and Expand Health Care Anti-Fraud Activities,"* prepared for the Office of the National Coordinator, US Department of Health and Human Services, September 30, 2005.

- The system does not provide for record integrity. Even a closed transmission network does not protect against insider actions. Many computer crimes, such as identity thefts, are committed by insiders who have the knowledge to overcome internal protections. Because the third parties routinely open prescriptions, the opportunity for insider alterations will be substantial. The systems may also not protect against determined outside hackers.
- The system provides limited protection of the record's integrity once it reaches the pharmacy.

Overall, the existing electronic prescribing systems provide no assurance of security against identity theft, insider attacks, or outsider attacks. Although some existing systems might have voluntarily implemented effective security measures, they are not legally obligated to do so and – in the absence of binding regulatory requirements – there is no way to ensure that they or others who might enter the market will have effective measures in the future. With prescriptions moving through multiple parties from creation to dispensing, a security failure at any link in the chain could undermine the entire system, often leaving no evidence of the problem.

1.3 OPTIONS CONSIDERED

DEA has analyzed four options to consider the impact of varying requirements to address its concerns and provide adequate security. Under the Base Case, the following would be required:

- The electronic prescription service provider would conduct in-person identity proofing. At the service provider's office, a clerk would check the registrant's State license and DEA registration to ensure that they are active and in good standing and enter an electronic record of the check, and then file the original hard copy of the proofing document. The service provider would keep a record of the identification checked, the person who checked it, and the date on which it was checked.
- Authentication: Access to the electronic prescribing system for the purposes of signing prescriptions for controlled substances would meet the standards for Level 4 authentication in NIST SP 800-63. That is, the system would require at least two-factor authentication to access the system; one factor would be on a hard token that meets the requirements for Level 4 authentication in NIST SP 800-63.
- The security of the system would be audited annually using an independent third-party audit that meets the requirements of a SysTrust or WebTrust audit for security and processing integrity.
- The system would limit signing authority to those practitioners that have a legal right to sign prescriptions for controlled substances (i.e., the system would set varying levels of access to the system based on responsibilities).
- The system would have an automatic lock out if the system is unused for more than 2 minutes.

- The prescription would contain all of the required data (date of issuance; patient name and address; registrant full name, address, DEA registration number; drug name, dosage form, quantity prescribed, and directions for use; and any other information specific to certain controlled substances prescriptions mandated by law or DEA regulations). Prior to signing the controlled substance prescription, The system would show the prescribing practitioner at least the patient name and address, drug name, dosage unit and strength, quantity, directions for use, and the DEA registration number of the prescriber whose identity is being used to sign the prescription.
- Where more than one prescription has been prepared for signing, prior to authenticating to the system the practitioner would positively indicate which prescription(s) are to be signed.
- The practitioner would authenticate himself to the system immediately before signing a prescription.
- After authenticating to the system but prior to transmitting the prescription, the system would present the practitioner with a statement indicating that the practitioner understands that he is signing the prescription being transmitted. If the practitioner does not so indicate, by performing the signature function, the prescription could not be transmitted.
- The system would transmit the electronic prescription immediately upon signature. The system would not transmit a controlled substance prescription unless it is signed by a practitioner authorized to sign such prescriptions.
- The electronic data file would include an indication that the prescription was signed.
- The system would not allow printing of prescriptions that have been transmitted; if a prescription is printed, it would not be transmitted.
- The system would generate a monthly log of controlled substance prescriptions and transmit it to the practitioner for his review. The practitioner would indicate that the log was reviewed.
- The first recipient of the prescription would digitally sign the prescription and archive the digitally signed prescription as received.
- The first pharmacy system that receives the prescription would digitally sign and archive a copy of the prescription as received. Alternatively, the intermediary that transmits the prescription to the pharmacy could digitally sign the transmitted prescription and transmit both the record and the digitally signed copy for the pharmacy to archive.
- The pharmacy system would check to determine whether the DEA registration of the prescribing practitioner is valid. (Alternatively, any of the intermediary systems could conduct this check provided that the record indicates that the check has been conducted. The CSA registration database could be cached for one week from the date of issuance by DEA of the most current database.)

- The pharmacy system would be able to store the complete DEA number including extensions.
- The pharmacy system would have an audit trail that identifies each person who annotates or alters the record. The pharmacy system would conduct daily internal audits to identify any auditable events.
- The system would have a backup system of records stored at a separate location.
- The pharmacy system would have an independent third-party audit that meets the requirements of SysTrust or SAS 70 audits for security and processing integrity.
- A prescription created electronically for a controlled substance would remain in its electronic form throughout the transmission process to the pharmacy; electronic prescriptions may not be converted to other transmission methods, e.g., facsimile, at any time during transmission.

Many existing electronic prescription and pharmacy systems already meet some or all of these requirements.

In Option 1, the mechanism for in-person identity proofing is changed along with some of the ancillary procedures. The identity proofing would not be conducted by the service provider but by a DEA-registered hospital, State licensing board, or State or local law enforcement agency. The analysis assumes that in the great preponderance of cases, the identity proofing would be conducted by the hospital. Identity proofing of a registrant would be recorded in a hard document with signatures of the registrant and the agent who conducted the in-person identity proofing. The original document would be mailed from a practitioner's office to the service provider. At the service provider's office, a clerk would check the registrant's State license and DEA registration to ensure that they are active and in good standing, and enter an electronic record of the check, as in the Base Case, and then file the original hard copy of the identity proofing document. The service provider would phone the applicant to verify the submission of the application.

There is no change in the two-factor authentication or other requirements from the Base Case.

In Option 2, the authentication protocol is changed to require the registrant's digital signature, which is created by use of a digital certificate issued by a federally recognized Certification Authority. The original document recording in-person identity proofing would be stored at the Certification Authority's office rather than at the service provider's office; checking of the State license and DEA registration would be done at the service provider's office. The service provider would archive the digitally signed prescription, but would not be required to digitally sign the prescription on receipt. The digital signature would not be transmitted to the pharmacy. Because security now depends on the digital signature and digital certificate, and not on the service provider's system, systems would not have to be audited for security—only process integrity, a less intensive and less costly audit. The monthly log check would also be eliminated. The other requirements are the same as the Base Case.

Option 3 imposes no requirements for identity proofing, authentication, or system attributes. Instead, sole reliance for security is placed on a requirement for a callback from the pharmacy to the practitioner office for every electronic prescription for a controlled substance.

1.4 ORGANIZATION OF THIS REPORT

The remainder of this report is organized as follows:

Chapter 2 estimates the universe of entities potentially affected by the rule.
Chapter 3 presents the unit costs of each of the options considered.
Chapter 4 presents the total costs of each of the options considered.
Chapter 5 presents the small entity analysis.
Chapter 6 discusses the benefits of the proposed rule.
Chapter 7 presents conclusions and discusses uncertainties associated with the analysis.

CHAPTER 2: AFFECTED UNIVERSE

The proposed rule potentially affects any person authorized under State law to prescribe controlled substances and registered with DEA as an individual practitioner or exempt from the requirement of registration. It also directly affects registered pharmacies that process controlled substance prescriptions. This chapter discusses estimates of the number of entities that would incur costs for compliance if they elect to issue or receive electronic prescriptions for controlled substances. The rule would not require any registrant to issue or accept electronic prescriptions for controlled substances; paper and, where permitted, oral prescriptions are still allowed.

2.1 REGISTRANTS

As of December 2007, DEA had 1.18 million registered individual practitioners. Not all of these, however, are likely to prescribe controlled substances or do so often enough to justify any investment in an electronic prescription system. For example, veterinarians, optometrists, animal shelters, ambulance services, etc. rarely if ever prescribe controlled substances. Nurse practitioners and physicians assistants who work in hospitals or institutional settings may not prescribe controlled substances often. Similarly, many physician specialties either do not prescribe any controlled substances (anesthesiologists, radiologists, pathologists) or do not often prescribe controlled substances as part of their usual practices (dermatologists, obstetricians/gynecologists, ophthalmologists). In addition, many practitioners hold multiple DEA registrations because they practice in more than one State or dispense or administer controlled substances at multiple locations in a single State. Finally, some practitioners retain their registrations when they retire.

To estimate the number of practitioners who may use electronic prescribing for controlled substances, DEA used its registration data plus a Centers for Disease Control and Prevention (CDC) study of office-based physicians.[4] The CDC study used data from the American Medical Association (AMA) and the American Osteopathic Association (AOA), which indicated that there were 489,829 physicians engaged in non-federal office-based care.[5] The study found that a third of those were out-of-scope because they were hospital-based, federally employed, anesthesiologists, radiologists, pathologists (11.3 percent), retired or deceased (9.5 percent), non-office-based (4.7 percent), not practicing (4.4 percent) and otherwise ineligible (3.9 percent). The study estimated that there were 311,200 office-based physicians in 2004. DEA used this estimate as its baseline for physicians although the estimate includes a number of specialties that may rarely prescribe controlled substances. Adjusting the number for growth to 2007, DEA estimates that 312,135 physicians may now be writing controlled substances prescriptions.

[4] Hing, E., Burt, CW. "Characteristics of Office-Based Physicians and their Practices: United States, 2003-2004," Series 13, Number 164. Hyattsville, MD: National Center for Health Statistics. January 2007.
[5] Practitioners were limited to office-based because hospital-based practitioners do not usually write prescriptions and neither hospital-based nor federally employed practitioners would be purchasing electronic prescription systems.

The other three practitioner groups that are likely to prescribe controlled substances are dentists, nurse practitioners, and physicians assistants. Because DEA had no basis for estimating the number of dentists that may hold multiple registrations or have retired, DEA used the number of currently registered dentists (170,969), recognizing that the estimate is probably slightly high. For nurse practitioners and physicians assistants, DEA used its current registrant population (119,659) reduced by 25 percent to 89,744. DEA reduced the number because many of these mid-level practitioners work in hospitals, where they are unlikely to write prescriptions. For physicians assistants, only 63 percent work in office-based practices according to data from the Bureau of Labor Statistics;[6] DEA has no estimates of where nurse practitioners work because they are aggregated with all nurses in BLS data. Table 2-1 presents the estimate of total practitioners who could engage in electronic prescribing for controlled substances and the growth rate applied for estimating the number in each of the out-years.

Table 2-1: Practitioner Universe

	Current number	Future annual growth rate
Physicians	312,135	0.1 percent
Dentists	170,969	0.9 percent
Mid-level practitioners	89,744	2.2 percent
Total	**572,848**	**0.7 percent**

Estimated growth rates are based on recent trends. Regarding physicians, the trend since 2000 indicates a very slight negative growth rate. DEA does not believe this downward trend will continue; therefore, an annual growth rate for physicians of 0.1 percent has been estimated. The growth rate for dentists is based on the annual growth rate of DEA registrations for dentists from 2003 to 2007. The growth rate for mid-level practitioners is based on CDC data for increases in physicians assistants employment from 1999 to 2004. Nurse practitioners are a subset of nurses; employment of nurses grew 1.2 percent annually over that period.[7] Using the 2.2 percent growth rate is, therefore, slightly conservative. The rate for the total number of practitioners is the weighted average of the separate rates.

Part of the cost of initial in-person identity proofing depends on the number of practitioners' offices. The 2002 Economic Census reports 321,423 offices of physicians and dentists (203,118 physicians' offices and 118,302 dentists' offices.)[8] Consonant with DEA's estimate of the number of physicians likely to write controlled substances prescriptions, the number of physicians' offices is reduced by 25.0 percent and added to the dentists' offices to obtain 270,664 offices in 2002 where practitioners were likely to write controlled substances prescriptions. Using the 1997 and 2002 Economic Census,[9] DEA obtained the weighted

[6] http://www.bls.gov/oes/current/oes291071.htm.
[7] CDC, Health, United States, 2006, Table 108.
[8] http://www.census.gov/prod/ec02/ec0262ssszt.pdf
[9] http://www.census.gov/prod/ec97/97s62-sz.pdf

annual growth rate for these offices from 1997 to 2002—0.77 percent. DEA used that rate to estimate the number of practitioners' offices for this analysis in 2007—280,929 and to project the future growth of these offices.

According to the National Association of Chain Drug Stores, there are about 57,000 retail pharmacies in the United States.[10] Of these, about 40,000 stores are owned by chains. Since there are about 200 pharmacy chains in the United States, there are about 17,200 retail-pharmacy firms.

2.2 SYSTEM PROVIDERS

There is more than one kind of system provider, and confusion can arise if clear distinctions are not made among them. It is necessary to establish a clear terminology before addressing the universe of system providers.

A system provider is any firm that provides practitioners' offices or pharmacies with the services and software required for transmitting or processing electronic prescriptions. System providers can be described in several ways. Providers may install systems on practice computers and servers, or they may install software needed to link the practice to the service provider's systems. The latter are called application service providers (ASPs). An ASP system is usually less expensive initially because the practice does not need to purchase servers to store records and because trouble-shooting occurs at the ASP level rather than at the practice. Reprogramming can be done without needing to install patches or new software at the practice. ASPs also have the advantage that they can be accessed from any location through the Internet. Installed systems are more costly at least in the early years because they require more hardware and more on-site support. ASPs, however, may carry higher annual maintenance fees.

Systems may be further divided into two groups—those that provide only electronic prescription services (stand-alone systems) and those that provide electronic prescriptions as part of an electronic medical record system (EMRs). These may be referred to as e-prescription providers and EMR providers. The latter group is by far the larger; DEA expects the e-prescription providers to disappear over time because most practices transitioning to electronic records want a system that can integrate all of its records rather than just handle one function. Although most stand-alone e-prescription systems are ASPs, EMRs may be either ASPs or installed systems.

Prescriptions at pharmacies are handled by a pharmacy management system. These systems may be ASPs or installed systems. The largest chains generally maintain a centralized system that links all of their stores, functioning in effect as an ASP for the chain.

DEA estimated the number of electronic prescribing providers by combining the list of providers certified by SureScripts with the list of EMR system providers certified by the Certification Commission for Healthcare Information Technology (CCHIT) in December

[10] www.nacds.org/user-assets/pdfs/facts_resources/2006/Retail_Outlets2006.pdf

2007.[11, 12] The CCHIT list was used because any system certified under CCHIT must support electronic prescribing. Overall, 119 firms were listed. The number may be slightly high because some firms may be listed as both firms and software systems. Of the 119, 103 are EMR systems; the remainder are electronic prescription systems. Of the EMR systems, 86 are certified by CCHIT. SureScripts certifies 66 systems, including all of the stand-alone systems. The number of pharmacy system providers (20) is based on the number of these providers certified by SureScripts, which states that 95 percent of United States pharmacies are able to accept electronic prescriptions. The number may be slightly high because a few of the certified systems may be transmission networks rather than pharmacy management systems. Balancing that is the possibility that a few of the larger chain pharmacies may have their own systems, designed and maintained internally.

Because the pharmacy systems are generally already in operation, DEA assumed that it is a mature market and the number of providing firms would remain at 20 throughout the implementation period. A similar assumption cannot be made about the systems serving practitioners. The market is evolving rapidly. When DEA began considering electronic prescriptions for controlled substances, the majority of the firms were marketing e-prescription services. As the numbers above indicate, the great preponderance of firms is now selling EMR systems. It is reasonable to assume that most, and perhaps all, of the electronic prescription systems will be sold to an EMR firm, incorporate EMR capability, or simply fail. Similarly, it is likely that over the longer term, most of the EMR systems will not succeed in the competitive marketplace. These systems are not only internally complicated, requiring considerable investment in ongoing technical support from the provider, but they also must be able to interoperate with systems used by testing laboratories, hospitals, insurance companies, pharmacies, clinics, and other medical practices. In this situation, the tendency will be for a few systems to become dominant players and then replace the smaller systems because the dominant systems interoperate easily with other systems using the same basic platform. As a recent study of the evolution of word processing systems found, of more than 400 such systems being sold in the mid-1980s, only a very few remained 10 years later.[13]

Because the ongoing cost of the rule is driven in part by the cost to providers, DEA needed to estimate the number of firms serving practitioners that would exist over time. As discussed below under total costs, DEA projected that only 20 systems would remain in the market by the end of ten years. DEA also estimated that in the first year, only 110 firms would comply with the rule. This lower initial estimate (from the 119 firms certified) is based on the assumption that there are almost certainly too many firms competing for what is still a relatively small market; some will drop out rather than incur the effort and cost of becoming compliant with the rule.

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[11] SureScripts is a pharmacy industry organization that certifies electronic prescription and pharmacy systems that comply with the National Council for Prescription Drug Program SCRIPT standard; SureScripts certification indicates that the service provider's systems will interoperate with other systems using the SCRIPT standard. CCHIT establishes standards and certifies electronic medical record (EMR) systems.

[12] http://www.cchit.org/choose/ambulatory/2007/index.asp, accessed 12/7/07 and www.surescripts.com/get-connected.aspx?ptype=physician, accessed 12/5/07.

[13] Bergin, T.J, "The Proliferation and Consolidation of Word Processing Software: 1985-1995." IEEE Annals of the History of Computing. Volume 28, Issue 4, Oct.-Dec. 2006 Page(s):48 - 63

A 2006 CDC study of EMR use found that only 12 percent of physicians reported having fully electronic EMR systems, which implies that the 103 EMR providers are vying for a market that has fewer than 40,000 practitioners.[14] With the cost of building and maintaining a technically complex system, many existing firms are likely to run out of capital before they gain enough market share to be profitable, and the number of sellers in this market will continue to decline over time.

[14] Centers for Disease Control and Prevention, "Electronic Medical Record Use by Office-Based Physicians and Their Practices: United States 2006." Advance Data from Vital and Health Statistics, Number 393, October 26, 2007.

CHAPTER 3: UNIT COSTS

In estimating unit costs of the rule, the first step is to establish the baseline with which to determine the costs that are incremental with respect to the rule. DEA presumes that no practitioner's office will adopt electronic prescribing simply to write controlled substance prescriptions; controlled substances now constitute about 11.0 percent of the total number of prescriptions written annually in the United States.[15] The costs to a practitioner's office of complying with the rule, therefore, are only the system costs directly required by the electronic prescriptions for controlled substances rule and do not include any of the costs that the office would incur for setting up electronic prescription capability without controlled substances.

3.1 REQUIREMENTS

DEA is considering four variants on a rule to allow electronic prescription of controlled substances—the Base Case, and Options 1, 2, and 3. The Base Case would impose the following requirements on an electronic prescription system:

- In-person identity proofing imposes costs on practitioners and providers.
- Two-factor authentication requires that each practitioner with authority to sign controlled substance prescriptions have a unique hard token to gain access to the system. This imposes costs on some practitioners.
- Monthly review of controlled substance prescription logs by practitioners imposes a cost on practitioners.
- System requirements impose reprogramming costs on service providers.
- Requirements for annual independent third-party audits impose costs on service providers.

Effects of options:

- Under Options 1 and 2 in-person identity proofing also imposes costs on DEA-registered hospitals, State licensing boards, or law enforcement agencies; costs to practitioners rise because of the greater time required.
- Option 2 does not require log reviews.
- Option 2 requires that each registrant have a digital signature, generated by a digital certificate issued by a federally approved Certification Authority. This imposes costs on practitioners' offices.
- Option 2 imposes lower costs for independent third-party audits.

[15] The 11 percent is based on the percent of the top 200 brand name prescriptions filled (number of prescriptions, not value) and top 200 generic prescriptions that DEA identified as controlled substances. The analysis assumes that the remaining prescriptions (about one sixth of total prescriptions) will have the same proportion of controlled substance prescriptions as the top 400 do.

- Option 3 has none of the above requirements. Instead, sole reliance for security is placed on a requirement for a callback from the pharmacy to the practitioner office for every electronic prescription for a controlled substance received. This imposes costs on pharmacies and practitioners' offices.

3.2 COSTS

3.2.1 IDENTITY PROOFING

Base Case:

Identity proofing under the Base Case requires a face-to-face meeting between each practitioner who will use the system and a representative from the service provider. The meeting would take two minutes of the practitioner's time (to show the provider a government-issued photographic identification) and the service provider's time to look at the identification and make a record of the type of identification seen. For each practitioner, an information clerk would spend another eight minutes at the service provider's office verifying that the practitioner's State license and DEA registration are active and in good standing, and entering the practitioner's data into the service provider's record of identity proofing. In many cases, the service provider would meet practitioners while on a visit to the practitioner's office that would have been made for other purposes (e.g., installation, training, trouble-shooting). In some cases, however, the visit would be made for no other purpose than the identity proofing itself, particularly for some current electronic prescribing ASPs; in such a case, the service provider staff person's travel time to and from the practitioner's office would be a cost. DEA assumes an average round trip of two hours. Using a weighted average for practitioners' wages (fully loaded) of $222.51, $83.80 for the service provider representative, and $33.89 for the service provider clerk, the cost of identity proofing is $7.42 for practitioners, $2.79 for the service provider representative, and $4.52 for the service provider clerk. Thus, the cost of identity proofing without travel is $14.73. Two hours of travel adds $167.71, so the cost of identity proofing with travel is $182.34.

Options 1 and 2:

Identity proofing is conducted by a DEA-registered hospital, State licensing board, or State or local law enforcement agency—not by the service provider. DEA assumes that the great preponderance of the identity proofing would be done at hospitals. Since physicians routinely visit local hospitals, travel time to the hospital for a medical doctor is not included as a cost, but travel time for dentists and mid-level practitioners is regarded as incremental cost. Average round trip to a hospital is assumed as one hour. The identity proofing session at the hospital would require ten minutes of a practitioner's time and ten minutes for an agent of the hospital. A hard document is generated and signed by both practitioner and hospital agent. The document is mailed from the practitioner's office to the service provider's office. For Option 2, the document would be mailed to the Certification Authority. Mailing requires two minutes of a secretary's time plus postage. As in the Base Case, a clerk at the service provider's office takes eight minutes to ensure that the practitioner's State license and DEA registration are active and in good standing, and enter the data into the record. But, under

Options 1 and 2, the service provider's clerk also calls the practitioner's office to verify the application. This requires three minutes for the service provider clerk and one minute for the practitioner. Finally, the service provider clerk takes another two minutes to file the document.

For each identity proofing, then, 11 minutes are needed for the practitioner, ten minutes for the hospital agent, 13 minutes for the service provider clerk, and two minutes for the practitioner secretary. Full hourly cost for the hospital agent is $35.55, for the medical secretary, $30.33. Additional costs are $0.41 for postage and annual storage cost (in a standard filing cabinet) at the service provider's office of $0.01[16].

Table 3-1: Summary of Identity Proofing Cost—Base Case

Cost item	Time	Full hourly cost	Unit cost
Practitioner	2 minutes	$222.51	$7.42
Service provider representative	2 minutes	$83.80	$2.79
Service provider clerk	8 minutes	$33.89	$4.52
Travel for service provider representative	2 hours	$83.80	$167.61
Total without travel			$14.73
Total with travel			$182.34

Table 3-2: Summary of Identity Proofing Cost—Options 1 and 2

Cost item	Time	Full hourly cost	Unit cost
MD	11 minutes	$269.00	$49.32
Dentist	11 minutes	$214.07	$39.25
Mid-level practitioner	11 minutes	$76.94	$14.11
Hospital staff	10 minutes	$35.55	$5.93
Service provider clerk	13 minutes	$33.89	$5.65
Practitioner secretary	2 minutes	$30.33	$1.01
Dentist travel	1 hour	$214.07	$214.07
Mid-level travel	1 hour	$76.94	$76.94
Postage			$0.41
Storage			$0.01
Totals			
MD (no travel)			$63.84
Dentist			$267.83
Mid-level practitioner			$105.56

In Option 2, the hard copy of the identity proofing document is stored at the office of the Certification Authority rather than the service provider's office, but that does not change the cost.

3.2.2 TWO-FACTOR AUTHENTICATION

This requirement is the same for the Base Case and for Options 1 and 2. Two-factor authentication requires that access to the system can be gained only using a combination of a

[16] The annualized cost of a standard file cabinet is $10.98 a year (at 7%); a file cabinet holds about 1,100 files.

hard token, which holds the practitioner's private cryptographic key or one-time-password and a password. A number of devices may serve this purpose: e.g., PDAs, Blackberries, thumb drives, smart cards, multi-factor one-time-password devices. It is assumed that physicians and dentists will already have a PDA and be familiar with its use. The same cannot be assumed for mid-level practitioners. DEA assumes that tokens would have to be purchased for 75.0 percent of mid-level practitioners and those mid-level practitioners would require training in the use of the tokens. For mid-level practitioners, the tokens would be thumb drives. Time required for training is estimated to be ten minutes per mid-level practitioner. Using the hourly wages (including fringes and overhead) for physician's assistants of $76.94, the training cost is estimated to be $12.82. A thumb drive costs $12.00; total unit cost for mid-level practitioners only: $24.82.

DEA has not considered the cost of using two-factor authentication prior to signing because the actual authentication is no different, from the practitioner's point of view, from entering a password as persons that use electronic prescription systems already do. The protection in two-factor authentication is the storage of part of the authentication protocol on the hard token; the actual authentication does not add steps for the practitioner signing a prescription electronically although it may alter when the practitioner authenticates to the system.

3.2.3 Digital Certificates

An approved Certification Authority would charge each practitioner an annual fee of $30.00 for issuing a digital certificate for a digital signature. The costs for digital certificates vary from less than $20 a year to $80 or more depending on the security features.

3.2.4 Monthly Review Of Controlled Substance Prescription Logs

This is the same for the Base Case and Option 1. There is no log review in Option 2. Once a month, each practitioner would review the log of his controlled substance prescriptions for that month. DEA is not proposing to require a comprehensive review or a cross-check with medical records. Rather DEA is proposing that the practitioner check the log for obvious anomalies – prescriptions for patients he did not see, prescriptions for substances he generally does not prescribe, prescriptions for quantities that seem abnormal. DEA estimates that a practitioner can review the log for obvious anomalies in an average of two minutes. Although some practitioners will need more time than that, there will be a significant number of practitioners who write few, or no, controlled substance prescriptions in any given month. The average cost is estimated to be $7.42 per month or $89.01 per year, using a weighted hourly wage for all practitioners.

3.2.5 Programming Costs

As shown in Table 3-1, a number of the proposed requirements would necessitate reprogramming by some or all of the existing service providers. Any system currently able to transmit prescriptions electronically should be complying with the NCPDP SCRIPT standard, which includes fields for all of the basic prescription data elements that DEA requires. If any existing program is not transmitting those elements (e.g., practitioner or

patient address), their programs should nonetheless already be capable of doing so with little effort because the fields already exist in the program. Some of the additional requirements, such as the pop-up screen prior to signing, should require relatively minor programming. Similarly, any ASP that does not have an automatic time-out function can add it relatively easily. Any system provider that conducts secure transactions over the Internet will already have a digital certificate and have done the programming needed to implement digital signing; they will need to program to sign these prescriptions, but the more complex programming for adding the digital signing functionality should already exist. The more complicated programming may be adding access limitations where they do not currently exist and adding two-factor authentication with a cryptographic key. Systems that do not support these functions may need more substantial reprogramming.

Table 3-3 presents detail on the individual requirements that affect programming costs. The items in italics are those that will require few, if any, entities to incur such costs.

Table 3-3: System Requirements

Requirement	Current practice
Two-factor Level 4 authentication	*EMRs certified by CCHIT must support 2-factor authentication.*[17] *Most EMRs have this capability. E-prescribing systems may need to reprogram to require cryptographic keys.*
Limit access to signing function	*EMRs certified by CCHIT must do this. Many stand-alone systems also already do this. Some systems may need to add this functionality.*
Automatic lockout after a period of inactivity	*EMRs certified by CCHIT must do this. Most systems may have this function. For ASPs, the programming is relatively simple.*
Prescription must contain all DEA data elements	*All systems should already have this capability. All of the required elements are included in SCRIPT. If any system does not include all of these elements, it would have to reprogram.*
Present the required data elements to the practitioner	*Most systems present the full prescription information on a single screen.*
Indicate that each prescription is ready to be signed	Some existing systems already do this, requiring practitioners to check off each prescription they want to sign. Others may need to reprogram to include this function.
Authenticate to the system just before signing	Unclear when current systems require authentication. At least one requires entry of separate password to sign. Most may need to reprogram to apply this function at signing.
Transmit immediately upon signature	*May be common practice in existing systems because signing is the equivalent of transmitting. Some systems may need to reprogram to add this function.*
Do not transmit if printed; do not print if transmitted	May be a new function for most systems. (This requirement does not prevent printing a copy of a medical record.) Systems may need to reprogram.

[17] CCHIT Security Criteria 2007 Final 16Mar07.

Requirement	Current practice
Indicate that the prescription was signed	A new field for e-prescriptions; industry has indicated that this is not a problem. SCRIPT will need to be revised to indicate which field will be used. SCRIPT has available fields that can be used.
Generate monthly logs for practitioner review	All systems should be able to generate records.
First recipient digitally signs the prescription as transmitted	At least one service provider is already doing so. Service providers all have digital certificates and the capability to sign records digitally. They will need to reprogram to include the function.
Do not convert to fax if cannot be delivered	May alter existing practice for some intermediaries. HHS has proposed removing an exemption from the SCRIPT standard for faxes.
No alteration of the content during transmission except for formatting	*Industry says this does not happen so requirement should not impose a burden.*
First pharmacy (or last transmitter) digitally signs the prescription as received	Intermediaries and at least some pharmacy system providers have digital certificates and the capability to sign records. Any system that conducts secure transactions on the Internet will have digital signature capability. They may all have to reprogram to add the signing function.
Check the validity of the prescriber's DEA registration (Pharmacy)	Many pharmacies already check the DEA registration database for registration information. This will probably require some reprogramming to automate the check for each prescription.
Store all of the DEA data in the pharmacy system	*Pharmacy systems already do this. Some may have problems with extensions to DEA registration numbers.*
Have an internal audit trail and analyze for auditable events (Pharmacy)	*Most systems have this capability.*

To estimate the cost of reprogramming, DEA divided the universe into systems that already implement many of the functions required and those that may not. EMRs are assumed to support most of the functions that may require more extensive programming. Stand-alone electronic prescription systems are assumed to need more programming to support two-factor Level 4 authentication and access limitations. For pharmacies, those systems that operate as ASPs are assumed to require lower levels of programming because they will already have digital signature functionality; the rest of the systems are assumed to need to add digital signature functionality.

Based on industry information presented to DEA when the Agency developed the Controlled Substances Ordering System, DEA estimated that adding digital signature functionality or the authentication/access limits would require about 2,000 hours of programming time to install and test.[18] For systems that only need to add new screens or less complex instructions, DEA

[18] 70 FR 16911, April 1, 2005. Economic analysis is available at http://www.deadiversion.usdoj.gov/ecomm/csos/csos_eia_03112005.pdf.

estimated that they would need 500 hours of programming and testing. DEA recognizes that these estimates are averages and that there will be considerable variability based on the functions that each system already has. Some systems may already meet almost all or all of the requirements. Others may require more extensive revision. DEA notes that given the complexity of even electronic prescribing systems, which are usually designed to link to drug and formulary databases as well as in-house record systems (schedules/calendars, patient databases, billing, etc.), the elements DEA is requiring are relatively simple and do not alter any basic functions of the system. For cost estimates, DEA assumes that systems with EMR capability and systems for providers to pharmacies will require 500 hours of reprogramming; systems for practitioners with capability only for electronic prescriptions will require 2,000 hours.

Given the hourly cost of a programmer of $73.24, 500 hours of reprogramming costs $36,619, and 2,000 hours costs $146,477. Both levels of reprogramming would be needed under the Base Case and Option 1, according to capabilities of providers' existing systems. Under Option 2, however, only 500-hour reprogramming would be required. Because security would depend on the digital signature of a practitioner, complex authentication procedures would not be required for service providers' systems.

DEA also recognizes that the NCPDP SCRIPT standard itself will need revision to add an indication that the prescription has been signed. The standard is being revised on a continuing basis; HHS testing of elements of the standard indicated that three of the six elements tested were not ready for implementation. DEA, therefore, does not consider that the cost of what is a minor revision — designating one of the open fields to indicate that the prescription was signed — to impose any significant burden on the standard or on systems using the standard. SureScripts and other intermediaries may also have to reprogram their systems to ensure that no controlled substance prescription file is converted into a fax if the electronic transmission fails. These systems, however, are constantly adjusting to new service providers and existing service provider upgrades. This change should not impose a burden on them. DEA notes that transforming an electronic data file into a fax would create an illegal prescription because faxed prescriptions must be manually signed by the practitioner prior to transmission.

3.2.6 AUDITING REQUIREMENTS

For the Base Case and Option 1, all system providers that serve practitioners would be required to undergo an annual third-party security audit for system security, processing integrity, and compliance with the rule. The audits would have to meet the standards of a SysTrust, WebTrust, or SAS 70 audit; these audit protocols are established and maintained by the American Institute of Certified Public Accountants and are widely recognized and used in the commercial sector for IT systems.[19] The same level of audit would be required for providers that serve pharmacies under the Base Case and both Options 1 and 2. The level of audit for service providers to practitioners would drop under Option 2; reliance on the

[19] For a description of these audits, see http://www.ffiec.gov/ffiecinfobase/booklets/audit/audit_06_3_party.html.

digital signature for security would lessen the need to audit for system security. Only audits for processing integrity would be required for practitioner service providers under Option 2.

The first audit for a service provider is generally more costly than subsequent audits because the auditors need to familiarize themselves with the system and document its elements. Subsequent audits, if conducted by the same audit firm, do not involve the same learning curve. DEA estimates the following per-vendor costs for audits: First-year audits: $125,000; subsequent audits: $100,000. DEA notes that the costs of a SysTrust or SAS 70 audit range from $15,000 to $250,000 depending on the size of the company. DEA used a conservative estimate of $125,000 for the initial audit although in many cases the cost for the DEA required audit elements would be less. A full SysTrust or SAS 70 audit covers five areas; DEA is requiring that the audit address only two of those, physical security and processing integrity. For Option 2 audits, addressing only processing integrity, DEA estimates annual audit cost of $25,000, including first-year audits.

Table 3-4: Summary of Costs, Other Than Identity Proofing—Base Case, Options 1 and 2

Cost item	Time	Full hourly cost	Unit cost
Two-factor token (mid-level practitioners only)			
Learning	2 minutes	$76.94	$12.82
Token			$12.00
Total			$24.82
Digital certificate (annual cost) (Option 2)			$30.00
Monthly log review (Base Case, Option 1)	2 minutes per month	$222.51	$89.01
Reprogramming			
Pharmacy systems	500 hours	$73.24	$36,619
Practitioner systems (EMR capability) (all systems in Option 2)	500 hours	$73.24	$36,619
Practitioner systems (E-prescription only) (Base Case and Option1)	2,000 hours	$73.24	$146,477
Audits—annual cost			
Pharmacy systems (first year)			$125,000
Pharmacy systems (2nd and subsequent years)			$100,000
Practitioner systems (first year) (Base Case, Option 1)			$125,000
Practitioner systems (2nd and subsequent years) (Base Case, Option 1)			$100,000
Practitioner systems (all years) (Option 2)			$25,000

3.2.8 OPTION 3 REQUIREMENTS

Option 3 requires that a technician at the pharmacy call a practitioner's office and speak to the prescribing practitioner for every electronic prescription of a controlled substance

received by the pharmacy. DEA estimates that this will take three minutes for the pharmacy technician, three minutes for a medical secretary who receives the call and retrieves the file, and one minute for the practitioner to look at the file and speak to the pharmacy technician.

Table 3-5: Option-3 Unit Cost

Cost item	Time	Full hourly cost	Unit cost
Pharmacy technician	3 minutes	$26.63	$3.71
Practitioner secretary	3 minutes	$30.60	$1.53
Practitioner	1 minute	$222.51	$3.71
Total			$6.55

CHAPTER 4: TOTAL COSTS

To proceed from unit costs to total costs, it is necessary to establish the frequency of occurrence of cost items and the distribution of those occurrences, and thus of costs, over time.

4.1 NUMBERS OF PRACTITIONERS, OFFICES, AND SERVICE PROVIDERS

The first step is selection of the time horizon for the analysis. DEA has chosen 15 years for the period of the analysis. DEA expects that full implementation of electronic prescriptions for controlled substances will require 15 years, i.e., at the end of the 15th year of the analysis, all practitioners' offices will have controlled substance electronic prescribing capability in their IT systems.

Fifteen years is essentially an estimate of the time required for implementation of electronic prescription and EMR systems. As practitioners adopt EMR and electronic prescription systems, they will include electronic prescribing of controlled substances in the package, as the incremental cost of doing so for an office is very slight. (Going forward, DEA expects few practices to buy electronic prescription systems without getting the entire package with EMR.) Although the selection of the implementation period is somewhat arbitrary, DEA believes that 15 years is a reasonable estimate to reflect the balance between pressure from insurers, who want practitioners to implement EMR systems, and the reluctance of practitioners to invest in expensive systems that are time-consuming to implement and perhaps not yet fully tested. The larger practices may well acquire EMR systems early on, but the practices with five or fewer physicians—which employ 74.5 percent of all practitioners—will take much longer to do so.[20] It is reasonable to assume that for the 35.8 percent of practitioners in solo practice, it could take at least 15 years before they adopt EMRs.

To distribute costs over time, year by year, it is necessary to project the rate at which electronic prescribing systems will be implemented in practitioners' offices. Table 4-1 shows the schedule at which DEA projects implementation over time.

Table 4-1: Implementation Schedule

	Percentage of offices implementing in a year	Cumulative implementation percentage
Year 1	6.0	6.0
Year 2	4.0	10.0
Year 3	4.0	14.0

[20] Hing, E., Burt, CW. "Characteristics of Office-Based Physicians and their Practices: United States, 2003-2004," Series 13, Number 164. Hyattsville, MD: National Center for Health Statistics. January 2007.

	Percentage of offices implementing in a year	Cumulative implementation percentage
Year 4	5.0	19.0
Year 5	5.0	24.0
Year 6	5.0	29.0
Year 7	6.0	35.0
Year 8	6.0	41.0
Year 9	7.0	48.0
Year 10	9.0	57.0
Year 11	10.0	67.0
Year 12	11.0	78.0
Year 13	11.0	89.0
Year 14	6.0	95.0
Year 15	5.0	100.0

The rate in Year 1 is somewhat higher than the rate in the next several years, because some percentage of offices has already adopted electronic prescription systems. After dropping in Year 2, the rate rises gradually to a peak in Years 12 and 13 and then drops as full implementation approaches.

Total costs for practitioners and some costs for providers will also be affected by the annual growth rates of the different classes of practitioners—0.1 percent for physicians, 0.9 percent for dentists, 2.2 percent for mid-level practitioners, and 0.7 percent for the weighted growth rate for all practitioners. Table 4-2 shows the effect of the overall growth rate on number of practitioners and the combined effects of the implementation rate and the growth rate on the annual increment in the number of practitioners in offices with implemented e-prescription systems.

Table 4-2: Annual Increments in Affected Practitioners

	Total practitioners	Practitioners adding EPCS systems	Cumulative practitioners in offices with EPCS
Year 1	572,848	34,371	34,371
Year 2	576,673	23,296	57,667
Year 3	580,524	23,606	81,273
Year 4	584,400	29,763	111,036
Year 5	588,303	30,157	141,193
Year 6	592,231	30,554	171,747
Year 7	596,186	36,918	208,665

	Total practitioners	Practitioners adding EPCS systems	Cumulative practitioners in offices with EPCS
Year 8	600,167	37,403	246,068
Year 9	604,174	43,935	290,004
Year 10	608,209	56,675	346,679
Year 11	612,270	63,542	410,221
Year 12	616,359	70,539	480,760
Year 13	620,474	71,462	552,222
Year 14	624,618	41,165	593,387
Year 15	628,789	35,402	628,789

As noted in the chapter on unit costs, there are both start-up costs and ongoing costs driven by the number of practitioners. Start-up costs incurred in each year will be based on the number of practitioners in offices implementing electronic prescriptions for controlled substances in that year plus new hires in offices that have already adopted controlled substances prescribing. The combination of implementation and growth rates captures both the newly implementing offices and the new hires.

Ongoing costs for practitioners will be based on the total number of practitioners in offices where electronic prescriptions for controlled substances has been implemented in a given year, i.e., the cumulative number of practitioners in offices that have adopted electronic prescribing of controlled substances.

While most costs depend on number of practitioners, there are two exceptions for ASPs. One has to do with office visits for in-person identity proofing (Base Case), the other with annual audits. In some cases, as noted in Chapter 3, under the Base Case, ASP staff would have to visit practitioners' offices for no purpose other than to conduct initial identity proofing. In that case, an ASP staff person's travel time to and from such offices is an incremental cost with respect to the rule, and the travel costs depend, in part, on the number of practitioners' offices in which electronic prescriptions for controlled substances has been adopted. Table 4-3 shows DEA's projection of the total number of practitioners' offices and the year-by-year number of offices implementing electronic prescriptions for controlled substances.[21] The EPCS implementation rate for offices is the same as the implementation rate for practitioners as shown in Table 4-1.

[21] Growth rate is the weighted average of the growth rates of physicians' and dentists' offices based on the number of such offices in 1997 and 2002 as found in the 2002 Economic Census—0.77 percent for physicians' offices, 0.71 percent for dentists' offices, weighted average growth rate of 0.75 percent.

Table 4-3: Practitioners' Offices Implementing Electronic Prescribing of Controlled Substances

	Offices adopting EPCS in a year	Total offices
Year 1	16,856	280,929
Year 2	11,448	283,032
Year 3	11,618	285,152
Year 4	14,663	287,287
Year 5	14,881	289,438
Year 6	15,100	291,605
Year 7	18,261	293,788
Year 8	18,529	295,988
Year 9	21,783	298,204
Year 10	28,111	300,437
Year 11	31,551	302,687
Year 12	35,063	304,953
Year 13	35,577	307,237
Year 14	20,620	309,537
Year 15	17,795	311,855

DEA believes that visits only for initial identity proofing would be made almost entirely by ASPs offering only electronic prescription systems, not EMRs. A significant amount of work is required to set up and maintain an EMR system. It is highly unlikely that, during the initial set-up of the system, EMR provider staff would be in a practitioner's office with no task to perform other than identity proofing. DEA expects that the electronic prescription system providers will disappear fairly quickly, either going out of business or expanding their services to include EMR. As this happens, the percentage of initial visits made only for identity proofing will decline to zero by the end of Year 5. This is shown in Table 4-4.

Table 4-4: Initial Visits Only for Proofing (Base Case)

	Percentage of initial visits only for identity proofing
Year 1	15.0
Year 2	12.0
Year 3	9.0
Year 4	6.0
Year 5	3.0

	Percentage of initial visits only for identity proofing
Year 6	0.0
Year 7	0.0
Year 8	0.0
Year 9	0.0
Year 10	0.0
Year 11	0.0
Year 12	0.0
Year 13	0.0
Year 14	0.0
Year 15	0.0

Regarding audit costs for system providers, total cost is a function of the number of providers. DEA expects that there will be 110 firms offering services to practitioners' offices in Year 1, and that this number will drop to 20 in Year 11 and stabilize at that level. The number of providers serving pharmacies remains stable at 20 throughout the analysis period. Table 4-5 shows the projected number of providers to practitioners over the analysis period.

Table 4-5: Projected Reduction in Providers to Practitioners

	Number of providers serving practitioners
Year 1	110
Year 2	95
Year 3	80
Year 4	70
Year 5	60
Year 6	50
Year 7	40
Year 8	30
Year 9	25
Year 10	25
Year 11	20
Year 12	20
Year 13	20
Year 14	20
Year 15	20

4.2 START-UP COSTS AND ON-GOING COSTS

Start-up costs are those incurred by an entity when it first implements electronic prescriptions for controlled substances and takes the steps needed to comply with the rule. Under the assumptions of this analysis, all start-up costs will be incurred during the 15-year analysis period. Ongoing costs are those incurred after initial implementation and which will continue indefinitely thereafter.

Start-up costs for practitioners are the initial identity proofing and the purchase of hard tokens, and training in their use, for some of the mid-level practitioners. The major ongoing cost is the monthly log review (absent in Option 2). Under Option 2, the digital certificate is an ongoing cost for practitioners. There is also some ongoing cost associated with turnover of personnel in practitioners' offices. When a practitioner moves to a new office, there is a high likelihood that the transfer will also be a move between providers; when that is the case, there must be a new identity proofing for that individual. Transfers of mid-level practitioners are assumed to require new purchases of hard tokens.

For providers, the start-up cost is the required reprogramming. The major ongoing cost is the annual audit. But providers also incur ongoing cost for identity proofing, both when a practitioner's office adopts electronic prescriptions for controlled substances and in the case of identity proofing required when practitioners transfer between offices with different providers. Most identity proofing costs are shifted from providers to hospitals in Options 1 and 2. Table 4-6 presents a summary of start-up and ongoing costs and the timing of each group of costs.

Table 4-6: Start-up and Ongoing Costs
Base Case, Options 1 and 2

	Practitioners	Providers
Start-up costs	Initial identity proofing Buying tokens for mid-levels Training for mid-levels in use of tokens	Reprogramming for providers
Timing of start-up costs	These costs will accrue throughout the analysis period as practitioners adopt EPCS.	All these costs will accrue in Year 1 of the analysis.
Ongoing costs	Monthly log reviews (not in Option 2) Digital certificates (only in Option 2) Proofing of transfers Buying tokens for transferring mid-levels	Annual audits for providers Identity proofing for start-up practitioners Identity proofing of transfers (Identity proofing costs borne by hospitals in Options 1 and 2)
Timing of ongoing costs	All of these costs will accrue in the time after initial implementation in a practitioner office.	These costs will accrue throughout the analysis period.

All callbacks in Option 3 are ongoing costs.

Some further assumptions regarding these costs must be made to estimate total costs. These are as follows:

- For ongoing identity proofing visits due to personnel turnover, there is no incremental travel cost in the Base Case.
- Percentage of personnel transfers between offices that are also transfers between service providers: 90.0 percent.
- Annual turnover rate for physicians and dentists: 2.5 percent.
- Annual turnover rate for mid-level practitioners: 5.0 percent.

DEA assumes that ongoing identity proofing will not involve travel costs in the Base Case because provider staff may have to visit practices for other reasons, such as system upgrades, maintenance, and staff training. Identity proofing can occur during those visits. Identity proofing for transfers in Options 1 and 2 will still require travel to hospital for dentists and mid-level practitioners.

4.3 TOTAL COSTS

Table 4-7 shows the annualized costs over the analysis period for each of the four variants. The discounted present values over the analysis period are summed to yield present value of total cost for the period. The present-value total is then annualized with a capital recovery factor to yield annualized total costs.

Table 4-7: Total Costs ($)

	7.0 percent	3.0 percent
Base Case	$32,561,452	$33,392,270
Option 1	$38,256,015	$39,220,948
Option 2	$18,594,831	$18,928,003
Option 3	$1,280,040,536	$1,404,204,487

Tables 4-8 and 4-9 show annualized costs of individual cost items for the Base Case and the three options with 7.0 and 3.0 percent interest rates. For simplicity, start-up and ongoing costs have been combined for the same item, e.g., identity proofing includes both start-up and ongoing identity proofing. Monthly log reviews are the largest single component of costs for the Base Case and Option 1. It is the absence of log reviews in Option 2 that makes it the low-cost variant. Annual audits for providers are large cost items. All the other costs are relatively trivial compared to these items, except for the enormous cost of the call-backs in Option 3.

Table 4-8: Annualized Costs by Cost Item

7.0 percent

	Practitioners	Providers	Total
	Base Case		
Identity proofing	$352,367	$459,425	$811,792
Tokens	$90,757		$90,757
Training	$75,147		$75,147
Log reviews	$22,495,039		$22,495,039
Reprogramming		$824,224	$824,224
Audits		$8,264,492	$8,264,492
Total			$32,561,452
	Option 1		
Identity proofing	$6,151,445	$354,910	$6,506,355
Tokens	$90,757		$90,757
Training	$75,147		$75,147
Log reviews	$22,495,039		$22,495,039
Reprogramming		$824,224	$824,224
Audits		$8,264,492	$8,264,492
Total			$38,256,015
	Option 2		
Identity proofing	$6,151,445	$354,910	$6,506,355
Tokens	$90,757		$90,757
Training	$75,147		$75,147
Digital Certificates	$7,582,154		$7,582,154
Reprogramming		$703,606	$703,606
Audits		$3,636,812	$3,636,812
Total			$18,594,831
	Option 3		
	Practitioners	**Pharmacies**	**Total**
Callbacks	$1,023,778,891	$256,261,645	$1,280,040,536

Table 4-9: Annualized Costs by Cost Item
3.0 percent

	Practitioners	Providers	Total
	Base Case		
Identity proofing	$357,789	$443,823	$801,612
Tokens	$94,227		$94,227
Training	$76,832		$76,832
Log reviews	$24,389,580		$24,389,580
Reprogramming		$628,833	$628,833
Audits		$7,401,186	$7,401,186
Total			$33,392,270
	Option 1		
Identity proofing	$6,269,439	$360,851	$6,630,290
Tokens	$94,227		$94,227
Training	$76,832		$76,832
Log reviews	$24,389,580		$24,389,580
Reprogramming		$628,833	$628,833
Audits		$7,401,186	$7,401,186
Total			$39,220,948
	Option 2		
Identity proofing	$6,269,439	$360,851	$6,630,290
Tokens	$94,227		$94,227
Training	$76,832		$76,832
Digital Certificates	$8,220,726		$8,220,726
Reprogramming		$536,808	$536,808
Audits		$3,369,812	$3,369,812
Total			$18,928,003
	Option 3		
	Practitioners	**Pharmacies**	**Total**
Callbacks	$1,123,085,458	$281,119,029	$1,404,204,487

Tables 4-10 through 4-13 present the cost for each year, the total cost over 15 years, and the annualized costs for each option at both discount rates.

Table 4-10: Base Option - Yearly, 15-Year, and Annualized Costs

	Total Costs	
	Present value	
	7%	3%
YEAR 1	$27,861,426	$27,861,426
YEAR 2	$16,169,934	$16,797,893
YEAR 3	$15,604,822	$16,840,382
YEAR 4	$16,009,317	$17,947,852
YEAR 5	$16,209,149	$18,877,585
YEAR 6	$16,338,328	$19,766,983
YEAR 7	$16,881,782	$21,217,666
YEAR 8	$17,246,153	$22,517,392
YEAR 9	$18,185,251	$24,665,602
YEAR 10	$19,881,208	$28,013,138
YEAR 11	$21,282,559	$31,152,247
YEAR 12	$22,952,181	$34,900,853
YEAR 13	$24,300,482	$38,386,059
YEAR 14	$24,012,809	$39,404,711
YEAR 15	$23,631,498	$40,284,965
Total	**$296,566,901**	**$398,634,754**
Annual	**$32,561,452**	**$33,392,270**

Table 4-11: Option 1 - Yearly, 15-Year, and Annualized Costs

	Total Costs	
	Present value	
	7%	3%
YEAR 1	$31,550,781	$31,550,781
YEAR 2	$18,673,871	$19,399,070
YEAR 3	$18,100,551	$19,533,717
YEAR 4	$19,042,767	$21,348,615
YEAR 5	$19,220,924	$22,385,174
YEAR 6	$19,322,054	$23,376,854
YEAR 7	$20,264,251	$25,468,882
YEAR 8	$20,532,343	$26,807,997
YEAR 9	$21,806,335	$29,577,067
YEAR 10	$24,209,769	$34,112,192
YEAR 11	$25,870,551	$37,867,899
YEAR 12	$27,769,551	$42,226,097
YEAR 13	$28,977,479	$45,774,038
YEAR 14	$26,938,424	$44,205,609
YEAR 15	$26,152,841	$44,583,136
Total	**$348,432,492**	**$468,217,128**
Annual	**$38,256,015**	**$39,220,948**

Table 4-12: Option 2 - Yearly, 15-Year, and Annualized Costs

	Total Costs	
	Present value	
	7%	3%
YEAR 1	$17,424,141	$17,424,141
YEAR 2	$8,834,926	$9,178,030
YEAR 3	$8,671,300	$9,357,877
YEAR 4	$9,409,060	$10,548,383
YEAR 5	$9,432,139	$10,984,907
YEAR 6	$9,422,978	$11,400,422
YEAR 7	$10,061,005	$12,645,054
YEAR 8	$10,089,256	$13,173,009
YEAR 9	$10,755,886	$14,588,767
YEAR 10	$12,063,256	$16,997,440
YEAR 11	$12,803,342	$18,740,833
YEAR 12	$13,579,798	$20,649,303
YEAR 13	$13,843,780	$21,868,214
YEAR 14	$11,786,863	$19,342,092
YEAR 15	$11,182,396	$19,062,796
Total	**$169,360,125**	**$225,961,268**
Annual	**$18,594,831**	**$18,928,003**

Table 4-13: Option 3 - Yearly, 15-Year, and Annualized Costs

	Total Costs	
	Present value	
	7%	3%
YEAR 1	$112,983,045	$112,983,045
YEAR 2	$181,265,632	$188,305,074
YEAR 3	$244,285,086	$263,627,104
YEAR 4	$319,136,124	$357,779,641
YEAR 5	$388,049,433	$451,932,179
YEAR 6	$451,364,352	$546,084,716
YEAR 7	$524,385,591	$659,067,761
YEAR 8	$591,316,516	$772,050,805
YEAR 9	$666,393,630	$903,864,357
YEAR 10	$761,759,541	$1,073,338,924
YEAR 11	$861,928,610	$1,261,643,999
YEAR 12	$965,927,528	$1,468,779,581
YEAR 13	$1,060,946,280	$1,675,915,162
YEAR 14	$1,090,135,393	$1,788,898,207
YEAR 15	$1,104,613,335	$1,883,050,744
Total	**$9,324,490,097**	**$13,407,321,299**
Annual	**$1,023,778,891**	**$1,123,085,458**

CHAPTER 5: SMALL ENTITY ANALYSIS

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601-612) (RFA), Federal agencies must evaluate the impact of rules on small entities and determine whether the rule will have a significant economic impact on a substantial number of small entities. This section discusses DEA's analysis of the impact on small entities. DEA emphasizes that the rule is voluntary. No businesses are required to comply with this rule unless they elect to issue or process controlled substance prescriptions as electronic data files; practitioners and pharmacies have the option to continue to use paper and, for Schedule III-V substances, oral prescriptions.

5.1 CHARACTERISTICS OF SMALL ENTITIES

As discussed in previous sections, the small entities directly affected by the proposed rule are practitioners and, to a limited extent, pharmacies. The firms marketing services and software are not directly affected by the rule because they will recover their costs from practitioners. Nonetheless, DEA will discuss the impact on these firms. Table 5-1 shows Small Business Administration's standards for these firms.

Table 5-1: SBA Definitions of Small Entities

Affected Entity	Industry Description	NAICS Code	Small Business Definition (sales in $)
Practitioner and Mid-Level Practitioner	Offices of Physicians	62111	$9,000,000
	Offices of Dentists	621210	$6,500,000
Service Provider	Software Publishing	511210	$23,000,000
Pharmacy	Pharmacies and Drug Stores	44611	$6,500,000
	Supermarkets and Other Grocery Stores	44511	$25,000,000
	General Merchandise Stores Mail Order Houses	45291 454113	$25,000,000 $23,000,000

Although some practitioners are part of large practices that may qualify as large businesses, so few practitioners fall into the large category that it is simpler to assume that they are all small entities. It is also the case that the service providers generally charge on a per practitioner basis rather than a per practice basis so that the costs may be considered as applying to individual practitioners. Mid-level practitioners are generally employed by a practice so their costs would be incurred by the practice, not the individual. They are not, therefore, small businesses.

The lowest average net income for a physician in private practice listed in the Allied-Physician Survey is $135,000.[22] The American Dental Association states that the average net income of a dentist in private practice is $185,940 for a general practitioner. The average gross billings for a dentist in general practice per dentist are $595,340.[23] For pharmacies, the 17,500 independent pharmacies are small entities; the other pharmacies belong to about 200 chains that are mostly large firms. There may be a few chains with fewer than 3 pharmacies, which could be small. In 2006, National Association of Chain Drug Stores data indicate that the average independent pharmacy had prescription sales of $2.48 million a year; average total sales are about $2.675 million.[24]

As discussed in Chapter 2, DEA estimates that there are about 130 service providers (110 for electronic prescriptions, 20 for pharmacies) that will be indirectly affected by this rule. A few of these are large entities or part of large companies (e.g., General Electric and McKesson). DEA has no information on the revenues of most of these firms. DEA notes that fully electronic EMRs cost between $20,000 and $50,000 per practitioner, with a usual monthly maintenance fee of $500 per practitioner. A provider, therefore, would need fewer than 4,000 practitioners to qualify as a large business. The providers of stand-alone electronic prescribing systems charge a tenth as much and are assumed to be small entities.

5.2 SMALL ENTITY COSTS

The costs to DEA registrants are relatively small. As discussed in Chapter 4, the initial costs to the practitioner would range from about $62 to $266 for identity proofing, mostly for the time to have the identification checked. The main ongoing costs for the proposed rule would be the monthly log review by practitioners (about $89 a year) plus any incremental cost of the software or service. The initial and ongoing costs for the basic rule elements represent less than 0.2 percent of the annual income of the lowest paid practitioner.

[22] www.allied-physicians.com/salary-surveys, accessed 1/16/2008.
[23] www.ada.org/ada/prod/survey/faq.asp, accessed 1/16/2008.
[24] http://www.nacds.org/wmspage.cfm?parm1=507, accessed 1/18/2008.

Determining the incremental cost of the system requirements per practitioner is difficult because it depends on the number of providers, the number of customers, the number of system requirements that a provider does not already meet, and how costs are recovered (in the year in which the money is spent or over time). For example, an EMR system that had to reprogram to the full extent would have incremental system costs of $161,000 ($125,000 for the third-party audit and $37,000 for reprogramming). If the service provider had 1,000 practitioners enrolled in the first year, it would also incur about $5,660 for identity proofing. If the provider recovered the costs ($167,000) from its 1,000 customers, the incremental cost to those customers would be $167 or about $14 a month. The costs in the out years would be lower because no further programming is needed and the audit cost is lower ($100,000). If the provider added 1,000 practitioners a year over 15 years, the incremental cost per practitioner would fall as shown in Table 5-2. The costs shown are conservative because the audits may cost considerably less depending on the complexity of the system; many EMRs may need little reprogramming. Either or both of these factors in combination could reduce their costs considerably and, therefore, reduce the incremental costs to practitioners.

Table 5-2: Incremental Cost of EMR Systems to Practitioners

Year	# Practitioners	Total Provider Costs	Annual Cost/Practitioner	Monthly Cost/ Practitioner
1	1000	$167,270	$167.27	$13.94
2	2000	$105,648	$52.82	$4.40
3	3000	$105,648	$35.22	$2.93
4	4000	$105,648	$26.41	$2.20
5	5000	$105,648	$21.13	$1.76
6	6000	$105,648	$17.61	$1.47
7	7000	$105,648	$15.09	$1.26
8	8000	$105,648	$13.21	$1.10
9	9000	$105,648	$11.74	$0.98
10	10000	$105,648	$10.56	$0.88
11	11000	$105,648	$9.60	$0.80
12	12000	$105,648	$8.80	$0.73
13	13000	$105,648	$8.13	$0.68
14	14000	$105,648	$7.55	$0.63
15	15000	$105,648	$7.04	$0.59

In the first year, the total cost to a physician for DEA's requirements would be less than $300; dentists would have higher initial costs because of travel time. After that, the cost will decline over time to about $100 to $150 a year including the incremental costs charged for the systems. The lowest paid physician earns about $135,000 a year. For none of the registrants will the cost represent a significant economic impact.

For pharmacies, the only costs will be the incremental cost that their service provider charges to cover the costs of reprogramming and audits. In the first year, if the providers recover the programming costs in a single year, the average incremental cost to a pharmacy would be $85. After that, the incremental charge to recover the cost of the third-party audit would be $35 per pharmacy, assuming the cost is evenly distributed across all pharmacies. The first year charge represents 0.003 percent of an independent pharmacy's annual sales. It also

represents a far lower cost than the pharmacy will pay SureScripts or another intermediary for processing the prescriptions. Currently, SureScripts charges the pharmacy $0.215 per electronic prescription to process and reformat prescriptions to ensure that the pharmacy system will be able to capture the data electronically. Based on National Association of Chain Drug Stores data on the average price of prescriptions ($68.26) and the average value of prescription sales, an independent pharmacy processes about 36,400 prescriptions a year and would have to pay SureScripts about $7,800.[25]

5.3 ALTERNATIVES CONSIDERED

Although these costs do not represent a significant economic impact, as discussed above, DEA considered options. The Base Case option would be less expensive initially, particularly for dentists and mid-level practitioners, because much less time would be needed for identity proofing. Once the identity proofing has occurred, however, the costs would be the same for the Base Case and Option 1. Option 2 would be less expensive for practitioners because the monthly log check would not be needed and the service provider costs would be lower because less stringent auditing requirements would be imposed, which would reduce the incremental costs recovered from the practitioner.

DEA has not proposed the Base Case because of two concerns about identity proofing. First, DEA is concerned that having a service provider employee conduct the in-person identity proofing would make it easier for insider collusion to occur. Putting the in-person identity proofing in the hands of a DEA registrant or a public employee lessens that threat. Second, others expressed a concern that service providers would not visit practitioners' offices often, which could delay implementation and adoption, particularly for rural practices. DEA is not proposing Option 2, the digital signature option, except for Federal healthcare systems because of the concerns expressed by industry with regard to the use of digital signatures and the problems they would create for intermediaries. The third option, which would impose no costs on service providers, would be very expensive for pharmacies and practitioners. If the average independent pharmacy processes 36,400 prescriptions, about 11 percent of those are likely to be for controlled substances. Their annual cost for conducting callbacks on each of those would be about $5,200 in 2008; eliminating callbacks that already occur, the costs would be about $3,800 in 2008. If the number of controlled substance prescriptions (359 million original and newly authorized refills in 2008) were equally distributed among practitioners (about 573,000 in 2008), the average practitioner would incur costs of about $3,300 for callbacks under Option 3. Eliminating the callbacks that already occur, the average practitioner would incur new costs of about $2,200 under Option 3.

DEA has, therefore, determined that the proposed rule would not impose a significant economic impact on a substantial number of small entities directly subject to the rule. Less expensive options are considered too burdensome by the service providers and intermediaries. The option that would impose no burden on service providers would impose substantially higher costs on practitioners and pharmacies.

[25] http://www.nacds.org/wmspage.cfm?parm1=507, accessed 1/18/2008.

5.4 OTHER ISSUES

Another issue that DEA considered is whether the incremental costs might affect practitioners' decisions about purchasing a system that provides electronic prescribing. As discussed previously in this analysis, the market for these systems has shifted away from stand-alone systems to EMRs. The cost of an EMR system for the functionalities that CCHIT requires ranges from $20,000 and $50,000 per practitioner with a usual annual maintenance charge of $6,000 per practitioner. (There are some less expensive systems marketed as EMRs that have only some of the functions; some appear to provide billing, scheduling, and simple records, but none of the more complex functions such as electronic prescribing, database links, etc.) Even in the first year, where the incremental cost of adding DEA's requirements would be between $150 and $200, this additional charge is unlikely to affect the decision to invest in an EMR, where the first year cost would be, at the low end $26,000 ($20,000 plus the $6,000 maintenance fee). The incremental costs would add less than 1 percent of the cost of the system; in the out-years, the incremental costs would similarly be a small fraction of the annual system maintenance cost. For stand-alone electronic prescription systems, the initial incremental costs will be higher because they are expected to need more programming. After the initial year, however, their incremental costs should be similar. These costs will represent a greater percentage increase in their monthly charges, which average $50 per month, but this is unlikely to affect the initial decision because most of these systems are being provided free to practitioners by insurers that want to encourage electronic prescribing.

DEA considers it unlikely that any provider would attempt to market a product or service that could not be used for controlled substance records and, therefore, no provider will be disadvantaged by complying because all providers will incur costs and recover them from customers. The situation may be similar to certification of EMRs by CCHIT. Some were concerned that the standards would create barriers, but most of the companies certified have been small. The chairman of CCHIT, Mark Leavitt stated that the data on the revenues of firms that gained certification "laid to rest this concern that it was going to squeeze out small vendors. It actually seems to have done the opposite. It's created a level playing field."[26]

DEA notes that the barriers to adoption of electronic prescribing cited in various government studies relate to the high cost of the systems, the disruption caused by implementing these systems, and the relatively early stage of system development and interoperability provided by the existing systems. Despite the benefits of legible prescriptions, both in terms of patient safety and fewer callbacks from pharmacies, practitioners have resisted adoption of electronic prescriptions. Insurance companies that have offered the systems for free have had difficulty finding practitioners willing to accept them because, while the service is free, the cost of additional hardware, training, and staff disruption is a barrier to adoption. In 2005, Wellpoint offered physicians $42 million in hardware, software, and support. "Of the 25,000 physicians contacted, only 19,000 accepted these free gifts," Wellpoint then-CEO Leonard Schaeffer said. "And of those 19,000, only 2,700 physicians chose e-prescribing PDAs. The rest selected a paperwork reduction package. ... Free is not cheap enough," Schaeffer

[26] California HealthCare Foundation, "Gauging the Progress of the National Health Information Technology Initiative: Perspectives from the Field." January 2008.

concluded.[27] The likelihood that the electronic prescribing systems will be part of EMR systems probably is also slowing adoption because practices do not want to invest in a stand-alone system that will be redundant later.

A study of physicians' experiences with commercial electronic prescription systems that was funded by HHS and published in Health Affairs on April 3, 2007, examined the implementation of electronic prescribing.[28] The study focused on larger medical practices (12 of the 21 practices had more than 50 doctors; none had fewer than 5), which meant that many of the practices had IT staff and support. Many of the problems encountered involved not the basic function of writing a prescription, but other functions that are designed to improve patient safety (e.g., medication histories, clinical decision support) and formulary compliance. Connectivity with pharmacies was also a problem. Practice estimates of the number of prescriptions printed out for the patient ranged from 10 percent to close to 100 percent. Despite the theoretical level of pharmacy readiness for electronic prescriptions, "most practices using electronic fax or EDI [electronic data interchange] reported spending substantial time educating pharmacies about e-prescribing." Many practices noted that "at least some of the mail-order PBMs [pharmacy benefit managers] routinely rejected prescriptions sent via electronic fax or EDI…"

Implementing a system was reported to be very complicated. One physician reported working with the IT department 4 hours a week for 6 months to iron out the "kinks" in the electronic prescribing module before the system could be tested. Maintenance of the system continued to demand staff resources. The study concluded:

> Much of the literature assessing barriers to electronic prescribing adoption and use has focused on cost, physician resistance, and changing practice workflow. Our findings highlight the role of product limitations, external implementation challenges, and physicians' preferences for how to use system features and are consistent with several other assessments of e-prescribing system functionality and provider pharmacy connectivity.
>
> Respondents' implementation hurdles belie the view that electronic prescribing products are relatively simple "plug-and-play" applications. It is hard to imagine that e-prescribing as it exists today can be the "killer app" that will drive further IT adoption. All of the practices we examined, regardless of size, IT expertise, geographic location, or vendor, had invested many financial and human resources in implementing and maintaining e-prescribing.

These findings are consistent with the CDC study cited above, which found that electronic prescribing was one of the less used functions in a fully or partially electronic EMR system.

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[27] Schaeffer, L. WellPoint Health Networks, Thousand Oaks, CA. Transforming an IT-Enabled Health Care System: The Health Plan Role. Presentation at the Second Annual National Health Information Summit. Washington DC, October 20, 2004. http://www.managedcaremag.com/archives/0504/0504.pharmacy.html

[28] Grossman, Joy M. et al., "Physicians' Experiences Using Commercial E-Prescribing Systems," Health Affairs, 26, no. 3 (2007), w393-w404.

Creating an electronic prescription takes more time than writing a paper prescription and handing it to a patient. The electronic prescription system shifts some responsibility from the pharmacy to the practitioners. At present, it is the pharmacy that checks to see if a particular drug is covered by the patient's insurance and that checks for drug interactions by examining other medications the patient is taking. With electronic prescriptions, all of these checks may occur before the practitioner signs the prescription. While this process may significantly reduce processing time at the pharmacy and ensure that more prescribed drugs are on the insurance companies' formularies, it may substantially increase the time a practitioner must spend to create a prescription. Rather than spending a few seconds writing a prescription while talking to the patient, the practitioner has to move through a series of drop-down menus to select the patient, drug, dosage unit, and directions, then determine whether the insurance company will cover it and at what level of co-pay. Finally the practitioner will have to find the pharmacy from a drop-down menu. Electronic prescriptions are likely to save practices staff time in reduced callbacks, but the practitioners may initially see mainly the additional time that needs to be spent creating the prescription and the office disruption that occurs when staff need to be trained on new systems. (An earlier Rand study noted that although electronic prescriptions will eliminate errors caused by misread or misunderstood prescriptions, practitioners may not review the prescription to check that the right items from successive menus have been selected. Electronic prescriptions may introduce new errors through system design flaws. They may also reduce the likelihood that the pharmacy will check the prescription for errors.)[29]

Although the rule could impose a burden on the smallest service providers, the costs are not so great that a service provider would not be able to recover them from customers or that the incremental price increase would discourage customers from purchasing a system. The programming that may be needed to implement a conforming system is not so onerous that a service provider would find it a significant burden; these firms are in the business of designing, programming, implementing, and upgrading software systems. The cost of the annual third-party audit may be burdensome, but without the audit there is no assurance that the system is protected against identity theft and insider attacks, two of the most likely sources of diversion. Some providers may drop out of the market if they cannot meet the security standards that an auditor would demand, but given other government requirements for security under HIPAA and the public's expectations for secure medical records, these providers would not be able to meet other standards and public expectations. The market for healthcare IT is evolving rapidly. As discussed above, DEA anticipates that most of the current providers will not be in this market by the time most practitioners have adopted EMR systems. Eventually, for reasons unrelated to DEA, a few systems will dominate the market; for these providers, DEA's requirements will not be a burden.

[29] Bell, D.S. et al., "Recommendations for Comparing Electronic Prescribing Systems: Results of An Expert Consensus Process," Health Affairs, May 25, 2004, W4-305-317.

CHAPTER 6: BENEFITS

6.1 INTRODUCTION

Electronic prescriptions are widely expected to reduce errors in medication dispensing because they will eliminate illegible written prescriptions and misunderstood oral prescriptions. They are also expected to reduce the number of callbacks from pharmacy to practitioner to address legibility, formulary, and contraindication issues. Electronic prescriptions may also reduce processing time at the pharmacy and wait time for patients. These benefits are likely to be mitigated to some extent. As the Rand study suggested, practitioners may fail to review the prescription and notice errors that occur when the wrong item is selected from one or more drop-down menus; pharmacists may be less likely to question a legible electronic prescription.[30] In addition, the formulary and contraindication checks are functions that practitioners sometimes disable because they do not work as they should or take too much time.[31] Nonetheless, electronic prescriptions may provide benefits in avoided medication errors, reduced processing time, and reduced callbacks. These benefits of electronic prescriptions are not directly attributable to this proposed rule except to the extent the rule facilitates implementation of electronic prescribing of controlled substances.

6.2 QUANTIFIED BENEFITS

DEA has quantified two types of benefits: reduced number of callbacks to clarify prescriptions and the reduction in wait time for patients picking up prescriptions. One of the greatest burdens in the paper system is the need for callbacks to clarify prescriptions. Clarifications and changes may be required for several reasons: the prescription is not legible; required information is not included on the prescription; the prescribed dosage unit does not exist; the particular medication is not approved by the patient's health insurance; and the drug prescribed is contraindicated because it reacts with other medications the patient is taking or because it negatively affects other conditions from which the patient suffers. Each callback involves the pharmacist and one or more staff at the practitioner's office, often including the practitioner. Electronic prescriptions will eliminate illegible prescriptions and should eliminate those with missing information or unavailable dosage units or forms. Whether the last two types of errors are eliminated will depend on the requirements of the software systems and the accuracy of the drug databases that they use.

The public is also affected by the current system. For the majority of controlled substance prescriptions, the patient (or someone acting for the patient) presents a paper prescription to the pharmacy and then waits for the pharmacy to fill it. The time between the point when the

[30] Bell, D.S. et al., "Recommendations for Comparing Electronic Prescribing Systems: Results of An Expert Consensus Process," *Health Affairs*, May 25, 2004, W4-305-317.
[31] Grossman, Joy M. et al., "Physicians' Experiences Using Commercial E-Prescribing Systems," *Health Affairs*, 26, no. 3 (2007), w393-w404.

prescription is handed to the pharmacist and the point when it is ready for pick-up is a cost to the public.

To estimate the part of these benefits that may accrue to the proposed rule, DEA estimated the number of controlled substance prescriptions that may require callbacks. Although there are widely varying estimates for callbacks, the best available data, based on the operation of the two largest mail order prescription pharmacies, support an estimate of 30 percent of original prescriptions.[32] DrugTopics.com surveys of pharmacists in 1996[33] and 1999[34] indicated that 80 percent or 95 percent of the prescription problems were of the type that electronic prescriptions could eliminate (illegible, missing information, or formulary).[35] The analysis estimates that 90 percent of the callbacks could be eliminated with electronic prescriptions because data from current operations indicate that formulary issues have become a more prevalent cause of callbacks than was the case in the earlier surveys.[36] Overall, the analysis estimates that 27 percent of original prescriptions require callbacks. DEA assumes that electronic prescriptions would phase in at the same rate as practitioners (i.e., if 6 percent of practitioners had adopted electronic prescribing for controlled substances, then 6 percent of the controlled substance prescriptions would be electronic.) Applying the cost of a callback as estimated for Option 3 ($6.58), Table 6-1 presents the annual data for the cost-savings from callbacks avoided over the 15 year implementation period. Table 6-2 presents the PV of the costs at 7 and 3 percent discount rates.

Table 6-1: Cost Savings of Callbacks Avoided

Year	# Original Prescriptions	# Callbacks	Implementation Rate	# Callbacks Avoided	Cost Savings
2008	326,767,500	88,227,225	0.06	5,293,634	$34,832,108
2009	336,570,525	90,874,042	0.1	9,087,404	$59,795,119
2010	346,667,641	93,600,263	0.14	13,104,037	$86,224,562
2011	357,067,670	96,408,271	0.19	18,317,571	$120,529,620
2012	367,779,700	99,300,519	0.24	23,832,125	$156,815,380
2013	378,813,091	102,279,535	0.29	29,661,065	$195,169,808
2014	390,177,484	105,347,921	0.35	36,871,772	$242,616,261
2015	401,882,808	108,508,358	0.41	44,488,427	$292,733,849
2016	413,939,293	111,763,609	0.48	53,646,532	$352,994,183
2017	426,357,471	115,116,517	0.57	65,616,415	$431,756,010
2018	439,148,195	118,570,013	0.67	79,441,909	$522,727,758
2019	452,322,641	122,127,113	0.78	95,259,148	$626,805,196

[32] "Company Pushes the Envelope to Get Prescriptions in the Mailbox," St. Petersburg Times, September 15, 2002. Story reports on Medco's mail order pharmacy operation. Barrett Toan, CEO of Express Scripts, also reported a 30 percent callback rate. Express Scripts and Medco process about 600 million prescriptions.
[33] "Where Does the Time Go?" Drugtopic.com, June 10, 1996.
[34] "No Rest for the Weary," Drugtopic.com, June 21, 1999.
[35] The analysis assumes that electronic prescriptions will be produced using prescription software that has fields that must be completed and a database of formularies that will prompt the practitioner to select both the drug name and an available dosage unit. Existing prescription software systems include formularies.
[36] Medco reports 43 percent of its callbacks are for formulary issues; the Drugtopic surveys put the formulary callbacks at less than 25 percent.

Year	# Original Prescriptions	# Callbacks	Implementation Rate	# Callbacks Avoided	Cost Savings
2020	465,892,321	125,790,927	0.89	111,953,925	$736,656,824
2021	479,869,090	129,564,654	0.95	123,086,422	$809,908,654
2022	494,265,163	133,451,594	1	133,451,594	$878,111,488

Table 6-2: PV and Annualized Cost Savings for Callbacks

Year	PV at 7%	PV at 3%
2008	$34,832,108	$34,832,108
2009	$55,883,289	$58,053,514
2010	$75,311,872	$81,274,920
2011	$98,388,073	$110,301,677
2012	$119,633,702	$139,328,434
2013	$139,153,376	$168,355,191
2014	$161,665,459	$203,187,299
2015	$182,299,929	$238,019,408
2016	$205,445,828	$278,656,867
2017	$234,846,662	$330,905,030
2018	$265,728,286	$388,958,544
2019	$297,790,633	$452,817,410
2020	$327,084,440	$516,676,275
2021	$336,083,298	$551,508,383
2022	$340,546,775	$580,535,141
Total	**$2,874,693,730**	**$4,133,410,200**
Annualized	**$315,625,919**	**$346,241,638**

Assuming that electronic controlled substance prescriptions phased in over 15 years, as described above, the annualized time-saving for eliminating these callbacks would be $316 million (at 7% discount) or $346 million (at 3% discount).

Electronic prescriptions could also reduce the patient's wait time at the pharmacy. The number of original controlled substance prescriptions that could require public wait time is based on the estimated number of original prescriptions (approximately 328 million in 2008), reduced by 19 percent, to account for those prescriptions phoned to the pharmacy[37] plus another 15 percent to remove those that are currently filled by mail order pharmacies or long-term care facilities.[38] Assuming the average wait time is 15 minutes for the 81 percent of original prescriptions that are presented on paper to retail pharmacies (not mail order or long-

[37] A 1999 Drugtopics.com survey indicated that 36% of all prescriptions were phoned in; because refills are usually authorized on the original prescription and do not require second calls, and slightly less than half of prescriptions are refills, the analysis uses 19% for phoned in prescriptions.
[38] Based on IMS Health 2007 channel distribution by U.S. dispensed prescriptions. http://imshealth.com, accessed April 16, 2008.

term care prescriptions), at the current United States average hourly wage ($19.62)[39], Table 6-3 presents the annual estimates.

Table 6-3: Costs Savings for Public Wait Time

Year	Original Paper Prescriptions	Paper Prescriptions Avoided	Hours Saved	Cost-Savings
2008	220,767,123	13,246,027	3,311,507	$64,971,764
2009	227,390,137	22,739,014	5,684,753	$111,534,862
2010	234,211,841	32,789,658	8,197,414	$160,833,271
2011	241,238,197	45,835,257	11,458,814	$224,821,937
2012	248,475,342	59,634,082	14,908,521	$292,505,173
2013	255,929,603	74,219,585	18,554,896	$364,047,063
2014	263,607,491	92,262,622	23,065,655	$452,548,160
2015	271,515,716	111,321,443	27,830,361	$546,031,680
2016	279,661,187	134,237,370	33,559,342	$658,434,299
2017	288,051,023	164,189,083	41,047,271	$805,347,452
2018	296,692,553	198,784,011	49,696,003	$975,035,572
2019	305,593,330	238,362,797	59,590,699	$1,169,169,521
2020	314,761,130	280,137,405	70,034,351	$1,374,073,974
2021	324,203,964	307,993,765	6,998,441	$1,510,709,420
2022	333,930,083	333,930,083	83,482,521	$1,637,927,055
Total				**$10,347,991,204**

The annualized savings over 15 years would be $589 million (at 7% discount) or $646 million (at 3% discount).

The estimates for public wait time are upper bounds. They assume that the practitioner will transmit the prescription and that the pharmacists will open the record and fill it before the patient arrives at the pharmacy. It is probably more realistic to assume that only a fraction of these benefits will be gained particularly in the early years when pharmacies are still getting used to electronic prescriptions. There may also be some offsetting costs to the pharmacy. The industry estimates that about 20 percent of prescriptions written are never presented to pharmacies. If these are sent to pharmacies electronically and prepared before the patient arrives, the pharmacy will have spent time for which it will not be reimbursed if the patient does not pick up the prescription. (It may be reasonable to expect the 20 percent to decline with electronic prescriptions, although probably not to zero.)

Table 6-4 presents the annualized benefits at a 7 percent and 3 percent discount rate.

[39] BLS, "Employer Costs for Employee Compensation," December 2007, March 12, 2008. Table 2. All civilian workers.

Table 6-4: Annualized Benefits

	7%	3%
Callbacks Avoided	$315,626,000	$346,242,000
Public Wait Time Avoided	$588,732,000	$645,839,000

The benefits, both of which represent time savings, clearly exceed by a wide margin the costs of the Base Case and Options 1 and 2. The costs of Option 3 at $1.3 to $1.4 billion a year exceed the benefits, which would not, of course, include callbacks eliminated.

6.3 QUALITATIVE BENEFITS

DEA is proposing additional security requirements for electronic controlled substance prescriptions to ensure that electronic prescriptions for controlled substances do not become an easy route for widespread and undetectable diversion of controlled substances. Properly secure electronic prescribing systems have the potential to reduce prescription forgeries, which will protect practitioners from identity theft and misuse of their DEA registration numbers by practice staff and others. Secure pharmacy systems may help identify diversion that occurs at pharmacies.

DEA has not attempted to quantify or monetize the benefits of the proposed rule that relate to diversion because of a lack of data on the extent of diversion of controlled substances through forged or altered prescriptions and alteration of pharmacy records. These benefits are, however, discussed qualitatively in this section. The immediate cost of misuse of prescription controlled substances is also reviewed in terms of data on deaths and emergency room (ER) visits that result from nonmedical use of these drugs.

6.3.1 REDUCTION IN CONTROLLED SUBSTANCE PRESCRIPTION FORGERY

Diversion of controlled substances through forgery, doctor shopping (where a patient visits more than one practitioner to receive prescriptions for the same controlled substance), and alteration of pharmacy records is a growing problem. Controlled substances are diverted in a number of ways, some of which will not be affected by electronic prescriptions. For example, diversion occurs when:

- Controlled substances are stolen from practitioners and pharmacies.
- Practitioners knowingly write non-legitimate prescriptions.
- Practitioners write prescriptions for people who have lied about symptoms to obtain the drugs. A commonly used term for these patients is “doctor shoppers,” people who routinely visit different doctors with the same ailment to obtain multiple prescriptions for controlled substances, usually pain relievers. These prescriptions are then filled at various pharmacies and the drugs are abused or sold on the illicit market.

Although DEA does not expect the proposed rule to eliminate these problems, it may act as a deterrent to practitioners who write non-legitimate prescriptions and to doctor shoppers

because it will be easier for States to monitor prescriptions when they are electronic through the use of State prescription monitoring programs. Digitally signed prescription records will make it very difficult for a practitioner to claim that a prescription has been forged or altered. Some States are already using prescription monitoring programs to identify practitioners who prescribe unusual quantities of controlled substances and patients filling multiple prescriptions at different pharmacies.

Electronic prescriptions for controlled substances will directly affect the following types of diversion:

- Stealing prescription pads or printing them, and writing non-legitimate prescriptions.
- Altering a legitimate prescription to obtain a higher dose or more dosage units (e.g., changing a "10" to a "40").
- Phoning in non-legitimate prescriptions late in the day when it is difficult for a pharmacy to complete a confirmation call to the practitioner's office.

These are examples of prescription forgery that contribute significantly to the overall problem of drug diversion. DEA expects this rule to reduce significantly these types of forgeries because only practitioners with secure prescription-writing systems will be able to issue electronic prescriptions for controlled substances and because any alteration of the prescription at the pharmacy will be discernible from the audit log and a comparison of the digitally signed records. DEA expects that over time, as electronic prescribing becomes the norm, practitioners issuing paper prescriptions for controlled substances may find that their prescriptions are examined more closely.

6.3.2 Cost of Diversion and Abuse of Prescription Drugs

A reduction in forged controlled substance prescriptions could result in a reduction in drug-related deaths and medical care. The 2006 National Survey on Drug Use and Health (NSDUH) found that 6.7 million people in the United States currently use prescription-type therapeutic drugs for nonmedical reasons.[40] This nonmedical use of prescription drugs can lead to death and emergency room visits. The Substance Abuse and Mental Health Services Administration (SAMHSA) runs the Drug Abuse Warning Network (DAWN), a public health surveillance system that monitors drug-related visits to hospital emergency departments and drug-related deaths investigated by medical examiners and coroners. SAMHSA reported that in 2003, in six States (Maine, Maryland, New Hampshire, New Mexico, Utah, and Vermont) there were 352 deaths from misuse of oxycodone and hydrocodone, both prescription controlled substances.[41] The 32 metropolitan areas that are part of DAWN reported 3,530 deaths from misuse of oxycodone and hydrocodone and 1,381 deaths that involved the misuse of benzodiazepines (Schedule IV controlled substances) in

[40] Substance Abuse and Mental Health Services Administration. (2007). *Results from the 2006 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-32, DHHS Publication No. SMA 07-4293). Rockville, MD.

[41] The DAWN Report – Opiate-related Drug Misuse Deaths in Six States, 2003. Issue 19, 2006.

2003.[42] These numbers do not include the 624 suicides that involved benzodiazepines or opiates other than heroin and methadone.) The 32 metropolitan areas represent about 24 percent of the United States population.

In another report, SAMHSA stated that in 2004 there were 42,491 emergency room visits involving nonmedical use of hydrocodone, 36,559 visits for nonmedical use of oxycodone, and 144,000 visits for nonmedical use of benzodiazepines.[43] By 2005, the number of emergency visits for nonmedical use of these drugs rose to 51,225 for hydrocodone, 42,810 for oxycodone, and 172,388 for the benzodiazepines. For all nonmedical use of prescription opiates except methadone, the number of visits was about 155,000.[44] ER visits for all controlled substances except methadone represented 60 percent of the 598,542 ER visits involving nonmedical use of drugs.[45] (With methadone, they represent 67 percent of these ER visits.) About 33 percent of all ER visits for nonmedical use of drugs resulted in the person being admitted to the hospital; about 12 percent of ER visits resulted in the person being admitted to an intensive care unit.

Using a value per life of $3 million, the costs of the 2003 deaths from misuse of prescription controlled substances in the six States is more than $1 billion. The cost of the 2003 deaths from misuse of prescription controlled substances in the 32 metropolitan areas is more than $10 billion. The cost of the 2005 emergency room visits is above $350 million (at $1,000 per visit), not including the cost of further in-patient care for those admitted. These costs are some fraction of the total cost to the nation. Nonetheless, they add to more than $11.35 billion in one year. DEA has no basis for estimating what percentage of these costs could be addressed by the proposed rule. If, however, the proposed rule prevents even a small fraction of the deaths and emergency care the benefits will far exceed the costs. DEA notes that, at 7.0 percent, the total annualized cost of the rule is $38 million, 0.3 percent of $11.35 billion.

These costs also do not represent all of the costs of drug abuse to society. Drug abuse is associated with crime and lost productivity. Crime imposes costs on the victims as well as on government. DEA does not track information on controlled substance prescription drug diversion because enforcement is generally handled by State and local authorities. The cost of enforcement is, however, considerable. In 2007, DEA spent between $2,700 for a small case and $147,000 for a large diversion case just for the primary investigators; adjudication costs and support staff are additional. It is reasonable to assume that State and local law enforcement agencies are spending similar sums per case. Some cases involve multiple jurisdictions, all of which bear costs for collecting data and deposing witnesses. The rule as proposed could reduce the number of cases and, therefore, reduce the costs to governments at all levels. A reduction in forgeries would also benefit practitioners who would be less likely to be at risk of being accused of diverting controlled substances and of then having to prove that they were not responsible.

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[42] Drug Abuse Warning Network, 2003: Area Profiles of Drug-Related Mortality, SAMHSA March 2005.
[43] The DAWN Report – Emergency Department Visits Involving Non-medical Use of Selected Pharmaceuticals. Issue 23, 2006.
[44] Drug Abuse Warning Network, 2005: National Estimates of Drug-Related Emergency Department Visits DAWN Series D-29, DHHS Publication No. (SMA) 07-4256, Rockville, MD, March 2007.
[45] Methadone is excluded because it may be obtained either by prescription or from narcotic treatment programs.

6.4 CONCLUSION

Electronic prescriptions for controlled substances would produce cost savings that may be well in excess of the costs of the rule for three of the four options considered. If the rule reduces diversion, it may also produce benefits in terms of reduced numbers of deaths and medical costs that far exceed the cost of the rule. The rule would also protect practitioners from misuse of their DEA registrations and reduce the costs to law enforcement. In contrast, a less secure electronic prescription system could greatly increase diversion, the deaths and medical costs associated with drug misuse, and the number of diversion cases. A less secure system would dramatically increase investigation costs because every provider and intermediary involved in a transaction would have to provide testimony to attempt to demonstrate that a prescription was not altered during transmission. The costs of such testimony would fall on law enforcement, service providers, and intermediaries. Finally, a less secure system would expose practitioners to the risk of identity theft, with the considerable costs associated with resolving those problems.

CHAPTER 7: CONCLUSIONS

This chapter discusses the limitations of the analysis and presents the overall conclusions.

7.1 UNCERTAINTIES

Any economic analysis involves some level of uncertainty about elements of the analysis. This is particularly true for this analysis, which must estimate costs for implementation of a new technology and project voluntary adoption rates. This section discusses the elements that have the greatest level of uncertainty associated with them.

7.1.1 RATES OF ADOPTION

In 2004, the President called for a majority of Americans to have interoperable electronic health records within 10 years.[46] This analysis does not project adoption of electronic prescribing to be that rapid in part because recent studies indicate that little progress has been made in health IT adoption outside of very large medical practices and systems. A recent report from the California HealthCare Foundation stated that "while larger physician groups are increasingly using health IT, those who practice alone or in small groups are no closer to using health IT now than they were three years ago." The report noted that even when practices install EMR systems, they do not necessarily use them.[47]

The barriers to adoption are the high cost of the systems, the disruption that implementation creates in a practice, and uncertainty about the systems themselves.[48] As discussed in Chapter 2, the pattern with software systems is that a large number of firms enter a market, but the vast majority of them fail, leaving a very few dominant providers.[49] The health IT market is still in the early phases of this process. DEA has no basis for estimating when dominant players will emerge. The 15-year implementation period projected may be too conservative or too optimistic.

7.1.2 COSTS TO SERVICE PROVIDERS

The time for reprogramming existing systems is estimated to be between 500 hours and 2,000 hours. DEA based the upper estimate on information provided by the industry for DEA's rulemaking regarding electronic orders for controlled substances. The actual cost to existing service providers is likely to vary widely. Some providers may meet all or virtually all of the requirements and need little reprogramming. Many of the requirements are

[46] California HealthCare Foundation, "Gauging the Progress of the National Health Information Technology Initiative: Perspectives from the Field." January 2008.
[47] Ibid.
[48] California HealthCare Foundation, Snapshot: The State of Health Information Technology in California, 2008.
[49] Bergin, T.J, "The Proliferation and Consolidation of Word Processing Software: 1985-1995." IEEE Annals of the History of Computing. Volume 28, Issue 4, Oct.-Dec. 2006 Page(s):48 – 63.

standard practice for software (e.g., access controls, automatic time outs) and should need minimal adjustments. Most electronic prescribing systems appear to present the data DEA would require on prescriptions. Any software firm that uses the Internet for any transaction will have digital signature capability. EMR systems must support two-factor authentication and control access to gain CCHIT certification. Nonetheless, DEA expects that for some existing providers, the requirements may take more than the estimated time.

Another uncertainty on provider costs relates to the third-party audit and security provisions that are needed to be judged acceptable under the SysTrust, WebTrust, or SAS 70 audit protocols. DEA did not assign a cost to actions that might be needed to meet the security standards because it has no basis for determining what may be needed by what fraction of the providers. To compensate for this, DEA used a high estimate for the cost of the audit itself. These audits range in cost from $15,000 to $250,000 depending on the complexity of the firm and the IT systems. DEA is requiring that the audit focus on only 2 of the 5 elements usually covered by the audit, hence the upper bound might be estimated to be $100,000 for the initial audit and less than that for subsequent years even for a large firm. Most of the firms marketing these systems are not large, so even lower costs might be appropriate. To deal with the uncertainty of the potential costs of additional security steps, DEA used an estimate of $125,000 for the first year and $100,000 for later years. DEA notes that many firms may decide to obtain a full audit, covering all elements, but the added costs would not accrue to this rule.

A final uncertainty of system provider costs relates to the proposed requirement for a back-up system for pharmacy records that would have to be at a separate location. Some pharmacy service providers already provide this, but it is possible that not all do. Nonetheless, DEA considers that the requirement may be standard business practice simply because the loss of the business records could have serious consequences unrelated to any DEA concerns.

7.2 COSTS AND BENEFITS

The costs of three of the four options considered ($19 million to $38 million annualized over 15 years at 7 percent) are far lower than the potential cost savings even if all of those savings are not realized. For the Base Case, about two thirds of the costs are attributed to a single requirement – that the practitioner review a log of controlled substance prescriptions once a month. The cost of this proposed requirement is so great because, although the time required is low, the cost of a practitioner's time and the number of practitioners are high. The cost of identity proofing in Options 1 and 2 is higher, because the cost of practitioner travel time. In Option 2, the cost of digital certificates is high because it is an annual cost. The costs to the service provider are mainly the costs of the annual third-party audit. DEA assumes that the service providers will recover their costs from the practitioners or pharmacies.

The cost savings that may occur could total $900 million a year although this is an upper bound estimate. It is unlikely, especially in the early years, that all of public wait time savings will be gained. Until pharmacies receive a substantial percentage of prescriptions electronically and learn to check the incoming prescription records, there may be a substantial lag between system receipt and pharmacist action. There may also still be

callbacks although some of these could be sent electronically. One uncertainty associated with callbacks is the frequency with which pharmacists will identify problems with electronic prescriptions. Although the prescriptions will be legible, pharmacists may find keying errors (e.g., wrong drug, wrong dosage unit, wrong form, etc.) and need to contact the practitioner to clarify the prescriptions. If practitioners have not checked formularies, either because they have turned off the function or because the particular formulary is not available to them, pharmacies will still need to do callbacks for formulary issues. In addition, the ability of e-prescribing systems to identify contraindication problems depends on the system having a complete record of a patient's medications and medical problems. Until EMR systems can interoperate with EMR systems at other practitioner offices to develop a complete medical history, the pharmacy will continue to be a principal means of identifying these issues. Needed contacts between a pharmacy and practitioner, whether electronic or telephone, will lower the cost savings for callbacks and for public wait time.

The benefits of the security requirements would be a reduction in diversion of controlled substances that are obtained from forged, altered, or invalid prescriptions. DEA has no basis for estimating the current level of diversion from these activities and, therefore, no basis for an estimate of a potential reduction. The cost of misuse of prescription controlled substances, however, is extremely high. Misuse of prescription controlled substances in 2003 was involved in almost 5,000 deaths in metropolitan areas that cover 25 percent of the United States population. The value of those deaths alone is above $10 billion. These drugs were also involved in more than 350,000 emergency room visits in 2005, a number that was more than 20 percent higher than the 2004 number. If the requirements of this rule reduce even 0.5 percent of these costs, the benefits will far outweigh the costs. DEA notes that a system that did not have the security controls DEA is proposing could lead to an upsurge of deaths and illness because it would facilitate diversion rather than limit it and make it far more difficult for law enforcement agencies to bring cases against the criminals involved.

7.3 SMALL ENTITY IMPACTS

DEA determined that this rule would affect a substantial number of small entities because almost all practitioners and all independent pharmacies are small businesses. The costs to these entities, however, are very low and would not impose a significant economic impact on them, being far below one percent of their annual revenues. DEA also notes that the proposed rule is voluntary; no practitioner or pharmacy would be required to handle electronic prescriptions for controlled substances.

The service providers are not directly regulated by DEA and would be expected to recover their costs from DEA registrants. DEA nonetheless considered their costs. Many of these firms are small entities and may find complying with the security requirements, particularly the audit, a burden. The cost, however, is not so great that they will not be able to pass it on to customers. DEA considers it unlikely that any provider would attempt to market a product or service that could not be used for controlled substance records and, therefore, no provider will be disadvantaged by complying because all providers will incur costs and recover them from customers. The situation may be similar to certification of EMRs by CCHIT. Some were concerned that the standards would create barriers, but most of the companies certified

have been small. The chairman of CCHIT, Mark Leavitt stated that the data on the revenues of firms that gained certification "laid to rest this concern that it was going to squeeze out small vendors. It actually seems to have done the opposite. It's created a level playing field."[50]

[50] California HealthCare Foundation, "Gauging the Progress of the National Health Information Technology Initiative: Perspectives from the Field." January 2008.

APPENDIX A: WAGES, FRINGE BENEFITS, AND WEIGHTED AVERAGES

Average hourly wages for following occupations:

Physicians: $111.90 (June 2003)
Adjusted to December 2007 (based on BLS Employment Cost Index): $130.41
Source: Allied Physicians Survey
http://www.allied-physicians.com/salary_surveys/physician-salaries.htm
Hourly wage is based on weighted average annual salary of $223,808 divided by 2,000 to obtain hourly wage. Average was weighted based on total number of physicians in specialties likely to prescribe controlled substances, earnings of each specialty, and each specialty's percentage share of total physicians in this universe.

Dentists: $93.00 (reported for 2004, treated as June 2004 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $103.78
Source: "What Can a Career in Dentistry Offer You?"
http://www.ada.org/public/careers/team/dentistry_fact.pdf
The online fact sheet is, in turn, based on *ADA 2004 Survey of Dental Practice*, *Characteristics of Dentists in Private Practice and their Patients*, American Dental Association.
Hourly wage is based on reported average earnings of $185,940 of a dentist with his own practice, divided by 2,000.

Mid-level practitioners: $35.64 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $37.30
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/naics4_621100.htm#b29-0000
Hourly wage for physicians' assistants (Standard Occupational Classification (SOC) Code 29-1071), taken as wage for all mid-level practitioners.

Medical secretaries: $14.05 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $14.70
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/oes436013.htm
Hourly wage for medical secretaries in physicians' offices (SOC Code 43-6013).

Hospital human-resource assistants: $15.73 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $16.56
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/naics4_622100.htm#b43-0000
Hourly wage for hospital human-resource assistants (SOC Code 43-4161).

Pharmacy technicians: $12.04 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $12.60
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/naics5_446110.htm#b29-0000
Hourly wage for pharmacy technicians (SOC Code 29-2052).

Service provider support/sales staff: $39.21 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $40.70
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/oes414011.htm#nat
Hourly wage for sales representatives for computer-system design and related services (SOC Code 41-4011).

Service provider information clerks: $15.70 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $16.46
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/oes434199.htm
Hourly wage for information and record clerks for computer-system design and related services (SOC Code 43-4199)

Computer programmers: $33.42 (May 2006, treated as June 2006 for indexing)
Adjusted to December 2007 (based on BLS Employment Cost Index): $35.19
Source: Office of Employment Statistics, May 2006 National Industry-Specific Occupational Employment and Wage Estimates.
http://www.bls.gov/oes/current/naics4_621100.htm#b15-0000
Hourly wage for computer programmers (SOC Code 15-1021).

Fringe Benefits and Overhead

Fringe benefits for health workers (except hospitals): 38.0 percent of wages
Fringe benefits for hospital staff: 44.0 percent of wages
Fringe benefits for service provider staff: 38.0 percent of wages
Fringe benefits for computer programmers and pharmacy staff: 40.0 percent of wages
Source: BLS Employer Cost of Employee Compensation, Table 14 for health workers, Table 9 for others.
http://www.bls.gov/news.release/pdf/ecec.pdf

Overhead for all offices in study: 49.0 percent
Source: Grant Thornton, LLP, 12th Annual Government Contractor Industry Survey, 2006, p. 8.

The overhead is applied as a multiplier to wages plus fringes. Therefore, the multiplier to convert hourly wages to fully loaded hourly cost is:
Health workers (except hospitals) and provider staff—1.38 x 1.49 = 2.06
Hospital staff—1.44 x 1.49 = 2.15
Computer programmers and pharmacy staff—1.40 x 1.49 = 2.09.

Thus, fully loaded hourly costs are:

Physicians	2.06 x 130.41 = $269.00
Dentists	2.06 x 103.78 = $214.07
Mid-level practitioners	2.06 x 37.30 = $76.94
Medical secretaries	2.06 x 14.70 = $30.33
Hospital HR staff	2.15 x 16.56 = $35.55
Pharmacy technicians	2.09 x 12.60 = $26.23
Service provider representatives	2.06 x 40.70 = $83.80
Service provider clerks	2.06 x 16.46 = $33.89
Computer programmers	2.09 x 35.19 = $73.24

To obtain hourly cost for all practitioners and for all dentists and physicians together, average costs were weighted by each group's percentage share of the total. A separate wage rate was calculated for physicians and dentists because turnover rates for these practitioners are assumed to be different from turnover rates for mid-level practitioners and are, therefore, costed separately.

	% all practitioners	% all MDs and dentists
Physicians	54.0	65.0
Dentists	30.0	35.0
Mid-levels	16.0	

Weighted growth rate for practitioners' offices was based on the relative population shares of physicians and dentists in the affected universe as shown above.

APPENDIX B: BIBLIOGRAPHY

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