Doctoring Prescriptions: Federal Barriers to Combating Prescription Drug Fraud Against On-Line Pharmacies in Washington

Eric M. Peterson
DOCTORING PRESCRIPTIONS: FEDERAL BARRIERS TO COMBATING PRESCRIPTION DRUG FRAUD AGAINST ON-LINE PHARMACIES IN WASHINGTON

Eric M. Peterson

Abstract: Prescription drug abuse represents a significant portion of drug abuse in the United States. Drug-seeking individuals alter, steal, or forge prescriptions to sustain their own dependence on prescription medications or to divert the drugs to sell to others at inflated rates. On-line pharmacies are a relatively new source for prescription medications and a potential target for prescription drug fraud. The federal government recently enacted the Electronic Signatures in Global and National Commerce Act (E-SIGN), which governs electronic signatures and preempts inconsistent provisions of state laws, such as the Washington Electronic Authentication Act (WEAA). WEAA is a legal framework that could be effectively amended to eliminate nearly all prescription drug fraud perpetrated against on-line pharmacies. However, E-SIGN preempts a crucial WEAA provision and prohibits enacting a key recommended amendment to WEAA, both of which are necessary to combat this problem. Options permissible after E-SIGN, such as voluntary self-regulation by the on-line pharmacy industry and amendment of WEAA, will not comprehensively and effectively prevent this type of fraud. Therefore, E-SIGN fundamentally alters Washington’s ability to protect the public’s health, safety, and welfare from prescription fraud perpetrated against on-line pharmacies.

Mark¹ is a thirty-three-year-old professional who is addicted to the prescription anti-anxiety medication Xanax.² At age twenty-nine, Mark began using Xanax under the care of his physician to treat anxiety attacks associated with the airline travel required by a new job. Xanax successfully treated Mark’s symptoms and he revisited his physician, who authorized one additional refill and recommended a counselor to help Mark learn to manage his fear of flying. However, Mark failed to schedule an appointment with the counselor and suffered through two extremely frightening flights after he ran out of Xanax. He returned to his physician’s office and promised to schedule an appointment with the counselor. The physician gave Mark an additional prescription for Xanax with two refills to last until he could schedule the appointment, admonishing him that there would be no further refills until Mark had seen the counselor. By the end of the second refill, Mark was using Xanax to cope with causes of stress other than just flying.

¹. This scenario is a hypothetical created by the author.
². Xanax is the brand name of the generic drug alprazolam, which is primarily used to treat anxiety disorders and can cause psychological dependence. See Medical Economics Company, Physicians’ Desk Reference (54th ed. 2000).
When the medication from Mark’s final refill was nearly gone he began to imagine ways to obtain Xanax without a prescription. Mark used his computer to create a fake prescription form. He filled out a prescription for Xanax, forged his physician’s signature, and indicated three refills. Late one evening, Mark presented the forged prescription to a pharmacist. Mark made nervous small talk, which might have created suspicion. Nonetheless, the pharmacist filled the prescription without verifying it with Mark’s physician because the pharmacist knew the clinic was closed.

Nearly three months later, as Mark was nearing the end of his final refill from the fraudulent prescription, he decided to find a more anonymous method for his deception. Mark filled out another forged prescription with two refills. He substituted his cellular telephone number for the physician’s clinic number and mailed the fraudulent prescription to an on-line pharmacy. A few days later the on-line pharmacy called his cellular number to verify the prescription. Mark answered several simple questions based on his knowledge of the medication and three days later the medication arrived at his home in the mail. When he needed a refill, he simply accessed the on-line pharmacy’s home page using his computer and ordered the refill. Mark used this technique for three years, varying the on-line pharmacy he used to avoid attracting attention to both his fraud and addiction.

Mark’s situation is surprisingly common in the United States, where prescription drug abuse makes up a large portion of the drug abuse problem. Two categories of people engage in prescription drug fraud in the United States: prescription drug abusers who perpetrate fraud to maintain an addiction and individuals who obtain prescription medications to divert them for sale to an illegal street market.

Prescription fraud can be relatively simple to accomplish and is not always detectable by pharmacists, particularly those working for on-line pharmacies. Altering, forging, and photocopying prescriptions are common methods of perpetrating prescription fraud. Although pharmacists use a variety of methods to detect prescription drug fraud,

---


4. See infra notes 21–28 and accompanying text.


these methods are not always successful because prescription fraud can be quite sophisticated.  

On-line pharmacies are uniquely vulnerable to prescription fraud. Unlike community pharmacists, an on-line pharmacist is unable to evaluate the behavior of patients presenting prescriptions, is unlikely to be familiar with the signatures of distant physicians, and may have difficulty verifying prescriptions with prescribing physicians because drug-seeking individuals can provide false telephone numbers and verify prescriptions themselves. Thus, on-line pharmacies exacerbate the problems faced in combating prescription fraud.

The Electronic Signatures in Global and National Commerce Act (E-SIGN) is not an effective tool to prevent prescription drug fraud against on-line pharmacies. E-SIGN ensures that digital signatures in nearly all types of communications are not denied legal recognition solely because of their electronic form. However, E-SIGN lacks the necessary provisions governing electronic signatures that would create a comprehensive and effective law to prevent prescription drug fraud against on-line pharmacies nationwide.

Unlike E-SIGN, the Washington Electronic Authentication Act (WEAA) is a state law that, if amended, could effectively prevent prescription drug fraud against on-line pharmacies. WEAA grants electronic signatures the equivalent legal status of handwritten signatures. WEAA also requires the use of electronic signature technology that offers users the ability to verify both if a message has been altered and the identity of the sender.

However, E-SIGN preempts statutes and regulations that are inconsistent with E-SIGN. E-SIGN prohibits both a crucial existing WEAA provision and a necessary amendment that would nearly eliminate prescription drug fraud against on-line pharmacies in

---

8. See Blumenschein, supra note 6, at 186.
10. See id.
11. See Blumenschein, supra note 6, at 186.
Washington and effectively protect the public's health, safety, and welfare. Therefore, not only is E-SIGN itself an ineffective tool for nearly eliminating prescription fraud against on-line pharmacies, it precludes state laws and regulations that otherwise would achieve this goal through an effective and comprehensive regulatory framework.

Part I of this Comment examines the problem of prescription drug abuse and fraud against community pharmacies and how these problems are exacerbated in the context of on-line pharmacies. Part II explains the technology available for transmitting private electronic communications between individuals to guarantee against alteration of data. It also describes E-SIGN and WEAA, which both ensure the legal validity of electronic communications using digital signatures. Part III discusses the effects of E-SIGN on both WEAA and efforts to combat prescription fraud against on-line pharmacies. It demonstrates how E-SIGN threatens Washington's ability to protect the public's health, safety, and welfare from this problem. Part IV examines potential options for combating prescription drug fraud against on-line pharmacies after E-SIGN. It recommends that Washington funds not be used to pay for prescriptions dispensed by on-line pharmacies that do not require the electronic transmission of prescriptions using asymmetric cryptography. It also examines the arguments for self-regulation by the on-line pharmacy industry and reviews the limitations of this approach.

I. THE PERPETRATION OF PRESCRIPTION DRUG FRAUD AGAINST COMMUNITY AND ON-LINE PHARMACIES

Prescription drug abuse constitutes a significant portion of the drug-abuse problem in the United States. Several factors affect the prevalence of prescription drug abuse, including the availability of prescription medications, physician prescribing habits, and patient expectations. Despite attempts by pharmacists to detect prescription fraud, patients can subvert the process for filling a legitimate prescription and illegally obtain prescription medications. The problem of prescription drug fraud is even more acute in the growing market of on-line pharmacies.

19. See infra notes 224–25 and accompanying text.
A. The Problem of Prescription Drug Abuse in the United States

Prescription drug abuse is a major social problem in the United States.\(^{21}\) Prescription drug abuse is the inappropriate use of medications, which results in an individual’s loss of control over use of a drug and continued use despite negative consequences.\(^{22}\) One-third of the total drug abuse problem in the United States has been attributed to prescription drugs.\(^ {23}\) The problem extends to all socioeconomic and geographic segments of society, from suburban housewives to street addicts.\(^ {24}\) Approximately three percent of the U.S. population deliberately misuses or abuses prescription drugs each year.\(^ {25}\) The National Household Survey of Drug Abuse estimates that 15.7% of the U.S. population over twelve years of age has used prescription psychotherapeutic drugs\(^ {26}\) for non-medical reasons at some point in time.\(^ {27}\) Approximately two-thirds of all drug-related injuries and deaths involve prescription drugs.\(^ {28}\)

There are two general categories of prescription drug abusers.\(^ {29}\) The first category includes individuals with previously established drug dependencies on substances other than those legitimately prescribed by a physician.\(^ {30}\) For these individuals, a prescribed medication is a "very attractive street drug"\(^ {31}\) because it offers a degree of "label confidence and safety."\(^ {32}\) The second category includes iatrogenic drug


\(^{22}\) See James Finch, Prescription Drug Abuse, Primary Care, Mar. 1993, at 233.

\(^{23}\) See Blumenschein, supra note 6, at 184.

\(^{24}\) See Behr, supra note 21, at 43.

\(^{25}\) See Blumenschein, supra note 6, at 184.

\(^{26}\) Psychotherapeutic drugs are prescribed to relieve mental disorders. See Mosby’s Medical, Nursing, and Allied Health Dictionary 1349 (5th ed. 1998) [hereinafter Mosby’s Dictionary].


\(^{28}\) See Behr, supra note 21, at 44.

\(^{29}\) See Wilford, supra note 5, at 609.

\(^{30}\) See Finch, supra note 22, at 237.

\(^{31}\) Behr, supra note 21, at 42.

\(^{32}\) Kevin Beary, Countering Prescription Fraud, Police Chief, Mar. 1996, at 33. Prescription drugs offer a sense of safety to drug abusers because they can achieve the desired psychopharmacologic effect while reducing the risks associated with consuming unknown substances. See id.
An iatrogenic result is an unintended harm caused by medical treatment designed to benefit a patient. For example, a medication prescribed for pain control also may result in addiction, an iatrogenic result. Iatrogenic drug dependence develops from poorly managed prescription practices by physicians, the use of multiple physicians, or self-medication that does not comply with a physician's directions.

Physician prescribing habits and patient expectations both contribute to prescription drug abuse. Many patients in the United States respond to a societal “mania” for the use of medications by expecting a “quick pharmacologic fix for all forms of distress.” Therefore, common patient complaints such as anxiety, chronic pain, stress, and insomnia often result in prescription drug treatment. These prescribing patterns pose the potential for iatrogenic drug dependence.

The quantity of prescription medications also affects the prevalence of prescription drug abuse. Legitimately manufactured prescription drugs comprise thirteen of the top twenty controlled substances most frequently resulting in emergency room visits in the United States. More than 231 million prescriptions are written for controlled substances per year; this figure does not include controlled substances dispensed in hospitals. The most frequently prescribed medications are among the

33. See Wilford, supra note 5, at 609.
34. See Dictionary of Pharmacy 153 (1986).
35. See Wilford, supra note 5, at 609.
36. See Finch, supra note 22, at 231–32.
37. Id. at 232.
38. See id. at 231.
39. See Wilford, supra note 5, at 609–12. Physicians may be liable for malpractice if they cause an addiction by providing indiscriminate prescriptions. See Michael J. Farrell, Medication Malpractice: Claims, Culprits and Defenses, 16 Am. J. Trial Advoc. 65, 75–76 (1992). Physicians can assert that they “reasonably monitored” a patient's drug usage or that the “patient misrepresented facts to induce additional undetected prescriptions.” Id. at 76. However, a patient is not contributorily negligent for the solicitation and use of addictive drugs if a patient does not know the doctor is negligent. See Ballenger v. Crowell, 247 S.E.2d 287, 291 (N.C. Ct. App. 1978).
41. Controlled substances are any drugs defined in the five categories of the Uniform Controlled Substances Act of 1970. See Mosby's Dictionary, supra note 26, at 396.
43. See Beary, supra note 32, at 33.
most frequently misused or abused, including drugs such as Xanax and Valium.\textsuperscript{44}

Prescription drugs are tightly regulated because of their potential for abuse, causing some prescription drug abusers to turn to illicit means to maintain their addictions. The federal government regulates prescription drugs under the Uniform Controlled Substances Act,\textsuperscript{45} which categorizes all drugs into five schedules according to their potential for abuse\textsuperscript{46} as determined by the Drug Enforcement Administration (DEA).\textsuperscript{47} Although theft and burglary are sometimes used, most prescription drug abusers acquire drugs via prescription fraud.\textsuperscript{48} The perpetrators of prescription fraud may be individual addicts, such as Mark, or third parties who acquire prescription drugs through fraud and then divert them for illegal sale to others.\textsuperscript{49} A significant component of the drug problem in the United States involves legally produced drugs diverted to illicit channels of distribution.\textsuperscript{50} The street sale of diverted prescription medications generates large profits,\textsuperscript{51} with brand-name products tending to have a higher street value because of name and sight recognition.\textsuperscript{52}

B. The Process of Filling a Legitimate Prescription at a Community Pharmacy

Strict limitations govern who may prescribe medications and for what purposes. To issue a prescription,\textsuperscript{53} physicians must be authorized by

\begin{itemize}
\item \textsuperscript{44} See Finch, supra note 22, at 231.
\item \textsuperscript{46} See 21 U.S.C. § 812.
\item \textsuperscript{47} See Pharmacy Law Digest CS-3 (Joseph Fink et al. eds., 34th Revision July 1998).
\item \textsuperscript{48} See Wilford, supra note 5, at 609–12.
\item \textsuperscript{49} See id.
\item \textsuperscript{50} See Behr, supra note 21, at 44.
\item \textsuperscript{51} See id. at 42.
\item \textsuperscript{52} For example, a one-milligram tablet of Xanax costs $1.40 if purchased at a pharmacy, compared to a street value of $5 to $10. See Blumenschein, supra note 6, at 185 (providing street value price); interview with pharmacist at Bartell’s Drug Store in Seattle, Wash. (Jan. 10, 2000) (providing community-pharmacy prices).
\item \textsuperscript{53} Prescriptions are usually written on printed forms that contain the name, address, telephone number, and other information about the physician’s practice. A prescription should include patient information such as name, address, and date of birth; the date of the prescription; an “Rx” symbol (contraction of the Latin verb \textit{recipe} meaning “you take”); the medication prescribed; the dispensing directions to the pharmacist; directions for use by the patient; any refills or other special instructions;
\end{itemize}
state authorities to prescribe controlled substances and be registered with the DEA. Physicians receive individual DEA numbers authorizing them to prescribe controlled substances. A prescription for controlled substances must be issued for a "legitimate medical purpose by a practitioner acting in the usual course of his professional practice." Prescriptions used to maintain drug-dependent individuals are not valid.

The process of obtaining prescription medication with a legitimate paper prescription at a community pharmacy is relatively simple. A patient presents a legitimate paper prescription to a pharmacist. The pharmacist or pharmacy technician usually obtains a patient’s insurance or payment information, collects any required payment, and inquires if the individual is taking any other medications. The pharmacist then evaluates whether any potential drug interactions exist and counsels a patient regarding the appropriate use of the prescribed medication. Finally, the medication is dispensed.

Community pharmacies also accept prescriptions from physicians via telephone and facsimile and transferred from other pharmacies. Physicians can telephone a patient’s chosen pharmacy and prescribe most medications over the phone. Pharmacists may ask physicians to provide their DEA number authorizing them to prescribe medications or their state license number, and possibly engage physicians in a brief conversation using medical jargon regarding the patient’s diagnosis and the prescriber’s signature; and the prescriber’s DEA number. See Remington’s Pharmaceutical Sciences 1828 (Alfonso R. Gennaro et al. eds., 18th ed. 1990) [hereinafter Remington’s].

55. See Remington’s, supra note 53, at 1925.
56. See id.
57. Id.
58. See id.
59. As used in this Comment, the term “community pharmacy” refers exclusively to brick-and-mortar pharmacies and excludes both mail-order and on-line pharmacies.
60. See Remington’s, supra note 53, at 1830.
61. See id. at 1828–35.
62. See id. at 1834–37.
63. See id. at 1828–35.
64. The Washington Pharmacy Board is authorized to adopt rules governing the electronic communication of prescription information. See Wash. Rev. Code § 69.50.312 (1998). Thus, a prescription for a controlled substance may be electronically communicated to a pharmacy if the process complies with Washington statutes. See Wash. Rev. Code § 69.50.312.
65. See Remington’s, supra note 53, at 1926.
condition. Pharmacies may also telephone clinics to verify facsimile prescriptions. In addition, pharmacies accept prescriptions transferred from one pharmacy to another at the request of patients.

C. General Methods of Prescription Drug Fraud

Drug-seeking individuals obtain prescription drugs illegally through alteration, theft, or forgery. Burglary and robbery are less frequent methods of obtaining prescription drugs illegally, primarily because of the more severe penalties for these crimes and increased security measures in pharmacies. As a result of increased security measures, prescription fraud has increased both in frequency and sophistication. According to the DEA, prescription fraud accounts for nearly half of the legally manufactured controlled substances that are diverted to illegal use.

Altering a legitimate prescription is the easiest method of prescription fraud. Changing the quantity, strength, or number of refills on a legitimate prescription is fairly simple, particularly when the quantity or strength is not spelled out in words, but rather written in Arabic numerals. In addition, a second drug may be added to an otherwise legitimate prescription.

Stealing blank prescription pads and prescription forgery are additional methods of perpetrating prescription fraud. Blank prescription pads may be illegally used in a manner similar to forging a blank check. However, fewer security precautions exist to scrutinize paper prescriptions as compared to protections used to verify the accuracy and

66. See Blumenschein, supra note 6, at 187.
67. See Keown, supra note 7, at 19.
69. This Comment uses the term “drug-seeking individual” to refer those who perpetrate prescription fraud to maintain addictions or divert drugs for illegal sale or both.
70. See Wilford, supra note 5, at 609.
71. See Blumenschein, supra note 6, at 185.
72. See id.
73. See id.
74. See Blumenschein, supra note 6, at 185.
75. See id. For example, the Arabic number 10 can easily be changed to 40 or 100. Likewise, the number 30 can be altered to 80 with little chance of detection.
76. See Blumenschein, supra note 6, at 186.
77. See id. at 186.
authenticity of checks.\textsuperscript{78} In addition, prescription drug pads can be ordered from a print shop without any special credentials or created with a home computer.\textsuperscript{79} Having created or obtained a blank prescription pad, an individual with a basic knowledge of prescription formats can forge prescriptions with relative ease and sophistication by entering all the necessary information and forging a physician’s signature.\textsuperscript{80}

D. Methods Available for Pharmacists to Detect Prescription Fraud

Pharmacists have a legal duty of vigilance when dispensing prescriptions for controlled substances.\textsuperscript{81} Federal law forbids pharmacists from dispensing prescription medications if the pharmacist harbors any doubts concerning the legitimacy of the prescription.\textsuperscript{82} Pharmacists may refuse to fill or refill a prescription if they suspect that a prescription is forged.\textsuperscript{83} Nonetheless, because of the relative ease of perpetrating prescription fraud and the difficulty of detecting it,\textsuperscript{84} pharmacists unknowingly fill fraudulent prescriptions despite following established precautions.\textsuperscript{85}

The DEA recommends a variety of methods to detect fraudulent prescriptions for community pharmacies.\textsuperscript{86} The pharmacist should know the physician, the physician’s signature, and the physician’s DEA

\textsuperscript{78} See id.
\textsuperscript{79} See id.
\textsuperscript{80} The information necessary to complete a prescription is widely available from a variety of sources that show the format of a prescription as well as the common terms and abbreviations used by physicians when writing a prescription. See, e.g., Basic and Clinical Pharmacology 970–72 (Bertram Katzung ed., 6th ed. 1995).
\textsuperscript{82} Under the statute, a prescription for controlled substances can only be issued for a legitimate medical purpose. See 21 U.S.C. §§ 812, 829. It is the responsibility of the physician and the pharmacist to ensure the proper prescribing and dispensing of controlled substances. See 21 U.S.C. §§ 812, 829; see also United States v. Kershman, 555 F.2d 198, 200 (8th Cir. 1977) (affirming conviction of pharmacist for knowing and intentional distribution of controlled substances when pharmacist deliberately ignored good reasons to believe prescriptions were not for legitimate medical purpose). A person knowingly filling a prescription that is not issued for legitimate medical treatment is subject to penalties. See 21 U.S.C. §§ 812, 829. Washington enacted a similar statute. See Wash. Rev. Code § 69.50 (1998).
\textsuperscript{83} See Pharmacy Law Digest, supra note 47, at CL-37.
\textsuperscript{84} See interview with pharmacist at Bartell’s Drug Store in Seattle, Wash. (Jan. 10, 2000).
\textsuperscript{85} See id.
\textsuperscript{86} See Keown, supra note 7, at 16.
number. In addition, the pharmacist should be familiar with the patient. The DEA recommends using a patient profile form to discourage fraudulent prescriptions by tracking patient demographics and medication usage. Finally, the DEA recommends that pharmacists ask a patient for a plausible explanation for any discrepancy in the prescription and, if suspicious, telephone the physician for verification.

When a prescription is presented at a community pharmacy, pharmacists can directly observe a patient's behavior to detect prescription fraud. Individuals committing fraud commonly remain close to the pharmacy counter while the prescription is being filled, engage in excessive conversation with the pharmacist, and become irritated or angry at delays. Pharmacists practicing in community pharmacies develop a sense for patients who attempt to fill fraudulent prescriptions based on the totality of the circumstances presented. In addition, pharmacists in community pharmacies use their familiarity with local physicians and patients to evaluate prescriptions for fraud. Pharmacists also may ask for identification from a patient.

Pharmacists also can closely examine the paper prescriptions presented by patients by evaluating the consistency of the ink used, any variations in writing styles, and other cues on the paper prescription, such as photocopy residue. Pharmacists also use their therapeutic knowledge to evaluate the amount or type of medication prescribed for a patient's reported disease or condition. Other incongruities also may indicate that the prescription is fraudulent, such as a dentist prescribing anti-anxiety medications or a psychiatrist prescribing a narcotic pain medication.

---

87. See id.
88. See id.
89. See id.
90. See id.
91. See Tamika Simmons, Prescription Fraud Seen in Rising Doses, Fort Lauderdale Sun-Sentinel, Sept. 17, 1998, at 4B.
92. See id.
93. See generally Blumenschein, supra note 6.
94. See id.
95. See Keown, supra note 7, at 19; see generally Blumenschein, supra note 6.
96. See generally Blumenschein, supra note 6.
97. See id.
98. See Simmons, supra note 91, at 4B.
E. Consumer Use of On-line Pharmacies

The development of on-line commerce has expanded into the pharmaceutical field.99 The pharmaceutical market is worth approximately $90 billion annually in the United States.100 The first large and exclusively on-line pharmacies began filling prescriptions as recently as 1999.101 Since then, a growing number of on-line pharmacies has attempted to capture business from community pharmacies102 by forming partnerships with familiar names such as America Online, Yahoo.com, Women.com,103 and the Mayo Clinic104 to develop exposure and credibility among potential consumers. However, an estimated 400 sites currently sell prescription medications on-line.105 As on-line pharmacies become more prevalent they are likely to take business away from community pharmacies.106 Fearing a loss of customers and profits similar to the experience of large bookstore retailers that waited too long to go on-line,107 many community pharmacies seek to provide same-day delivery to patients by combining on-line and community-pharmacy services.108

The convenience and occasionally lower prices of on-line pharmacies appeal to consumers.109 On-line pharmacies are convenient for the
On-line Pharmacies and E-SIGN

elderly,\textsuperscript{110} those living in rural areas,\textsuperscript{111} and those wanting personal privacy or seeking to avoid the hassle of lines and waiting time at a community pharmacy.\textsuperscript{112} Sending patients e-mails reminding them to refill prescriptions is another appeal of on-line pharmacies.\textsuperscript{113} On-line pharmacies have lower operating costs than community pharmacies and generally pass these savings on in the form of lower prices.\textsuperscript{114} Because mail-order pharmacies deliver one out of every seven prescriptions in the United States, many consumers are already familiar with obtaining prescription drugs from sources other than community pharmacies and are comfortable buying them sight-unseen.\textsuperscript{115}

To purchase prescription medications on-line, a patient must register with the on-line pharmacy and provide an e-mail account.\textsuperscript{116} A patient creates an individual account with the on-line pharmacy, using a password for privacy protection.\textsuperscript{117} Next, a patient submits insurance information or a credit card number for payment.\textsuperscript{118} Then, a patient must complete a health profile, including patient demographic data, drug allergies, medical conditions or illnesses, and current medications.\textsuperscript{119} Next, a patient enters the name of the medication on the prescription\textsuperscript{120} and completes the checkout process.\textsuperscript{121} Customers pay for their orders


\textsuperscript{111}. See Drugs on the Internet, The Virginian-Pilot and The Ledger-Star, Jan. 2, 2000, at J4.


\textsuperscript{114}. See Kim Komando, Things to Know About Online Pharmacies, Ariz. Republic, July 12, 1999, at E2.

\textsuperscript{115}. See Gaw, supra note 101, at 1A.


\textsuperscript{117}. See, e.g., id.


with credit cards over secured connections on the Internet or via telephone.\footnote{122} Several sites offer free mail delivery of prescription drugs.\footnote{123} Customer service representatives and pharmacists generally are available toll-free via telephone or e-mail twenty-four hours a day to provide assistance and answer drug-related questions.\footnote{124}

After a customer creates an account, there are various methods to obtain prescription medications from an on-line pharmacist. Prescriptions can be faxed, mailed, or called to the pharmacy by the physician; a patient can mail or fax the prescription to the pharmacy; or a patient can request that a refill be transferred from another pharmacy.\footnote{125} Some on-line pharmacies also accept e-mail prescriptions, but the pharmacy generally will verify the prescription with the physician.\footnote{126} For certain medications with a higher potential for abuse, the on-line pharmacy may require that the original paper prescription be mailed.\footnote{127}

F. Prescription Fraud and On-line Pharmacies

The U.S. government has recognized potential problems with on-line pharmacies and has proposed regulating on-line drug sales.\footnote{128} On-line pharmacies dispense prescription medications with a potential for abuse.\footnote{129} Because regulation of drug sales is traditionally a state role,\footnote{130} gaps exist in the regulation of drug sales caused by variable state

requirements, increasing the potential illegal access to addictive medications. In addition, on-line pharmacies vary in their practices for verifying the legitimacy of prescriptions. Therefore, state governments have requested federal regulation of on-line pharmacies by the Food and Drug Administration (FDA) to help curb illegal on-line drug sales by creating civil penalties of up to $500,000 for selling a prescription drug to a person without a valid prescription.

The techniques traditionally used by pharmacists to screen for prescription fraud are impaired when patients use on-line pharmacies. For example, unlike the community pharmacy setting, on-line pharmacies lack any direct patient-pharmacist interaction. Thus, pharmacists cannot observe patient behavior and demeanor to detect clues of prescription fraud. In addition, no method exists to verify if a legitimate or fraudulent prescription was sent to numerous on-line pharmacies.

It is also difficult for on-line pharmacists to comply with DEA-recommended methods to detect prescription fraud. For example, because on-line pharmacies are often located great distances from the prescribing physician, the familiarity of pharmacists with the prescribing habits and signatures of local physicians is absent. In addition, patients can easily circumvent the traditional process used by pharmacists to verify prescriptions with physicians. For example, when suspicious, a pharmacist generally will attempt to verify the prescription by calling the prescribing physician, particularly when the prescription is received via
facsimile or telephone. However, physicians are difficult to reach and pharmacists often speak with another clinic staff member. In sum, because on-line pharmacies receive prescriptions out of the presence of a patient and usually a great distance from the prescribing physician, the verification problems encountered by pharmacists in community pharmacies are magnified in the on-line pharmacy context.

Finally, anecdotal evidence suggests that it is relatively easy to obtain medications from some on-line pharmacies without a prescription. This is particularly true of on-line pharmacies that prescribe and dispense medications without a patient ever having seen a physician. These on-line pharmacies accept questionnaires completed by patients that are reviewed by a physician, after which the requested medication is dispensed. For example, in 1999 Congress heard testimony that individuals obtained prescription medications from on-line pharmacies for a cat named “Tom,” using the animal’s actual height and weight and obtained a prescription diet drug for a seven-year-old girl using her actual age.

II. DIGITAL SIGNATURE TECHNOLOGY AND GOVERNING LEGISLATION

Electronic signatures are increasingly used to replace handwritten signatures. A digital signature is one type of electronic signature that uses a unique technology to protect the integrity of messages. Most states, and recently the federal government, have enacted legislation governing electronic signatures. The Electronic Signatures in Global and National Commerce Act governs the scope and legal authority of electronic signatures nationwide. Similarly, the Washington Electronic Authentication Act establishes the scope and legal authority of digital signatures in Washington.

142. See id. at 186; see also Keown, supra note 7, at 19.
143. See Blumenschein, supra note 6, at 186.
145. See id.
146. See id.
A. Digital Signature Technology and Infrastructure

Electronic commerce is one of the fastest growing areas of business worldwide. However, because the Internet allows anonymous access to cyberspace, it appeals to individuals with dishonorable intentions. In one study, more than half of the on-line user population polled had provided false information on-line at some point. Therefore, to recreate in cyberspace the trust placed in handwritten signatures, electronic forms of signatures are increasingly used for on-line business and legal transactions.

A digital signature is an electronic substitute for a handwritten signature that is created using a computer instead of a pen. It is not a digital replica of a handwritten signature, but rather an unintelligible string of letters and numbers created by a computer program. To sign a message digitally requires no technical expertise beyond basic computer skills.

Digital signature technology uses cryptography, which is based on the processes of encrypting and decrypting information. During encryption, the computer program uses a hash function to convert the original electronic text of a message into an alternate format, which is then encrypted with the sender’s encryption key. An encryption key, sometimes called a private key, is merely a computer program that runs the hash function. The encryption key is unique for each individual owner and kept confidential.

During decryption, the reverse process

150. See James, supra note 148, at 6.
152. See id. at 146–47.
153. See id. at 148.
154. A hash is the altered format, consisting of a unique string of letters and numbers, generated by the automatic mathematical computation of a computer program. See Lui-Kwan, supra note 149, at 467. A hash function is the conversion of the message to the altered format. See id.
155. See Smedinghoff, supra note 151, at 147.
156. See id.
157. See id.
occurs as the hash is converted back into the text of the original message using the recipient's decryption key.\textsuperscript{158} The decryption key, generally called the public key, can be disclosed to the recipient by attaching it to the message or by posting it in on-line databases for easy access.\textsuperscript{159} If the hashes match after opening the message with the decryption key, the message has not been altered since the sender signed it.\textsuperscript{160}

There are two common types of cryptography: symmetric and asymmetric. Symmetric cryptography uses one secret key for both the encryption and decryption of messages.\textsuperscript{161} If the secret key is intercepted, the messages can be easily decrypted, altered, and forwarded without the knowledge of the sender or intended recipient.\textsuperscript{162} Asymmetric cryptography is a more secure type of cryptography that requires a unique key pair consisting of one private and one public key.\textsuperscript{163} Only the keys in a given pair function together.\textsuperscript{164} The key pair owner keeps the private key confidential and uses it to encrypt messages to be opened by a recipient possessing the corresponding public key, which is usually attached to the message when sent.\textsuperscript{165}

Asymmetric cryptography offers a high level of certainty that the holder of the private key sent the encrypted message and that the encrypted message has not been altered since it was generated.\textsuperscript{166} As long as the owner protects access to the private key, messages encrypted using the private key are verifiably written by the private-key owner.\textsuperscript{167} In addition, by decrypting the message using the corresponding public key, the recipient can determine if the message was altered in any way since its generation.\textsuperscript{168}

\begin{itemize}
\item \textsuperscript{158} See Lui-Kwan, supra note 149, at 467–68.
\item \textsuperscript{159} See Smedinghoff, supra note 151, at 147.
\item \textsuperscript{160} See Lui-Kwan, supra note 149, at 467.
\item \textsuperscript{161} See \textit{whatis.techtarget.com} (visited Sept. 26, 2000) \texttt{<http://whatis.techtarget.com/WhatIs_Definition_Page/0,4152,214299,00.html>} (defining PKI).
\item \textsuperscript{162} See id.; see also Lonnie Eldridge, Comment, \textit{Internet Commerce and the Meltdown of Certification Authorities: Is the Washington State Solution a Good Model?}, 45 UCLA L. Rev. 1805, 1811 (1998).
\item \textsuperscript{163} See Smedinghoff, supra note 151, at 148.
\item \textsuperscript{164} See id.
\item \textsuperscript{165} See Lui-Kwan, supra note 149, at 467.
\item \textsuperscript{166} See Smedinghoff, \textit{supra} note 149, at 467.
\item \textsuperscript{167} See id. at 147, 149.
\item \textsuperscript{168} See \textit{id.} at 147.
\end{itemize}
Certification authorities\textsuperscript{169} issue digital certificates\textsuperscript{170} that include asymmetric cryptographic key pairs.\textsuperscript{171} Depending on state statutes, a certification authority may be a state agency or a private entity.\textsuperscript{172} A subscriber contacts a certification authority to obtain the digital certificate and corresponding asymmetric key pair.\textsuperscript{173} The certification authority verifies the subscriber's identity itself\textsuperscript{174} or by using a registration authority.\textsuperscript{175} A registration authority is usually a component of a licensed certification authority and verifies the information of an individual seeking a digital certificate.\textsuperscript{176} Once the subscriber's information has been verified, the certification authority issues a digital certificate with a corresponding asymmetric key pair.\textsuperscript{177} The digital certificate is stored in a directory, known as a repository, where recipients of messages can verify on-line the identity of the public key owner.\textsuperscript{178}

A digital certificate establishes an individual's credentials to use a given asymmetric cryptographic key pair.\textsuperscript{179} Digital certificates contain the individual's name, a corresponding serial number, the expiration date of the certificate, and a copy of the public key belonging to the

\textsuperscript{169} See id. at 149. A certification authority issues security credentials and public keys for message encryption and decryption as part of a public key infrastructure (PKI). The entities and processes required to obtain and use a digital signature based on asymmetric cryptography are known as a PKI. See whatis.techtarget.com (visited Sept. 26, 2000) <http://whatis.techtarget.com/WhatIsDefinition_Page/0,4152,214299,00.html> (defining PKI). Private corporations support the PKI infrastructure, including RSA (a developer of algorithms used in PKI technology) and Verisign (a certification authority and a company that sells software that allows other companies to create their own certification authorities). See id.

\textsuperscript{170} See Smedinghoff, supra note 151, at 149. A digital certificate establishes an individual's credentials for transactions on the Internet. Usually, it is maintained in an on-line database for public reference. See id. at 151; see also infra notes 179–182.

\textsuperscript{171} See Smedinghoff, supra note 151, at 149.


\textsuperscript{173} See Smedinghoff, supra note 151, at 149.

\textsuperscript{174} At least one Internet site offers a uniform application method to streamline the process of obtaining a certificate in participating states. See The Uniform Certificate of Authority Application (visited Sept. 26, 2000) <http://www.naic.org/ucaa/>.


\textsuperscript{176} See id.

\textsuperscript{177} See Smedinghoff, supra note 151, at 150.

\textsuperscript{178} See id. Repositories store other information regarding the subscriber and the status of the digital certificate (e.g., suspended or revoked). See id.

\textsuperscript{179} See id.
A digital certificate also includes the digital signature of the certification authority that issued it. Thus, the recipient of a message with a digital signature can contact a repository of digital signatures to verify that the certificate and associated public key is correct.

B. The Electronic Signatures in Global and National Commerce Act

The federal government recently enacted the Electronic Signatures in Global and National Commerce Act (E-SIGN), ensuring that electronic signatures are not denied legal recognition merely because they are in an electronic form. Although most states have enacted legislation to give legal recognition to certain types of electronic signatures, E-SIGN was enacted to create a uniform nationwide standard governing electronic signatures. E-SIGN generally applies to all types of communications, with some exceptions. However, E-SIGN does not require individuals to use or accept electronic signatures.

E-SIGN is technology neutral because it prohibits requiring the use of a specific type of electronic signature technology. E-SIGN prohibits statutes or regulations that deny the legal validity of an electronic signature based on the type of technology used. E-SIGN’s definition of an electronic signature is also technology neutral, defining it as

180. See id.
181. See James, supra note 148, at 6.
182. See Smedinghoff, supra note 151, at 150.
185. See Lui-Kwan, supra note 149, at 472.
information in an electronic form that is "attached to or logically associated with an electronic record," and used by an individual with the intent to sign a document. This allows parties to a transaction to determine the electronic signature technology they will use.

Federal and state statutes or regulations must be consistent with E-SIGN. This requirement will preempt any state laws that mandate the use of electronic signatures or require the use of a specific type of technology. Although E-SIGN preserves the existing rulemaking authority of state regulatory agencies pursuant to other statutes, promulgated regulations must be consistent with E-SIGN, technology neutral, and not additions to E-SIGN’s requirements. For example, E-SIGN permits states to modify E-SIGN’s requirements through statutes and regulations by adopting the Uniform Electronic Transactions Act (UETA). UETA is consistent with E-SIGN because it is technology neutral and does not require the use of electronic signatures.

C. The Washington Electronic Authentication Act

The Washington Legislature enacted the Washington Electronic Authentication Act (WEAA) in March 1996. WEAA is one of the most comprehensive and advanced statutes governing electronic signatures in the United States. Like E-SIGN, WEAA ensures that digital signatures are not denied legal recognition solely because they are in electronic form. However, unlike E-SIGN, WEAA uses the term "digital signature" instead of electronic signature and defines it as an

---

199. See Eldridge, supra note 162, at 1828. Washington modeled WEAA on Utah Code Annotated §§ 46-3-101 to -504 (1997), which is a model statute for governing digital signatures. Id. at 1828 n.90.
asymmetric-cryptographic system. WEAA applies generally to all types of communications. Compliance with WEAA is voluntary. However, failure to comply with WEAA jeopardizes the legal status of a digital signature.

WEAA establishes the legal status of a digital signature obtained in compliance with the statute. WEAA states that "[w]here a rule of law requires a signature, or provides for certain consequences in the absence of a signature, that rule is satisfied by a digital signature" when three factors are met. First, the "digital signature is verified by reference to the public key listed in a valid certificate issued by a licensed certification authority." Second, the digital signature must have been used with the intention of signing the message. Third, the "recipient of the message must have no knowledge or notice that the signer either breached a duty" in obtaining the certificate or "[d]oes not rightfully hold the private key used to affix the digital signature.

Under WEAA, an individual applying for a digital certificate is called a subscriber and must provide a licensed certification authority with specific information for confirming the subscriber's identity prior to issuing a digital certificate. The licensed certification authority must make a reasonable inquiry into the information provided by each subscriber. When a subscriber accepts a certificate issued by a licensed certification authority under WEAA, the subscriber has a duty to use reasonable care to control access to the private key and prevent its disclosure to someone not authorized to use the subscriber's digital signature. A private key is the personal property of the subscriber.

202. Examples include communications between business, consumer, legal, governmental, and other types of entities. See Wash. Rev. Code § 19.34.010(3).
203. See Wash. Rev. Code § 19.34.010(3).
204. See infra note 201.
207. See Wash. Rev. Code § 19.34.300(1)(b).
208. Wash. Rev. Code § 19.34.300(1)(c). The recipient of a message signed with a digital signature "assumes the risk that the signature was forged" if that individual's reliance "is not reasonable under the circumstances." Wash. Rev. Code § 19.34.310 (1998).
210. See Wash. Rev. Code § 19.34.210(2) (1998). The reasonableness of the inquiry depends on the quality of statements the certification authority will later make regarding the reliability of the certificate, the reliance limit of the certificate, and the recommended uses of the certificate.
Thus, because WEAA has more technical requirements than E-SIGN it provides more opportunities for combating prescription fraud.

III. E-SIGN INCAPACITATES WEAA AS A TOOL TO COMBAT PRESCRIPTION FRAUD AGAINST ON-LINE PHARMACIES

E-SIGN restricts Washington’s ability to implement a comprehensive and effective program to combat prescription fraud against on-line pharmacies. E-SIGN preempts WEAA’s asymmetric cryptography requirement and prohibits requiring that on-line pharmacies only receive prescriptions transmitted electronically. Thus, E-SIGN inhibits Washington’s ability to protect the public’s health, safety, and welfare from the harms of prescription fraud against on-line pharmacies.

A. E-SIGN Preempts WEAA’s Asymmetric-Cryptography Requirement

E-SIGN preempts a fundamental strength of WEAA, the requirement that electronic signatures in Washington use asymmetric cryptography. E-SIGN is technology neutral and preempts statutes and regulations that discriminate for or against a particular type of electronic signature technology.213 Because it is inconsistent with E-SIGN, WEAA’s asymmetric-cryptography requirement214 could be invalidated. Thus, without WEAA’s asymmetric-cryptography requirement, E-SIGN vests legal status in electronic signatures that are less secure than a handwritten signature because E-SIGN lacks any requirement that an electronic signature be secure from even the simplest fraud.215

E-SIGN significantly reduces the relative advantage of WEAA over other state statutes governing electronic signatures for combating prescription fraud against on-line pharmacies. Statutory schemes that do not use asymmetric cryptography are less secure against undetected

215. See Paul Hoffman, The Pen Is Mightier Than the Electronic Signature, Network World, July 24, 2000, at 41, available in 2000 WL 9435775. At least one commentator equates an electronic signature without asymmetric cryptography or other security technology to an oral contract, arguing that either party to the transaction can later claim that what was sent is different than the copy kept in a computer hard drive. See id. The lack of security is a high price to pay for Congress’s desire to promote new electronic signature technologies, regardless whether they meet the basic security needs of future users. Cf. H.R. Rep. No. 106-341, pt. 1, at 8 (1999).
interception and alteration prior to delivery to the intended recipient.\textsuperscript{216} Unable to require asymmetric cryptography, Washington and other states must now permit individuals to use technologies that are less secure against forgery for electronically transmitting prescriptions. For example, a prescription sent electronically to an on-line pharmacy using symmetric cryptography\textsuperscript{217} could be easily altered and forwarded without the knowledge of either the original sender or the receiving pharmacist.

E-SIGN ensures new opportunities to transmit prescriptions electronically without an assurance of the authenticity of the prescription’s content and author. Without the use of asymmetric cryptography, on-line pharmacists will be unable to determine if the contents of an electronically transmitted prescription have been altered since being signed by a physician.\textsuperscript{218} Similarly, on-line pharmacists will be unable to determine accurately from the electronic prescription itself if the electronic signature belongs to the physician who purportedly electronically signed and sent the prescription to the pharmacy.\textsuperscript{219} By preempting WEAA’s asymmetric-cryptography requirement, E-SIGN actually reduces the effectiveness of electronic signatures for preventing prescription fraud against on-line pharmacies.

B. E-SIGN Precludes the Ability of States To Require that On-line Pharmacies Only Receive Prescriptions Transmitted Using Digital Signatures

E-SIGN frustrates attempts to combat fraud by prohibiting states from requiring the use of electronic signatures. E-SIGN does not require individuals to use or accept electronic signatures and prohibits state statutes and regulations from requiring the use or acceptance of electronic signatures.\textsuperscript{220} Prior to E-SIGN, statutes such as WEAA could have been amended to require that on-line pharmacies only accept prescriptions electronically. Now, E-SIGN prohibits states from enacting such statutes or regulations because they would be inconsistent with E-SIGN.\textsuperscript{221} State pharmacy boards, therefore, no longer have the power to require that on-line pharmacies only accept prescriptions transmitted

\textsuperscript{216} See supra note 161 and accompanying text (defining symmetric cryptography).

\textsuperscript{217} See id.

\textsuperscript{218} See supra note 168 and accompanying text.

\textsuperscript{219} See supra note 167 and accompanying text.


using electronic signatures. By limiting the traditional role of pharmacy boards, E-SIGN diminishes the effectiveness of statutes like WEAA for combating prescription fraud against on-line pharmacies.

E-SIGN reinforces on-line pharmacies as unique targets of prescription fraud. On-line pharmacists will remain unable to detect and prevent fraudulent paper or electronic prescriptions. On-line pharmacies are poorly situated to detect prescription fraud using the traditional methods available to community pharmacists. On-line pharmacists are unable to observe a patient’s behavior directly for cues that a prescription is fraudulent. They are unable to verify if a prescription has been sent to numerous on-line pharmacies. In addition, on-line pharmacies are unable to comply fully with DEA-recommended methods to detect and prevent prescription fraud. Therefore, on-line pharmacies remain a uniquely vulnerable target of prescription fraud through traditional methods such as altering or forging paper prescriptions, or new methods of electronic fraud.

C. E-SIGN Threatens Washington's Ability to Protect the Public's Health, Safety, and Welfare Related to Prescription Fraud Against On-line Pharmacies.

E-SIGN inhibits the efforts of state agencies charged with protecting the public's health, safety, and welfare. The Washington State Board of Pharmacy is authorized by statute to promulgate regulations for the protection and promotion of the public’s health, safety, and welfare. Public policy warrants strengthening safeguards against prescription fraud by requiring the use of digital signatures for all prescriptions dispensed by on-line pharmacies. Because prescription drug abuse is a serious and sometimes deadly threat to the health of many Americans, the Board of Pharmacy must be able to prevent prescription fraud. Requiring electronic signatures is one way the Board could combat prescription fraud against on-line pharmacies. Therefore, sufficient controls are necessary to erect a barrier to obtaining prescription medications fraudulently from on-line pharmacies. However, the Board of Pharmacy cannot implement via regulation a comprehensive and

222. See supra notes 135–38 and accompanying text.
223. See supra note 86 and accompanying text.
225. See supra notes 21–30.
effective program because E-SIGN preempts WEAA’s asymmetric-cryptography requirement and prohibits requiring that on-line pharmacies only receive prescriptions transmitted using electronic signatures. Thus, E-SIGN threatens the public’s health, safety, and welfare by prohibiting actions by state agencies that would nearly eliminate prescription drug fraud against on-line pharmacies.

IV. OPTIONS AFTER E-SIGN FOR COMBATING PRESCRIPTION FRAUD AGAINST ON-LINE PHARMACIES IN WASHINGTON

Despite its restrictions, E-SIGN allows some options to combat prescription drug fraud against on-line pharmacies. Washington should require that all prescriptions dispensed by on-line pharmacies and paid for with public funds be transmitted electronically using asymmetric-cryptography technology. This requirement would encourage the on-line pharmacy industry to move toward self-regulation by accepting prescriptions only transmitted electronically using such technology. However, such self-regulation is unlikely to develop because of industry concerns regarding perceived barriers for consumers to access on-line pharmacies. Moreover, self-regulation without a comprehensive statutory framework will achieve only limited success in preventing prescription fraud against on-line pharmacies.

A. Washington Should Deny State Funds to On-line Pharmacies that Do Not Accept Only Prescriptions Transmitted Electronically Using Asymmetric-Cryptography Technology

The Washington Legislature should require that all prescriptions dispensed by on-line pharmacies and paid for with public funds be transmitted electronically using asymmetric-cryptography technology. Under E-SIGN, states as market participants are not restricted from according a greater legal status to a specific electronic signature technology. Washington is a market participant because, under the state’s Medical Assistance Program, Washington pays for prescription medications that provide health care benefits for more than 700,000 low-income, disabled, or pregnant Washington residents. By requiring the

electric transmission of prescriptions using asymmetric-cryptography technology for payment of prescriptions with state Medical Assistance funds, Washington would prevent the abuse of state funds for fraudulent prescriptions sent to on-line pharmacies. Therefore, Washington can mandate certain requirements before disbursing state funds for prescriptions dispensed by an on-line pharmacy.

B. The On-line Pharmacy Industry Should Voluntarily Mandate that All Prescriptions Be Transmitted Electronically Using Asymmetric Cryptography-Technology

E-SIGN relies on the market rather than government regulation to define both who will use electronic signatures and the type of electronic signature technology those individuals will choose.\footnote{228. See Federal Courts and the Internet, 2000: Hearing on Electronic Signature Legislation Before the Subcomm. on Courts and Intellectual Property of the House Judiciary Comm., 106th Cong. (2000) (statement of the Honorable Andrew J. Pincus), available in 2000 WL 23831150, at *12.} This approach favors voluntary solutions between private parties to the use of electronic signatures. On-line pharmacies should voluntarily require that all prescriptions received be signed using an electronic signature capable of authenticating the author’s identity and verifying that the prescription’s content has not been altered since signed.\footnote{229. Ultimately, all pharmacies, including community and mail-order businesses, should implement an electronically transmitted and digitally signed requirement for all prescriptions filled. The harm caused by prescription drug abuse and diversion results from prescription fraud perpetrated against all types of pharmacies. However, this Comment recognizes that not all patients have access to computers to open on-line pharmacy accounts and order refills, particularly the elderly and patients with limited incomes. Although some patients can access computers at public libraries or cyber cafes (coffee shops offering Internet access), others may live in remote areas or lack the time, motivation, or knowledge to access the Internet. Until such access concerns can be adequately addressed, these recommendations should only apply to on-line pharmacies.} At a minimum, this approach would deter prescription fraud perpetrated using paper prescriptions. However, the industry is unlikely to implement this requirement voluntarily because of perceived barriers to obtaining customers. Moreover, such a standard would be only marginally effective at eliminating on-line prescription fraud absent a comprehensive statutory framework. Thus, E-SIGN fails to encourage the type of voluntary use of electronic signatures by industries it purports to prefer.
1. The Favorable Consequences of Self-Regulation by the On-line Pharmacy Industry.

Self-regulation by the on-line pharmacy industry would promote industry growth by increasing consumer confidence and encouraging more use of on-line pharmacies. Some on-line pharmacy executives are already voluntarily seeking heightened regulation of on-line pharmacies. Proactive implementation of voluntary standards, which protect the public and legitimize the industry, would help minimize the potential costs of compliance with government regulations that would otherwise be imposed as the on-line pharmacy industry matures. Any future regulation likely will occur in response to public concern that on-line pharmacies fail to protect adequately against prescription fraud and subsequent harms. Imposed regulations may be reactionary in nature, resulting in more restrictive constraints on the industry.

By voluntarily adopting digital signatures as the industry standard, on-line pharmacies would obtain several long-term benefits, despite the possibility of an initial short-term decrease in prescription orders. First, on-line pharmacies would gain an enhanced image of trustworthiness among more consumers if they accepted only prescriptions using digital signatures. Consumer perceptions of trustworthiness and convenience are crucial factors for attracting new customers to on-line pharmacies from the more familiar community pharmacy experience. On-line pharmacy executives already recognize the value of positive consumer perceptions. Self-regulation would create an image of on-line pharmacies as a trustworthy alternative to community pharmacies, evidenced by the concern of on-line pharmacies for patient welfare and safety. For example, on-line pharmacies could tout the use of digital signatures as a means to reduce prescription errors commonly caused by illegible handwritten prescriptions and responsible for significant harm to patients. Second, if all prescriptions were received electronically, the

230. See President Clinton's Initiative To Oversee Online Pharmacies Will Spur Growth, Info-Tech Chief Says, PR Newswire, Jan. 6, 2000 [hereinafter President Clinton's Initiative].

231. See Roan, supra note 112, at 1.

232. See supra notes 102, 106 and accompanying text.

233. See President Clinton's Initiative, supra note 230 and accompanying text.

cost to the on-line pharmacy of verifying and processing prescriptions using other methods would be nearly eliminated, thereby decreasing operating costs, improving profitability, and increasing competitiveness based on price. On-line pharmacies already have begun to compete in offering the least expensive prices,\textsuperscript{235} which will be increasingly important in securing contracts with large health care payers.\textsuperscript{236}

2. \textit{The On-line Pharmacy Industry Is Unlikely To Engage in Self-Regulation that Constrains Its Business Objectives in Order To Protect the Public's Health}

Despite these benefits, the on-line pharmacy industry is unlikely to mandate voluntarily that its pharmacies only receive prescriptions transmitted electronically using asymmetric-cryptography technology. Such a standard would threaten industry access to consumers by creating additional barriers to using on-line pharmacies. Although minimal, asymmetric cryptography requires that time and money be spent obtaining the public-private key pair.\textsuperscript{237} Those choosing not to obtain asymmetric key pairs could not use an on-line pharmacy. In the highly competitive on-line marketplace, barrier-free access to consumers is crucial to ensure the success of newly emerging businesses.\textsuperscript{238} Thus, the on-line pharmacy likely will not voluntarily implement this requirement.

However, it is plausible that patient and health care payer demand could overcome potential obstacles caused by physicians not yet having adopted digital signature technology. More than 22 million consumers accessed the Internet for health and medical information in 1998.\textsuperscript{239} More importantly, large health care payers such as managed-care organizations, pharmacy benefit managers,\textsuperscript{240} and self-funded employers\textsuperscript{241} on-line transmission of prescriptions to pharmacies to reduce errors caused by a failure to understand handwritten prescriptions. See id.  

\textsuperscript{236} See infra notes 242–43 and accompanying text.  
\textsuperscript{237} See supra notes 169–77 and accompanying text.  
\textsuperscript{238} See infra notes 110–13 and accompanying text.  
\textsuperscript{239} See Congressional Panel Discusses Online Pharmacies, supra note 144, at 212.  
\textsuperscript{240} Pharmacy benefit managers control the costs of providing prescription medications to a defined population of patients by negotiating rebate contracts with drug manufacturers, establishing reimbursement rates for pharmacy network providers, and entering into drug risk-sharing arrangements with physician groups for the cost of medications prescribed. See Helene Levens  

1359
recognize the cost savings available from on-line pharmacies because of lower overhead.\textsuperscript{242} For example, during 1999, one pharmacy benefit manager with more than 47 million patients, for whom the manager purchased more than $10 billion worth of prescription medications per year, contracted with an on-line pharmacy to reduce the cost of providing prescription medications.\textsuperscript{243} Thus, the minimal investment required by physicians to obtain an electronic signature for use with on-line pharmacies would be offset by the ability of physicians to offer a service in demand by both their patients and health care payers.

Furthermore, because most physicians have integrated the use of electronic communication technology into their practices, it is reasonable to expect physicians to use electronic signatures to send prescriptions to on-line pharmacies with great efficiency. In fact, the electronic exchange of medical information is a rapidly expanding trend in the medical profession.\textsuperscript{244} For example, physicians increasingly interact with patients using e-mail.\textsuperscript{245} Some physicians provide basic diagnostic and treatment services on-line.\textsuperscript{246} In addition, because handwritten prescriptions are time-consuming and costly, new software products exist that allow physicians to complete and transmit electronic prescriptions directly from the treatment room.\textsuperscript{247} Further, some pharmacies have begun testing programs to accept electronic prescriptions sent directly from physicians to pharmacists.\textsuperscript{248}

\textsuperscript{Lipton et al., Medicare Drug Benefit: Managing The Pharmacy Benefit in Medicare HMOs: What Do We Really Know?, Health Affairs, Mar.-Apr. 2000, at 42.}

\textsuperscript{241. Some employers choose to pay for all their employee health care claims out-of-pocket, as is authorized by ERISA. See Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001–1191(c) (1994).}

\textsuperscript{242. See Rx.com CEO Calls for the Creation of Internet Pricing Guidelines for Reimbursement of Pharmaceutical Costs: New Plan Aims To Reduce Managed Care Costs for Online Prescriptions, Bus. Wire, Jan. 13, 2000.}

\textsuperscript{243. See Larry Holyoke, Express Scripts Has Prescription for the Internet, St. Louis Bus. J., July 5, 1999, at 1A.}

\textsuperscript{244. See Ranney V. Wiesemann, On-line or On-call? Legal and Ethical Challenges Emerging in Cybermedicine, 43 St. Louis U. L.J. 1119, 1121 (1999).}

\textsuperscript{245. See id. at 1120.}

\textsuperscript{246. See id. at 1138–39.}

\textsuperscript{247. See ePhysician to Participate in New drugstore.com Certification Program for Electronic Prescriptions, Bus. Wire, Nov. 4, 1999.}

Nonetheless, because E-SIGN is technology neutral and prohibits contradictory statutes and regulations, the on-line pharmacy industry likely will choose the technology most suitable to expanding its business transactions. The industry likely will not choose the technology that best protects the public’s health, safety, and welfare. Rather, the on-line pharmacy industry is likely to choose the technology that is least costly and most efficient. E-SIGN might encourage the development of new forms of electronic signature technology, however, it will not encourage parties to choose the best technology for preventing prescription fraud.

3. The Limitations of Self-Regulation by the On-line Pharmacy Industry

Self-regulation by the on-line pharmacy industry is less effective than a comprehensive statutory framework, which would close the loopholes to prescription fraud against on-line pharmacies. Even if the industry adopted asymmetric-cryptography technology, a pharmacist receiving a prescription electronically could only determine the identity of the sender and that the contents of the message had not been altered. Thus, the pharmacist would not be certain that the sender was licensed to prescribe medications because such information would not be inherent in the electronic signature. To address this shortcoming, WEAA could have been amended to invalidate any prescriptions transmitted electronically to Washington on-line pharmacies using electronic signatures not verifiably owned by an individual authorized to prescribe medications. However, E-SIGN likely prohibits such an amendment. Thus, self-regulation is powerless to close the loopholes of asymmetric-cryptography technology.

Under E-SIGN, it is unlikely that WEAA could be amended to create a class of electronic signatures solely authorized to prescribe medications electronically. E-SIGN preempts statutes or regulations that accord a greater legal status or effect to a specific technology or technical

249. See supra notes 166–68 and accompanying text.
250. See id.
251. This would have required that all digital certificates issued by licensed certification authorities indicate whether the owner of any asymmetric key pair was licensed to prescribe medications. Under this scheme, after receiving a prescription signed with a digital signature, pharmacists could not only verify the identity of the sender of the prescription and if it had been altered since signed, but also determine whether the sender is licensed to prescribe medications.
252. See supra notes 220–21 and accompanying text.
specification. Creating a unique class of electronic signatures solely authorized to prescribe medications electronically would enhance the legal status of that type of electronic signature. Such an action, whether by amendment or regulation arguably would violate E-SIGN's prohibition against favoritism.

Finally, self-regulation is largely industry specific. Pharmacies cannot regulate doctors and doctors cannot regulate pharmacies; only governments can regulate both. Thus, on-line pharmacies requiring all prescriptions to be received electronically using asymmetric-cryptography technology would not ensure that physicians would exercise reasonable care to maintain the security of electronic signatures. Theoretically, a third party could obtain a physician's private key to obtain prescription medications illegally. WEAA creates a duty that the owner of an asymmetric cryptographic key pair exercise reasonable care to maintain the security of the private key. However, WEAA is silent regarding the consequences if the owner breaches this duty. Assuming E-SIGN preempts WEAA's asymmetric-cryptography system, no effective incentives remain to ensure that physicians electronically prescribing medications restrict access to their electronic signatures. E-SIGN will thus await the efforts of two industries where WEAA had already accounted for both.

Existing legal incentives for physicians to restrict access to their electronic signatures capable of prescribing medications are insufficient. Tort liability creates little or no incentive for physicians because defendants are generally not liable for the results of intervening criminal acts when no reasonable level of care by the defendant would prevent the subsequent harm. Because in Washington it is unlawful for any person knowingly or intentionally to forge a prescription or possess a false or fraudulent prescription with intent to obtain a controlled substance, physicians likely would not be liable in tort for any harms caused by the unauthorized use of their digital signatures.

---

256. See W. Page Keeton, Prosser and Keeton on Torts 313 (5th ed. 1984); see also, e.g., Guy v. McKenzie, 394 S.E.2d 576, (Ga. Ct. App. 1990) (holding pharmacist not negligent for failing to prevent employee from removing controlled substances that employee sold to motorist who later suffered injuries in accident caused by ingesting those controlled substances).
Washington could amend WEAA to create an incentive for physicians to restrict access to their electronic signatures capable of prescribing medications. One option would be to tie the privilege of possessing a state medical license to the duty to restrict access to electronic signatures. By breaching this duty, a physician's capacity to prescribe medications could be limited by state medical boards. State boards of medicine and pharmacy would likely support this amendment because both are concerned that existing enforcement mechanisms are inadequate to police the on-line environment. E-SIGN would allow this amendment because it would not conflict with the provisions of E-SIGN, nor would it give greater legal status to a specific type of technology.

However, the ability to restrict access to an electronic signature is not practical under E-SIGN. Electronic signature technology that is not based on asymmetric cryptography does not provide a private key realistically capable of being kept secret. It would be inappropriate to sanction physicians for the unauthorized use of other types of electronic signatures because those technologies are not reasonably secure from forgery, regardless of a physician's efforts to prevent its unauthorized use. Physicians could not meet their statutory duty to exercise reasonable care to maintain the security of their non-asymmetric technology electronic signatures. This frustration of possible incentives merely demonstrates another way in which E-SIGN will impede state efforts to combat on-line prescription fraud.

V. CONCLUSION

Prescription drug abuse and fraud are significant problems in the United States. Although prescription medications are regulated, individuals often obtain drugs fraudulently to maintain their own addictions or divert the drugs for illegal sale on the street. On-line pharmacies are particularly vulnerable to prescription fraud because of the limited ability of on-line pharmacists to employ traditional methods of detecting fraud in community pharmacies.

---


262. See supra notes 161–62 and accompanying text.
The Electronic Signatures in Global and National Commerce Act (E-SIGN) ensures that electronic signatures are not denied legal recognition merely because they are in an electronic form. E-SIGN does not require individuals to use or accept electronic signatures and preempts other laws that contradict its provisions. The Washington Electronic Authentication Act (WEAA) also ensures that digital signatures are not denied legal recognition solely because they are in electronic form. WEAA is one of the most comprehensive and advanced statutes governing digital signatures because it requires the use of asymmetric-cryptography technology.

E-SIGN frustrates Washington’s ability to protect the public’s health, safety, and welfare from the harms of prescription fraud against on-line pharmacies. Prior to E-SIGN, WEAA was a strong framework, which, once amended, could have been used as a comprehensive and effective mechanism that would have nearly eliminated this problem. However, E-SIGN will likely preempt WEAA’s asymmetric-cryptography requirement and it prohibits amending WEAA to require that on-line pharmacies receive only prescriptions transmitted electronically. These provisions are necessary to combat this problem and nearly eliminate prescription fraud against on-line pharmacies.

In the wake of E-SIGN, Washington should prohibit expenditures of state Medical Assistance funds to pay for prescriptions dispensed by on-line pharmacies that do not receive only prescriptions transmitted electronically using asymmetric-cryptography technology. In addition, the on-line pharmacy industry should voluntarily require that members receive only prescriptions transmitted electronically using asymmetric-cryptography technology. However, self-regulation is unlikely because of industry concerns regarding perceived barriers for consumers to access on-line pharmacies. Moreover, self-regulation will achieve only limited success in preventing prescription fraud against on-line pharmacies compared to a comprehensive statutory framework. Therefore, E-SIGN has effectively blocked Washington’s ability to address the problem of prescription fraud against on-line pharmacies and subsequently prevent the attendant harms to its citizens.