United States General Accounting Office

GAO

Report to Congressional Requesters

October 2000

INTERNET PHARMACIES

Adding Disclosure Requirements Would Aid State and Federal Oversight

GAO-01-69

Contents

Abbreviations

AG	Attorney General
AMA	American Medical Association
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FSMB	Federation of State Medical Boards
FTC	Federal Trade Commission
NAAG	National Association of Attorneys General
NABP	National Association of Boards of Pharmacy
VIPPS	Verified Internet Pharmacy Practice Sites

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Accountability * Integrity * Reliability

United States General Accounting Office
Washington, D.C. 20548

October 19, 2000

Congressional Requesters

The Internet offers consumers a convenient and sometimes cheaper method for purchasing, and obtaining information about, their prescription drugs than traditional retail pharmacies. The first Internet pharmacies began online service in early 1999, and federal officials estimated that between 200 and 400 businesses were selling prescription drugs on the Internet by July of that year. Almost 10 million Americans used the Internet to shop for health products during 1999, spending an estimated $160 million on prescription drugs.[1]

Public health officials agree that state-licensed Internet pharmacies offer consumers an alternative to the traditional "brick and mortar" corner drugstore. However, they are concerned about Internet pharmacies that do not adhere to state licensing requirements and standards and enable consumers to obtain prescription drugs without a prescription and adequate physician supervision. Public health officials are also concerned because prescription drugs obtained from Internet pharmacies without a valid prescription have harmed several individuals.

The rapid growth in Internet sales of prescription drugs and the increase in the practice of physicians prescribing to consumers on the basis of an online questionnaire challenge traditional state and federal safeguards. Moreover, these activities may occur anonymously across state and international borders, hampering state and federal efforts to identify noncompliant Internet pharmacies and physicians. State medical and pharmacy boards, as well as several federal agencies, have expressed concerns that their existing enforcement tools are not adequate to police Internet practices.

Concerned that the increases in Internet pharmacies and online prescribing may be outpacing formal state and federal controls, you asked us to review the regulation of prescription drug sales on the Internet. Specifically, you asked us to provide information on (1) the numbers and types of

[1]E. Rickert and D. Anderson, *Internet Pharmacy Practice: Legal and Marketplace Issues*, presentation at the American Pharmaceutical Association Annual Meeting (Washington, D.C.: Mar. 10-14, 2000), medscape.com/Medscape/CNO/2000/APHA/APHA-06.html (cited July 20, 2000).

pharmacies practicing on the Internet, (2) state efforts to regulate pharmacies and physicians practicing on the Internet, (3) the efforts of federal agencies to regulate pharmacies and physicians practicing on the Internet, and (4) proposals to regulate Internet pharmacies. (The complete list of requesters appears at the end of this letter.)

To obtain information on the number of Internet pharmacies, we conducted searches of the World Wide Web and obtained lists of Internet pharmacies. For this study, we defined "Internet pharmacy" to include any business that uses the Internet as the primary access point for customers, as well as traditional corner drugstores and mail-order prescription drug services that use the Internet to supplement their direct public access. To assess state efforts and proposals to regulate Internet pharmacies and physicians prescribing on the Internet, we surveyed pharmacy and medical boards in all 50 states and the District of Columbia. We interviewed officials from the National Association of Boards of Pharmacy (NABP), the Federation of State Medical Boards (FSMB), the American Medical Association (AMA), and the National Association of Attorneys General (NAAG), as well as representatives from several leading Internet pharmacies. To assess federal efforts and proposals to regulate Internet pharmacies and physicians prescribing on the Internet, we interviewed officials and obtained documents from the Food and Drug Administration (FDA), the Department of Justice, the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the U.S. Customs Service, and the U.S. Postal Service. We conducted our work from May 1999 through September 2000 in accordance with generally accepted government auditing standards. A detailed description of our scope and methodology is provided in appendix I.

Results in Brief

Determining the precise number of Internet pharmacies is difficult because Web sites can be easily created and removed, and many Internet pharmacies use multiple sites to attract consumers. We identified 190 Internet pharmacies selling prescription drugs directly to consumers, including 111 Internet pharmacies that required a prescription from a physician, 54 that would provide a prescription if a consumer completed an online questionnaire, and 25 that did not require a prescription. Many Internet pharmacies, including those that required a prescription, did not disclose enough information on their Web sites to allow consumers to determine if the drugs they were purchasing were approved in the United States and dispensed according to state and federal laws.

The licensing and regulation of pharmacies and physicians traditionally has taken place at the state level. However, with the advent of Internet pharmacies, pharmacies and physicians can anonymously reach across state borders to prescribe, sell, and dispense prescription drugs without complying with state requirements. Intent on shutting down Internet pharmacies that are unlicensed and employ physicians to prescribe drugs on the basis of their review of online questionnaires completed by consumers, 20 states have taken action against Internet pharmacies. But states have found it difficult to identify and take enforcement action against the many Internet pharmacies and physicians that may violate state laws. Moreover, even when a state successfully prosecutes an Internet pharmacy and its associated physicians and stops them from prescribing and dispensing drugs to residents of that state, the court action applies only in that state.

At the federal level, FDA, Justice, DEA, Customs, and FTC have increased their investigation and prosecution of Internet pharmacies and physicians that illegally dispense and prescribe prescription drugs. For example, FDA has taken enforcement action against Internet pharmacies dispensing unapproved drugs, and Justice has prosecuted pharmacies and physicians for dispensing prescription drugs without valid prescriptions.[2] The Customs Service has also increased its seizures of drugs illegally entering the country. While these agencies' actions are important, their efforts sometimes do not support each other. For example, FDA relies on Customs to implement FDA's guidance that restricts the importation of prescription drugs through the mail, including those from foreign Internet pharmacies. Yet, while Customs has expended resources to detain packages of prescription drugs that may violate FDA's guidance, FDA routinely directs Customs to release small packages of prescription drugs that have been detained. FDA plans to clarify its policy and to work more closely with Customs officials to better coordinate their efforts.

State and federal officials have proposed several approaches for improving the oversight of Internet pharmacies. The association representing state boards of pharmacy, NABP, has developed a voluntary program to certify Internet pharmacies. As of September 1, 2000, 11 Internet pharmacies had

[2]Unapproved drugs are any drugs, including foreign-made versions of U.S.-approved prescription drugs, that have not been manufactured in accordance with and pursuant to an FDA approval. Examples include unproven cancer therapies and products containing gamma hydroxy butyrate, an unapproved drug used recreationally for bodybuilding and for incapacitating victims of sexual assaults.

been certified by NABP and 25 others had applied for certification. The Congress is considering two bills that would require Internet pharmacies to disclose certain identifying information and expand the authority of the states and federal agencies to regulate Internet pharmacies. Specifically, these bills would require mandatory disclosure or certification of Internet pharmacies as well as grant authority to FDA and state Attorneys General to shut down noncompliant Internet pharmacies nationwide in federal courts.

To ensure that the operators of Internet pharmacies shipping prescription drugs to another state are easily discernable, we suggest that the Congress amend the Food, Drug, and Cosmetic Act (FDCA) to require that Internet pharmacies disclose certain identifying information on their Web sites. In general, in commenting on a draft of this report, FDA, Justice, FTC, and Customs, as well as the NABP and FSMB, agreed with our matter for congressional consideration. However, FDA, FTC, and NABP suggested that our matter be expanded to limit online prescribing, grant states nationwide injunctive relief, and require independent verification of information disclosed by Internet pharmacies. We believe that the current regulatory structure permits state pharmacy and medical boards to restrict online prescribing and verify disclosed information. In addition, an assessment of granting nationwide injunctive relief was beyond the scope of our study. Therefore, we did not modify our matter for congressional consideration.

Background

Three types of Internet pharmacies selling prescription drugs directly to consumers have emerged in recent years. First, some Internet pharmacies operate much like traditional drugstores or mail-order pharmacies: they dispense drugs only after receiving prescriptions from consumers or their physicians. Other Internet pharmacies provide customers medication without a physical examination by a physician. In place of the traditional face-to-face physician/patient consultation, the consumer fills out a medical questionnaire that is reportedly evaluated by a physician affiliated with the pharmacy. If the physician approves the questionnaire, he or she authorizes the online pharmacy to send the medication to the patient. This practice tends to be largely limited to “lifestyle” prescription drugs, such as those that alleviate allergies, promote hair growth, treat impotence, or control weight. Finally, some Internet pharmacies dispense medication without a prescription. Regardless of their methods, all Web sites selling prescription drugs are governed by the same complex network of laws and

regulations at both the state and federal levels that govern traditional drugstores and mail-order drug services.

In the United States, prescription drugs must be prescribed and dispensed by licensed health care professionals, who can help ensure proper dosing and administration and provide important information on the drug's use to customers. To legally dispense a prescription drug, a pharmacist licensed with the state and working in a pharmacy licensed by the state must be presented a valid prescription from a licensed health care professional. Every state requires resident pharmacists and pharmacies to be licensed. The regulation of the practice of pharmacy is rooted in state pharmacy practice acts and regulations enforced by the state boards of pharmacy, which are responsible for licensing pharmacists and pharmacies. The state boards of pharmacy also are responsible for routinely inspecting pharmacies, ensuring that pharmacists and pharmacies comply with applicable state and federal laws, and investigating and disciplining those that fail to comply.

In addition, 40 states require out-of-state pharmacies—called nonresident pharmacies—that dispense prescription drugs to state residents to be licensed or registered. Some state pharmacy boards regulate Internet pharmacies according to the same standards that apply to nonresident pharmacies. State pharmacy boards' standards may require that nonresident pharmacies do the following:

- maintain separate records of prescription drugs dispensed to customers in the state so that these records are readily retrievable from the records of prescription drugs dispensed to other customers;
- provide a toll-free telephone number for communication between customers in the state and a pharmacist at the nonresident pharmacy and affix this telephone number to each prescription drug label;
- provide the location, names, and titles of all principal corporate officers;
- provide a list of all pharmacists who are dispensing prescription drugs to customers in the state;
- designate a pharmacist who is responsible for all prescription drugs dispensed to customers in the state;
- provide a copy of the most recent inspection report issued by the home state; and
- provide a copy of the most recent license issued by the home state.

States also are responsible for regulating the practice of medicine. All states require that physicians practicing in the state be licensed to do so.

State medical practice laws generally outline standards for the practice of medicine and delegate the responsibility of regulating physicians to state medical boards. State medical boards license physicians and grant them prescribing privileges.[3] In addition, state medical boards investigate complaints and impose sanctions for violations of the state medical practice laws.

While states have jurisdiction within their borders, the sale of prescription drugs on the Internet can occur across state lines. The sale of prescription drugs between states or as a result of importation falls under the jurisdiction of the federal government. FDA is responsible for ensuring the safety, effectiveness, and quality of domestic and imported pharmaceutical products under the FDCA. Specifically, FDA establishes standards for the safety, effectiveness, and manufacture of prescription drugs that must be met before they are approved for the U.S. market.

FDA can take action against (1) the importation, sale, or distribution of an adulterated, misbranded, or unapproved drug; (2) the illegal promotion of a drug; (3) the sale or dispensing of a prescription drug without a valid prescription; and (4) the sale and dispensing of counterfeit drugs. If judicial intervention is required, Justice will become involved to enforce the FDCA. Justice also enforces other consumer protection statutes for which the primary regulatory authorities are administrative agencies such as FDA and FTC. FTC has responsibility for preventing deceptive or unfair acts or practices in commerce and has authority to bring an enforcement action when an Internet pharmacy makes false or misleading claims about its products or services. Finally, Justice's DEA regulates controlled substances, which includes issuing all permits for the importation of pharmaceutical controlled substances and registering all legitimate

[3]In most states, many nonphysicians have prescribing authority. For example, according to a study by the AMA, advanced practice nurses have prescribing authority in 48 states, physician assistants have prescribing authority in 45 states, and optometrists are authorized to prescribe pharmaceutical agents in all 50 states. See AMA, *Report of the Council on Medical Service on Non-Physician Prescribing*, CMS Report 1-A-99 (Feb. 1999), ama-assn.org (cited July 24, 2000). This report, however, discusses only the position of state medical boards regarding the practices of physicians prescribing on the Internet.

importers and exporters, while Customs and the Postal Service enforce statutes and regulations governing the importation and domestic mailing of drugs.[4]

Universe of Internet Pharmacies Is Unknown

The very nature of the Internet makes identifying all pharmacies operating on it difficult. As a result, the precise number of Internet pharmacies selling prescription drugs directly to consumers is unknown. We identified 190 Internet pharmacies selling prescription drugs directly to consumers, 79 of which dispense prescription drugs without a prescription or on the basis of a consumer's having completed an online questionnaire (see table 1). [5] Also, 185 of the identified Internet pharmacies did not disclose the states where they were licensed to dispense prescription drugs, and 37 did not provide an address or telephone number permitting the consumer to contact them if problems arose. Obtaining prescription drugs from unlicensed pharmacies without adequate physician supervision, including an examination, places consumers at risk of harmful side effects, possibly even death, from drugs that may be inappropriate for them.

[4]Under the Controlled Substances Act, all substances that are regulated under existing federal law are placed in one of five schedules on the basis of the substances' medicinal value, harmfulness, and potential for abuse or addiction. Schedule I is reserved for the most dangerous drugs that have no recognized medical use, while schedule V is the classification used for the least dangerous drugs. The act also regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances. To prescribe controlled substances, licensed physicians must be registered with the DEA.

[5]App. I contains a detailed description of our methodology for identifying Internet pharmacies.

Table 1: Characteristics of Internet Pharmacies We Reviewed

Information on pharmacy's Internet site	Pharmacies that require a prescription (n=111)	Pharmacies that issue prescriptions after reviewing questionnaires (n=54)	Pharmacies that do not require a prescription (n=25)	Total (n=190)
Mailing address or telephone number	108	31	14	153 (81%)
Information about available drugs	55	47	13	115 (61%)
Privacy statement	26	17	1	44 (23%)
Requirement that consumers agree to a liability waiver	0	45	18	63 (33%)

The Actual Number of Internet Pharmacies Is Unknown

Estimates of the number of Internet pharmacies range from 200 to 400. However, it is difficult to determine the precise number of Internet pharmacies selling prescription drugs directly to consumers because Internet sites can be easily created and removed and some Internet pharmacies operate for a period of time at one Internet address and then close and reappear under another name. In addition, many Internet pharmacies have multiple portal sites (independent Web pages that connect to a single pharmacy). We found 95 sites that at first appeared to be discrete Internet pharmacies but were actually portal sites. As consumers click on the icons and links provided, they are brought to an Internet site that is completely different from the one they originally visited. Consumers may be unaware of these site changes unless they are paying close attention to the Internet site address bar on their browser. Some Internet pharmacies had as many as 18 portal sites.

Some Internet Pharmacies Require a Prescription

About 58 percent, or 111, of the Internet pharmacies we identified told consumers that they had to provide a prescription from their physician to purchase prescription drugs. Prescriptions may be submitted to an Internet pharmacy in various ways, including by mail or fax and through contact between the consumer's physician or current pharmacy and the Internet pharmacy. The Internet pharmacy then verifies that a licensed physician actually has issued the prescription to the patient before it dispenses any drugs. Internet pharmacies that require a prescription from a physician generally operate similarly to traditional drugstore or mail-order

pharmacies. In some instances, the Internet site is owned by or affiliated with a traditional drugstore.

Some Internet Pharmacies Dispense Drugs on the Basis of a Questionnaire

We identified 54 Internet pharmacies that issued prescriptions and dispensed medications on the basis of an online questionnaire. Generally, these short, easy-to-complete questionnaires asked about the consumer's health profile, medical history, current medication use, and diagnosis. In some instances, pharmacies provided the answers necessary to obtain the prescription by placing checks next to the "correct" answers. Information on many of the Internet sites indicated that a physician reviews the questionnaire and then issues a prescription. The cost of the physician's review ranged from $35 to $85, with most sites charging $75.[6] Moreover, certain illegal and unethical prescribing and dispensing practices are occurring through some Internet pharmacies that focus solely on prescribing and dispensing certain "lifestyle" drugs, such as diet medications and drugs to treat impotence.

Some Internet Pharmacies Require No Prescription

We also identified 25 Internet pharmacies that dispensed prescription drugs without prescriptions. In the United States, it is illegal to sell or dispense a prescription drug without a prescription. Nevertheless, to obtain a drug from these Internet pharmacies, the consumer was asked only to complete an order form indicating the type and quantity of the drug desired and to provide credit card billing information. Twenty-one of these 25 Internet pharmacies were located outside the United States; the location of the remaining 4 could not be determined. Generally, it is illegal to import prescription drugs that are not approved by FDA and manufactured in an FDA-approved facility.[7] Obtaining prescription drugs from foreign-based Internet pharmacies places consumers at risk from counterfeit or unapproved drugs, or drugs that were manufactured and stored under poor conditions.

[6]A recent study found that obtaining a prescription on the Internet was 40 percent more expensive than visiting a local managed care physician. See B.S. Bloom and R.C. Iannacone, "Internet Availability of Prescription Pharmaceuticals to the Public," *Annals of Internal Medicine*, Vol. 131, No. 11 (Dec. 1999), acponline.org/journals/annals/05oct99/bloom.htm (cited Oct. 25, 1999).

[7]FDA officials may, on a case-by-case basis, permit the importation of unapproved drugs for the treatment of serious conditions and other reasons. See FDA's "Coverage of Personal Importations," *Regulatory Procedures Manual* (Washington, D.C.: FDA, 1997).

Internet Pharmacies' Web Sites Provide Varying Information

The Internet pharmacies that we identified varied significantly in the information that they disclosed on their Web sites. For instance, 153 of the 190 Internet pharmacies we reviewed provided a mailing address or telephone number (see table 1). The lack of adequate identifying information prevents consumers from contacting Internet pharmacies if problems should arise. More importantly, most Internet pharmacies did not disclose the states where they were licensed to dispense prescription drugs. We contacted all U.S.-based Internet pharmacies to obtain this information.[8] We then asked pharmacy boards in the 12 states with the largest numbers of licensed Internet pharmacies (70 in all) to verify their licensure status. Sixty-four pharmacies required a prescription to dispense drugs; of these, 22, or about 34 percent, were not licensed in one or more of the states in which they had told us they were licensed and in which they dispensed drugs.

Internet pharmacies that issued prescriptions on the basis of online questionnaires disclosed even less information on their Web sites. Only 1 of the 54 Internet pharmacies disclosed the name of the physician responsible for reviewing questionnaires and issuing prescriptions. We attempted to contact 45 of these Internet pharmacies to obtain their licensure status; we did not attempt to contact 9 because they were located overseas. We were unable to reach 13 because they did not provide, and we could not obtain, a mailing address or telephone number. In addition, 18 would not return repeated telephone calls, 3 were closed, and 2 refused to tell us where they were licensed. As a result, we were able to obtain licensure information for only nine Internet pharmacies affiliated with physicians that prescribe online. We found that six of the nine prescribing pharmacies were not licensed in one or more of the states in which they had told us they were licensed and in which they dispensed prescription drugs. The ability to buy prescription drugs from Internet pharmacies not licensed in the state where the customer is located and without appropriate physician supervision, including an examination, means that important safeguards

[8]We did not attempt to contact foreign-based Internet pharmacies. According to the Executive Director of NABP, pharmacies are licensed by the state, and state laws do not include a provision for licensing foreign pharmacies. Also, physicians located in foreign countries may not be licensed to prescribe to U.S. citizens. Therefore, in some states obtaining prescription drugs from foreign Internet pharmacies is tantamount to receiving medicine illegally. Nevertheless, some states may waive physician-licensing requirements and recognize foreign prescriptions. In these instances, the states require a valid physician/patient relationship and a physical examination.

related to the doctor/patient relationship and intrinsic to conventional prescribing are bypassed.

We also found that only 44 Internet pharmacies (23 percent) posted a privacy statement on their Web sites. As recent studies have indicated, consumers are concerned about safeguarding their personal health information online and about potential transfers to third parties of the personal information they have given to online businesses.[9] The majority of these pharmacies stated that the information provided by the patient would be kept confidential and would not be sold or traded to third parties. Our review of state privacy laws revealed that at least 21 states have laws protecting the privacy of pharmacy information. While the federal Health Insurance Portability and Accountability Act of 1996 called for nationwide protections for the privacy and security of electronic health information, including pharmacy data, regulations have not yet been finalized.

Regulating Pharmacies and Physicians Practicing on the Internet Poses Difficulties for State Regulators

State pharmacy and medical boards have policies created to regulate brick and mortar pharmacies and traditional doctor/patient relationships. However, the traditional regulatory and enforcement approaches used by these boards may not be adequate to protect consumers from the potentially dangerous practices of some Internet pharmacies. Nevertheless, 20 states have taken disciplinary action against Internet pharmacies and physicians that have engaged in illegal or unethical practices. Many of these states have also introduced legislation to address illegal or unethical sales practices of Internet pharmacies and physicians prescribing on the Internet. Appendix II contains details on state actions to regulate pharmacies and physicians practicing on the Internet.

State Pharmacy Boards Face New Challenges Regulating Internet Pharmacies

The advent of Internet pharmacies poses new challenges for the traditional state regulatory agencies that oversee the practices of pharmacies. While 12 pharmacy boards reported that they have taken action against Internet pharmacies for illegally dispensing prescription drugs, many said they have

[9]A recent study of the policies and practices of a sample of the most trafficked consumer health Web sites found that inconsistencies exist between the privacy policies and the actual practices of health Web sites and that policies fall short of truly safeguarding consumers. See J. Goldman, Z. Hudson, and R.M. Smith, *Privacy: Report on the Privacy Policies and Practices of Health Internet Sites* (Washington, D.C.: California HealthCare Foundation, Jan. 2000), ehealth.chcf.org/priv_pol3/index_show.cfm?doc_id=33 (cited Feb. 10, 2000).

encountered difficulties in identifying, investigating, and taking disciplinary action against illegally operating Internet pharmacies that are located outside state borders but shipping to the state.[10] State pharmacy board actions consisted of referrals to federal agencies, state Attorneys General, or state medical boards.

Almost half of the state pharmacy boards reported that they had experienced problems with or received complaints about Internet pharmacies. Specifically, 24 state pharmacy boards told us that they had experienced problems with Internet pharmacies not complying with their state pharmacy laws. The problems most commonly cited were distributing prescription drugs without a valid license or prescription, or without establishing a valid physician/patient relationship. Moreover, 20 state boards (40 percent) reported they had received at least 78 complaints, ranging from 1 to 15 per state, on Internet pharmacy practices. Many of these complaints were about Internet pharmacies that were dispensing medications without a valid prescription or had dispensed the wrong medication.

State pharmacy boards also reported that they have encountered difficulties in identifying Internet pharmacies that are located outside their borders. About 74 percent of state pharmacy boards reported having serious problems determining the physical location of an Internet pharmacy affiliated with an Internet Web site. Sixteen percent of state pharmacy boards reported some difficulty, and 10 percent reported no difficulty. Without this information, it is difficult to identify the companies and people responsible for selling prescription drugs.

More importantly, state pharmacy boards have limited ability and authority to investigate and act against Internet pharmacies located outside their state but doing business in their state without a valid license. In our survey, many state pharmacy boards cited limited resources, and jurisdictional and technological limitations, as obstacles to enforcing their laws with regard to pharmacies not located in their states. Because of jurisdictional limits, states have found that their traditional investigative tools—interviews, physical or electronic surveillance, and serving subpoenas to produce documents and testimony—are not necessarily adequate to compel disclosure of information from a pharmacy or pharmacist located out of state. Similarly, the traditional enforcement mechanisms available to state

[10]See app. III for the results of our survey.

pharmacy boards—disciplinary actions or sanctions against licensees—are not necessarily adequate to control a pharmacy or pharmacist located out of state.[11] In the absence of the ability to investigate and take disciplinary action against a nonresident pharmacy, state pharmacy boards have been limited to referring unlicensed or unregistered Internet pharmacies to their counterpart boards in the states where the pharmacies are licensed.

State Medical Boards Are Concerned About the Prescribing Services Offered by Some Internet Pharmacies

State medical boards have concerns about the growing number of Internet pharmacies that issue prescriptions on the basis of a simple online questionnaire rather than a face-to-face examination. The AMA is also concerned that prescriptions are being provided to patients without the benefit of a physical examination, which would allow evaluation of any potential underlying cause of a patient's dysfunction or disease, as well as an assessment of the most appropriate treatment. Moreover, medical boards are receiving complaints about physicians prescribing on the Internet. Twenty of the 45 medical boards responding to our survey reported that they had received complaints about physicians prescribing on the Internet during the last year.[12] The most frequent complaint was that the physician did not perform an examination of the patient. As a result, medical boards in eight states have taken action against physicians for Internet prescribing violations. Disciplinary actions and sanctions have ranged from monetary fines and letters of reprimand to probation and license suspension.

Thirty-nine of the 45 medical boards responding to our survey concluded that a physician who issued a prescription on the basis of a review of an online questionnaire did not satisfy the standard of good medical practice required under their states' laws. Moreover, ten states have introduced or enacted legislation regarding the sale of prescription drugs on the Internet; including five states that have introduced legislation to prohibit physicians and other practitioners from prescribing prescription drugs on the Internet without conducting an examination or having a prior physician/patient relationship. Twelve states have adopted rules or statements that clarify their positions on the use of online questionnaires for issuing prescriptions. Generally, these statements either prohibit online prescribing or state that

[11]In addition, no formal procedural mechanism exists for serving and enforcing a subpoena across state lines, although a state may extend its assistance to another state as a professional courtesy.

[12]See app. IV for the results of our survey.

prescribing solely on the basis of answers to a questionnaire is inappropriate and unprofessional (see app. II).

As in the case of state pharmacy boards, state medical boards have limited ability and authority to investigate and act against physicians located outside of their state but prescribing on the Internet to state residents. Further, they too have had difficulty identifying these physicians. About 55 percent of state medical boards that responded to our survey told us they had difficulty determining both the identity and location of physicians prescribing drugs on the Internet, and 36 percent had difficulty determining whether the physician was licensed in another state.

State Attorneys General Have Sued to Halt Sales by Internet Pharmacies Offering Prescription Services

Since February 1999, six state Attorneys General have brought legal action against Internet pharmacies and physicians for providing prescription drugs to consumers in their states without a state license and for issuing prescriptions solely on the basis of information provided in online questionnaires. Most of the Internet pharmacies that were sued voluntarily stopped shipping prescription drugs to consumers in those states. As a result, at least 18 Internet pharmacies have stopped selling prescription drugs to residents in Illinois, Kansas, Michigan, Missouri, New Jersey, and Pennsylvania.[13] Approximately 15 additional states are investigating Internet pharmacies for possible legal action.[14]

Investigating and prosecuting online offenders raise new challenges for law enforcement. For instance, Attorneys General also have complained that the lack of identifying information on pharmacy Web sites makes it difficult to identify the companies and people responsible for selling prescription drugs. Moreover, even if a state successfully sues an Internet pharmacy for engaging in illegal or unethical practices, such as prescribing on the basis of an online questionnaire or failing to adequately disclose identifying information, the Internet pharmacy is not prohibited from operating in

[13]One Internet pharmacy is suing the Attorney General of Michigan in federal court, arguing that the Attorney General has, among other things, unreasonably burdened interstate commerce by requiring pharmacies and pharmacists to be licensed in Michigan before they distribute prescription drugs in the state.

[14]Since our survey, the Attorneys General for Texas and West Virginia have each sued two online pharmacies to stop them from selling prescription drugs to state residents. Also, according to FSMB, five additional states either have taken action against a physician for violating state prescribing practices or introduced/enacted legislation regarding the sale of prescription drugs on the Internet.

other states. To stop such practices, each affected state must individually bring action against the Internet pharmacy. As a result, to prevent one Internet pharmacy from doing business nationwide, the Attorney General in every state would have to file a lawsuit in his or her respective state court.

Federal Agencies Have Increased Their Efforts to Regulate Internet Prescription Drug Sales

Five federal agencies have authority to regulate and enforce U.S. laws that could be applied to the sale of prescription drugs on the Internet. Since Internet pharmacies first began operation in early 1999, FDA, Justice, DEA, Customs, and FTC have increased their efforts to respond to public health concerns about the illegal sale of prescription drugs on the Internet.[15] FDA has taken enforcement actions against Internet pharmacies selling prescription drugs, Justice has prosecuted Internet pharmacies and physicians for dispensing medications without a valid prescription, DEA has investigated Internet pharmacies for illegal distribution of controlled substances, Customs has increased its seizure of packages that contain drugs entering the country, and FTC has negotiated settlements with Internet pharmacies for making deceptive health claims. While these agencies' contributions are important, their efforts sometimes do not support each other. For instance, to conserve its resources FDA routinely releases packages of prescription drugs that Customs has detained because they may have been obtained illegally from foreign Internet pharmacies. Such uncoordinated program efforts can waste scarce resources, confuse and frustrate enforcement program administrators and customers, and limit the overall effectiveness of federal enforcement efforts.

Federal Agencies Have Increased Enforcement Activity

FDA has recently increased its monitoring and investigation of Internet pharmacies to determine if they are involved in illegal sales of prescription drugs. FDA has primary responsibility for regulating the sale, importation, and distribution of prescription drugs, including those sold on the Internet. In July 1999, FDA testified before the Congress that it did not generally regulate the practice of pharmacy or the practice of medicine. Accordingly, FDA activities regarding the sale of drugs over the Internet had until then focused on unapproved drugs. As of April 2000, however, FDA had 54 ongoing investigations of Internet pharmacies that may be illegally selling

[15]The U.S. Postal Service has a minor role in regulating the practices of Internet pharmacies. Limited to providing all international mail to Customs for inspection, Postal Service officials told us that they do not have any activities specifically targeted to Internet pharmacies.

prescription drugs. FDA has also referred to Justice for possible criminal prosecution approximately 33 cases involving over 100 Internet pharmacies that may be illegally selling prescription drugs. FDA's criminal investigations of online pharmacies have, to date, resulted in the indictment and/or arrest of eight individuals, two of whom have been convicted. In addition, FDA is seeking $10 million in fiscal year 2001 to fund 77 staff positions that would be dedicated to investigating and taking enforcement actions against Internet pharmacies.[16]

Justice has increased its prosecution of Internet pharmacies illegally selling prescription drugs. Under the FDCA, a prescription drug is considered misbranded if it is not dispensed pursuant to a valid prescription under the professional supervision of a licensed practitioner. In July 1999, Justice testified before the Congress that it was examining its legal basis for prosecuting noncompliant Internet pharmacies and violative online prescribing practices. Since that time, according to FDA officials, 22 of the 33 criminal investigations FDA referred to Justice have been actively pursued. Two of the 33 cases were declined by Justice and are being prosecuted as criminal cases by local district attorneys, and 9 were referred to the state of Florida. In addition, Justice filed two cases involving the illegal sale of prescription drugs over the Internet in 1999 and is investigating approximately 20 more cases. Since May 2000, Justice has brought charges against, or obtained convictions of, individuals in three cases involving the sale of prescription drugs by Internet pharmacies without a prescription or the distribution of misbranded drugs.

While DEA has no efforts formally dedicated to Internet issues, it has initiated 20 investigations of the use of the Internet for the illegal sale of controlled substances during the last 15 months. DEA has been particularly concerned about Internet pharmacies that are affiliated with physicians who prescribe controlled substances without examining patients. For instance, in July 1999 a DEA investigation led to the indictment of a Maryland doctor on 34 counts of providing controlled substances to patients worldwide in response to requests made over the Internet. Because Maryland requires that doctors examine patients before prescribing medications, the doctor's prescriptions were not considered to be legitimately provided. The physician's conduct on the Internet also

[16]The appropriations bill for FDA (H.R. 4461), which as of October 18, 2000, had passed both the House and the Senate, provides $5 million for investigating and taking action against violative Internet pharmacies.

violated an essential requirement of federal law, which is that controlled substances must be dispensed only with a valid prescription.

The U.S. Customs Service, which is responsible for inspecting packages shipped to the United States from foreign countries, has increased its seizures of prescription drugs from overseas. Customs officials report that the number of drug shipments seized increased about 450 percent between 1998 and 1999—from 2,139 to 9,725. Most of these seizures involved controlled substances. Because of the large volume, Customs is able to examine only a fraction of the packages entering the United States daily and cannot determine how many of its drug seizures involve prescription drugs purchased from Internet pharmacies. Nevertheless, Customs officials believe that the Internet is playing a role in the increase in illegal drug importation. According to Customs officials, fiscal year 2000 seizures are on pace to equal or surpass 1999 levels.

FTC reports that it is monitoring Internet pharmacies for compliance with the Federal Trade Commission Act, conducting investigations, and making referrals to state and federal authorities. FTC is responsible for combating unfair or deceptive trade practices, including those on the Internet, such as misrepresentation of online pharmacy privacy practices. In 1999, FTC referred two Internet pharmacies to state regulatory boards. This year, FTC charged individuals and Internet pharmacies with making false promotional claims and other violations. Recently, the operators of these Internet pharmacies agreed to settle out of court. According to the settlement agreement, the defendants are barred from misrepresenting medical and pharmaceutical arrangements and any material fact about the scope and nature of the defendants' goods, services, or facilities.

Foreign Internet Pharmacies Challenge Federal Regulators

The sale of prescription drugs to U.S. residents by foreign Internet pharmacies poses the most difficult challenge for U.S. law enforcement authorities because the seller is not located within U.S. boundaries. Many prescription drugs available from foreign Internet pharmacies are either products for which there is no U.S.-approved counterpart or foreign versions of FDA-approved drugs. In either case, these drugs are not approved for use in the United States, and therefore it is illegal for a foreign Internet pharmacy to ship these products to the United States. In addition, federal law prohibits the sale of prescription drugs to U.S. citizens without a valid prescription. Although FDA officials said that the agency has jurisdiction over a resident in a foreign country who sells to a U.S. resident in violation of the FDCA, from a practical standpoint, FDA is hard-pressed

to enforce U.S. laws against foreign sellers.[17] As a result, FDA enforcement efforts against foreign Internet pharmacies have been limited mostly to requesting the foreign government to take action against the seller of the product. FDA has also posted information on its Web site to help educate consumers about safely purchasing drugs from Internet pharmacies.

FDA officials have sent 23 letters to operators of foreign Internet pharmacies warning them that they may be engaged in illegal activities, such as offering to sell prescription drugs to U.S. citizens without a valid, or in some cases without any, prescription. Copies of each letter were sent to regulatory officials in the country in which the pharmacy was based. In response, two Internet pharmacies said they will cease their sales to U.S. residents, and a third said it has ceased its sales regarding one drug but is still evaluating how it will handle other products. FDA has since requested that Customs detain packages from these Internet pharmacies.

Customs has been successful in working with one foreign government to shut down its Internet pharmacies that were illegally selling prescription drugs to U.S. consumers. In January 2000, Customs assisted Thailand authorities in the execution of search and arrest warrants against seven Internet pharmacies, resulting in the arrest of 22 Thai citizens for violating Thailand's drug and export laws and 6 people in the United States accused of buying drugs from the Thailand Internet pharmacy. U.S. and Thailand officials seized more than 2.5 million doses of prescription drugs and 245 parcels ready for shipment to the United States.

According to FDA, it is illegal for a foreign-based Internet pharmacy to sell prescription drugs to consumers in the United States if those drugs are unapproved or are not dispensed pursuant to a valid prescription. But FDA permits patients and their physicians to obtain small quantities of drugs sold abroad, but not approved in the United States, for the treatment of a serious condition for which effective treatment may not be available domestically. FDA's approach has been applied to products that do not represent an unreasonable risk and for which there is no known commercialization or promotion to U.S. residents. Further, a patient seeking to import such a product must provide to FDA the name of the licensed physician in the United States responsible for his or her treatment

[17]FDA confronts the same obstacles facing other U.S. regulatory and law enforcement agencies seeking to hold foreign parties accountable for violations of federal law.

with the unapproved drug or provide evidence that the product is for continuation of a treatment begun in a foreign country.[18]

FDA has acknowledged that its guidance concerning importing prescription drugs through the mail has been inconsistently applied. At many Customs mail centers, FDA personnel rely on Customs officials to detain suspicious drug imports for FDA screening. Although prescription drugs ordered from foreign Internet pharmacies may not meet FDA's criteria for importation under the personal use exemption, FDA personnel routinely release illegally imported prescription drugs detained by Customs officials. FDA has determined that the use of agency resources to provide comprehensive coverage of illegally imported drugs for personal use is generally not justified. Instead, the agency's enforcement priorities are focused on drugs intended for the commercial market and on fraudulent products and those that pose an unreasonable health risk. FDA's inconsistent application of its personal use exemption frustrates Customs officials and does little to deter foreign Internet pharmacies trafficking in prescription drugs. Accordingly, FDA plans to take the necessary actions to eliminate, or at least mitigate to the extent possible, the inconsistent interpretation and application of its guidance and work more closely with Customs.

FDA's approach to regulation of imported prescription drugs could be affected by enactment of pending legislation intended to allow American consumers to import drugs from certain other countries. Specifically, the appropriations bill for FDA (H.R. 4461) includes provisions that could modify the circumstances under which the agency may notify individuals seeking to import drugs into the United States that they may be in violation of federal law. According to an FDA official, it is not currently clear how these provisions, if enacted, could affect FDA's ability to prevent the importation of violative drugs.

[18]Agency guidance is contained in FDA's "Coverage of Personal Importations," *Regulatory Procedures Manual* (Washington, D.C.: FDA, 1997).

Initiatives for Improving State and Federal Oversight of Internet Pharmacies

Initiatives at the state and federal levels offer several approaches for regulating Internet pharmacies. The organization representing state boards of pharmacy, NABP, has developed a voluntary program for certifying Internet pharmacies. In addition, state and federal officials believe that they need more authority, as well as information regarding the identity of Internet pharmacies, to protect the public's health. The organization representing state Attorneys General, NAAG, has asked the federal government to expand the authority of its members to allow them to take action in federal court. In addition, the administration has announced a new initiative that would grant FDA broad new authority to better identify, investigate, and prosecute Internet pharmacies for the illegal sale of prescription drugs.

Concerned that consumers have no assurance of the legitimacy of Internet pharmacies, NABP is attempting to provide consumers with an instant mechanism for verifying the licensure status of Internet pharmacies. NABP's Verified Internet Pharmacy Practice Sites (VIPPS) is a voluntary program that certifies online pharmacies that comply with criteria that attempt to combine state licensing requirements with standards developed by NABP for pharmacies practicing on the Internet. To obtain VIPPS certification, an Internet pharmacy must comply with the licensing and inspection requirements of the state where it is physically located and of each state to which it dispenses pharmaceuticals; demonstrate compliance with 17 standards by, for example, ensuring patient rights to privacy, authenticating and maintaining the security of prescription orders, adhering to recognized quality assurance policy, and providing meaningful consultation between customers and pharmacists; undergo an on-site inspection; develop a postcertification quality assurance program; and submit to continuing random inspections throughout a 3-year certification period. VIPPS-certified pharmacies are identified by the VIPPS hyperlink seal displayed on both their and NABP's Web sites.[19] Since VIPPS began in the fall of 1999, its seals have been presented to 11 Internet pharmacies, and 25 Internet pharmacies have submitted applications to display the seal.

NAAG strongly supports the VIPPS program but maintains that the most important tool the federal government can give the states is nationwide

[19]The seal posted on certified sites incorporates as an integral part of its design the words "Click to verify." When a cursor passes over the VIPPS seal, a pop-up flag appears telling the visitor to click to verify the credentials of the Internet pharmacy. A code underlying the seal controls the flag and links the visitor to NABP's Web site.

injunctive relief. Modeled on the federal telemarketing statute, nationwide injunctive relief is an approach that would allow state Attorneys General to take action in federal court; if they were successful, an Internet pharmacy would be prevented from illegally selling prescription drugs nationwide.

Two federal proposals would amend the FDCA to require an Internet pharmacy engaged in interstate commerce to include certain identifying language on its Web site. The Internet Pharmacy Consumer Protection Act (H.R. 2763) would amend the FDCA to require an Internet pharmacy engaged in interstate commerce to include a page on its Web site providing the following information:

- the name, address, and telephone number of the pharmacy's principal place of business;
- each state in which the pharmacy is authorized by law to dispense prescription drugs;
- the name of each pharmacist and the state(s) in which the individual is licensed; and
- if the site offers to provide prescriptions after medical consultation, the name of each prescriber, the state(s) in which the prescriber is licensed, and the health professions in which the individual holds such licenses.

Also, under this act a state would have primary enforcement responsibility for any violation involving the purchase of a prescription drug made within the state, provided the state had requirements at least as stringent as those specified in the act and adequate procedures for enforcing those requirements.

In addition, the administration has developed a bill aimed at providing consumers the protections they enjoy when they go to a drugstore to have their prescriptions filled. For example, when consumers walk into a drugstore to have a prescription filled, they know the identity and location of the pharmacy, and the license on the wall provides visual assurance that the pharmacy meets certain health and safety requirements in that state. Under the Internet Prescription Drug Sales Act of 2000, Internet pharmacies would be required to be licensed in each state where they do business; comply with all applicable state and federal requirements, including the requirement to dispense drugs only pursuant to a valid prescription; and disclose identifying information to consumers. Internet pharmacies also would be required to notify FDA and all applicable state boards of pharmacy prior to launching a new Web site.[20] Internet pharmacies that met all of the requirements would be able to post on their

Web site a declaration that they had made the required notifications. FDA would designate one or more private nonprofit organizations or state agencies to verify licensing information included in notifications and to examine and inspect the records and facilities of Internet pharmacies. Internet pharmacies that do not meet notification and disclosure requirements or that sell prescription drugs without a valid prescription could face penalties as high as $500,000 for each violation.

While it supports the Internet Prescription Drug Sales Act of 2000, Justice officials have recommended that it be modified. Prescription drug sales from Internet pharmacies often rely on credit card transactions processed by U.S. banks and credit card networks. To enhance its ability to investigate and stop payment for prescription drugs purchased illegally, Justice has recommended that federal law be amended to permit the Attorney General to seek injunctions against certain financial transactions traceable to unlawful online drug sales. According to Justice officials, if the Department and financial institutions can stop even some of the credit card orders for the illicit sale of prescription drugs and controlled substances, the operations of some "rogue" Internet pharmacies may be disrupted significantly.

Conclusions

The unique qualities of the Internet pose new challenges for enforcing state pharmacy and medical practice laws because they allow pharmacies and physicians to reach consumers across state and international borders and remain anonymous. Internet pharmacies that fail to obtain licensure in the states where they operate may violate state law. But the Internet pharmacies that are affiliated with physicians that prescribe on the basis of an online questionnaire and those that dispense drugs without a prescription pose the most potential harm to consumers. Dispensing prescription drugs without adequate physician supervision increases the risk of consumers' suffering adverse events, including side effects from inappropriately prescribed medications and misbranded or contaminated drugs. Some states have taken action to stop Internet pharmacies that offer online prescribing services from selling prescription drugs to residents of their state. But the real difficulty lies in identifying responsible parties and enforcing laws across state boundaries.

[20]An Internet pharmacy that is already operational would also have to notify FDA and all applicable state boards of pharmacy.

Enforcement actions by federal agencies have begun addressing the illegal prescribing and dispensing of prescription drugs by domestic Internet pharmacies and their affiliated physicians. Enactment of federal legislation requiring Internet pharmacies to disclose, at a minimum, who they are, where they are licensed, and how they will secure personal health information of consumers would assist state and federal authorities in enforcing existing laws. In addition, federal agencies have taken actions to address the illegal sale of prescription drugs from foreign Internet pharmacies. Cooperative efforts between federal agencies and a foreign government resulted in closing down some Internet pharmacies illegally selling prescription drugs to U.S. consumers. However, it is unclear whether these efforts will stem the flow of prescription drugs obtained illegally from other foreign sources. As a result, the sale of prescription drugs from foreign-based Internet pharmacies continues to pose difficulties for federal regulatory authorities.

Matter for Congressional Consideration

To help ensure that consumers and state and federal regulators can easily identify the operators of Web sites selling prescription drugs, the Congress should amend the FDCA to require that any pharmacy shipping prescription drugs to another state disclose certain information on its Internet site. The information disclosed should include the name, business address, and telephone number of the Internet pharmacy and its principal officers or owners, and the state(s) where the pharmacy is licensed to do business. In addition, where permissible by state law, Internet pharmacies that offer online prescribing services should also disclose the name, business address, and telephone number of each physician providing prescribing services, and the state(s) where the physician is licensed to practice medicine. The Internet Pharmacy Consumer Protection Act and the administration's proposal would require Internet pharmacies to disclose this type of information.

Agency Comments and Our Response

We obtained comments on a draft of this report, from FDA, Justice, FTC, and Customs, as well as NABP and FSMB. In general, they agreed that Internet pharmacies should be required to disclose pertinent information on their Web sites and thought that our report provided an informative summary of efforts to regulate Internet pharmacies. Some reviewers also provided technical comments, which we incorporated where appropriate.

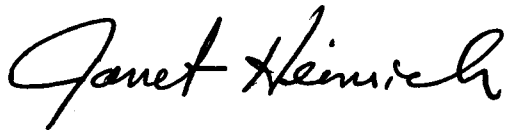
However, FDA suggested that our matter for consideration implied that online questionnaires were acceptable as long as the physician's name was properly disclosed. We did not intend to imply that online prescribing was proper medical practice. Rather, our report notes that most state medical boards responding to our survey have already concluded that a physician who issues a prescription on the basis of a review of an online questionnaire has not satisfied the standard of good medical practice required by state law. In light of this, federal action does not appear necessary. The disclosure of the responsible parties should assist state regulatory bodies in enforcing their laws.

FTC suggested that our matter for congressional consideration be expanded to recommend that the Congress grant states nationwide injunctive relief. Our report already discusses NAAG's proposal that injunctive relief be modeled after the federal telemarketing statute. While the NAAG proposal may have some merit, an assessment of the implications of this proposal was beyond the scope of our study. FTC also recommended that the Congress enact federal legislation that would require consumer-oriented commercial Web sites that collect personal identifying information from or about consumers online, including Internet pharmacies, to comply with widely accepted fair information practices. Again, our study did not evaluate whether a federal consumer protection law was necessary or if existing state laws and regulations may already offer this type of consumer protection.

NABP did not agree entirely with our assessment of the regulatory effectiveness of the state boards of pharmacy. It indicated that the boards, with additional funding and minor legislative changes, can regulate Internet pharmacies. Our study did not assess the regulatory effectiveness of individual state pharmacy boards. Instead, we summarized responses by state pharmacy boards to our questions about their efforts to identify and take action against Internet pharmacies that are not complying with state law, and the challenges they face in regulating these pharmacies. Our report notes that many states identified limited resources and jurisdictional limitations as obstacles to enforcing their laws. NABP also suggested that our matter for congressional consideration include a requirement for independent verification of the information that Internet pharmacies are required to disclose on their Web sites. In our view, the current state regulatory framework would permit state boards to verify this information should they choose to do so.

We are sending copies of this report to the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Jane E. Henney, Commissioner of FDA; the Honorable Janet Reno, Attorney General; the Honorable Donnie R. Marshall, Administrator of the DEA; the Honorable Robert Pitofsky, Chairman of the FTC; the Honorable Raymond W. Kelly, Commissioner of the U.S. Customs Service; the Honorable Kenneth C. Weaver, Chief Postal Inspector; appropriate congressional committees; and other interested parties. We will make copies available to others upon request.

If you or your staffs have any questions about this report or would like additional information, please call me at (202) 512-7119 or John Hansen at (202) 512-7105. See appendix V for another GAO contact and staff acknowledgments.



Janet Heinrich
Director, Health Care—Public Health Issues

List of Requesters

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
House of Representatives

The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives

The Honorable Sherrod Brown
Ranking Minority Member
Subcommittee on Health and Environment
Committee on Commerce
House of Representatives

The Honorable Henry A. Waxman
House of Representatives

Scope and Methodology

To obtain information on the number of pharmacies practicing on the Internet, we conducted searches of the World Wide Web and obtained a list of 235 Internet pharmacies that the National Association of Boards of Pharmacy (NABP) had identified by searching the Web and a list of 94 Internet pharmacies identified by staff of the House Committee on Commerce by searching the Web. After eliminating duplicate Web sites, we reviewed 296 potential sites between November and December 1999. Sites needed to meet two criteria to be included in our survey. First, they had to sell prescription drugs directly to consumers. Second, they had to be anchor sites (actual providers of services) and not portal sites (independent Web pages that connect to a provider). Most portal sites are paid a commission by anchor sites for displaying an advertisement or taking the user to the service provider's site through a "click through." We excluded 129 Web sites from our survey because they did not meet these criteria. See table 2 for details on our analysis of the Web sites that we excluded.

In April 2000, we obtained a list of 326 Web sites that FDA identified during March 2000. We reviewed all the sites on FDA's list and compared it to the list of Internet pharmacies we had previously compiled. We found 117 Internet pharmacies that duplicated pharmacies on our list. We also excluded 186 Web sites that did not meet our two criteria and added the remaining 23 Internet pharmacies to our list.

Table 2: Analysis of Identified Web Sites

	Original[a]	FDA[b]	Total
Total Web sites identified	**296**	**326**	**622**
Duplicate sites	0	117	117
Web sites excluded from our survey			
Did not sell prescription drugs	25	91	116
Did not offer online ordering of prescription drugs	7	3	10
Were portal sites	40	55	95
Were under construction or empty, could not be entered, or were not yet opened	13	4	17
Were closed	8	7	15
Could not locate	36	26	62
Total Web sites that were excluded	**129**	**303**	**432**
Total Web sites that sold prescription drugs directly to consumers	**167**	**23**	**190**

[a]Reviewed between November and December 1999.

[b]Reviewed April 2000.

To categorize Internet pharmacies, we analyzed information on the Web site to determine if the Internet pharmacy (1) required a prescription from the user's physician to dispense a prescription drug, (2) in the absence of a prescription, required the user to complete an online questionnaire to obtain a prescription, or (3) dispensed prescription drugs without a prescription. We also collected data on the types of information available on each Internet pharmacy Web site, including information about the pharmacy's licensure status, its mailing address and telephone number, and the cost of issuing a prescription.

Using the domain name from the uniform resource locator, we performed online queries of Network Solutions, Inc. (one of the primary registrars for domain names) to obtain the name, address, and telephone number of the registrant of each Internet pharmacy. We then telephoned all U.S.-based Internet pharmacies to obtain information on the states in which they dispensed prescription drugs and the states in which they were licensed or registered. See table 3 for details on our licensure information inquiry. Finally, we clustered Internet pharmacies by state and asked the pharmacy boards in the 12 states—10 of these had the largest number of licensed/registered Internet pharmacies—to verify the licensure status of each pharmacy that told us it was licensed in the state.[1]

[1]We verified the accuracy of licensure data in California, Colorado, Florida, Illinois, Maine, Nebraska, New Jersey, New York, North Carolina, Ohio, Pennsylvania, and Texas.

Table 3: Internet Pharmacy Licensure Information

	Require prescription	Issue prescription	No prescription	Total
Web sites that sold prescription drugs directly to consumers	111	54	25	190
Licensure information obtained	71	9	0	80
Licensure information not obtained	40	45	25	110
Declined to provide information	7	2	0	9
Did not return calls	11	18	0	29
Unable to contact	5	13	0	18
Closed, no longer providing services	9	3	0	12
Foreign Internet pharmacies	8	9	25	42

To assess state efforts to regulate Internet pharmacies and physicians prescribing over the Internet, we conducted two mail surveys in December 1999. To obtain information on state efforts to identify, monitor, and regulate Internet pharmacies, we surveyed pharmacy boards in all 50 states and the District Columbia. After making follow-up telephone calls, we received 50 surveys from the pharmacy boards in 49 states and the District Columbia, or 98 percent of those we surveyed. The survey and survey results are presented in appendix III. We also interviewed the executive directors and representatives of the state pharmacy boards in nine states—Alabama, Iowa, Maryland, New York, North Dakota, Oregon, Texas, Virginia, Washington—and the District of Columbia. In addition, we interviewed and obtained information from representatives of the NABP, the American Pharmaceutical Association, the National Association of Attorneys General, pharmaceutical manufacturers, as well as representatives of several Internet pharmacies.

To obtain information on state efforts to oversee physician prescribing practices on the Internet, we surveyed the 62 medical boards and boards of osteopathy in the 50 states and the District of Columbia.[2] After follow-up telephone calls, we received 45 surveys from the medical boards in 39 states, or 73 percent of those we surveyed. The survey and survey results are presented in appendix IV. We also interviewed officials with the medical boards in five states: California, Colorado, Maryland, Virginia, and

[2]We excluded the Florida Board of Osteopathic Medicine from our analysis because the executive director told us that the Florida Board of Medicine was the appropriate respondent.

Wisconsin. In addition, we interviewed and obtained information from representatives of the American Medical Association and the Federation of State Medical Boards (FSMB).

To assess federal efforts to oversee pharmacies and physicians practicing on the Internet, we obtained information from officials from the Food and Drug Administration; the Federal Trade Commission; the Department of Justice, including the Drug Enforcement Administration; the U.S. Customs Service; and the U.S. Postal Service. We also reviewed the report of the President's Working Group on Unlawful Conduct on the Internet.[3]

The availability of prescription drugs on the Internet has attracted the attention of several professional associations. As a result, over the past year, several associations have convened meetings of representatives of professional, regulatory, law enforcement, and private sector entities to discuss issues related to the practice of pharmacy and medicine on the Internet. We attended the May 1999 NABP annual conference, its September 1999 Executive Board meeting, and its November 1999 Internet Healthcare Summit 2000 to obtain information on the regulatory landscape for Internet pharmacy practice sites and the Verified Internet Pharmacy Practice Sites program. In January 2000, we attended a meeting convened by the FSMB of top officials from various government, medical, and public entities to discuss the efforts of state and federal agencies to regulate pharmacies and physicians practicing on the Internet. We also attended sessions of the March 2000 Symposium on Healthcare Internet and E-Commerce and the April 2000 Drug Information Association.

We conducted our work from May 1999 through September 2000 in accordance with generally accepted government auditing standards.

[3]The President's Working Group on Unlawful Conduct on the Internet, *The Electronic Frontier: The Challenge of Unlawful Conduct Involving the Use of the Internet* (Washington, D.C.: Mar. 2000).

Actions by 28 States to Regulate Internet Pharmacies and Physicians Prescribing on the Basis of an Online Questionnaire

State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
Alabama		Adopted rule that prescribing solely on the basis of answers to a set of questions is inappropriate and unprofessional			
Arizona	Introduced bill defining unprofessional conduct to include prescribing drugs without conducting a physical examination or having a prior relationship			Censured one physician and placed another on probation	
California	Introduced bill prohibiting prescribing, dispensing, or furnishing dangerous drugs on the Internet without a good-faith prior examination and medical indication, with a civil penalty of $25,000 per violation	Neither in-state nor out-of-state physicians may prescribe to state residents without meeting the patient, even if the patient completes an online questionnaire.	Issued monetary fines	Placed one physician on probation and issued monetary fines and a letter of reprimand	
Colorado		Internet exchange does not qualify as an initial medical examination, and no legitimate patient/physician relationship is established by it.			
Florida	Introduced bill requiring physicians practicing in the state using telecommunications to be licensed and to provide certain identifying information	Physicians prescribing a specific drug to residents without being licensed in the state may be criminally liable. Physicians prescribing on the Internet must follow standards of care.			

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State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
Illinois	Enacted bill amending the Pharmacy Practice Act to include pharmacies providing services via the Internet to be regulated as nonresident pharmacies and requiring out-of-state pharmacies dispensing drugs to residents to obtain nonresident special pharmacy registration			Suspended a physician's license for prescribing online without personally examining, meeting, or interviewing patients; placed a physician on probation; and referred another physician to the medical board in another state	AG filed suit against four out-of-state online pharmacies for selling, prescribing, dispensing, and delivering prescription drugs without the pharmacies or physicians being licensed and with no physical examination.
Indiana	Enacted bill requiring online pharmacies to comply with licensure laws in the state where the pharmacy is located				
Iowa			Conducted undercover buys from four Internet pharmacies and turned the information over to the AG for possible criminal prosecution		
Kansas	Introduced bill requiring Internet pharmacies to comply with federal laws and be properly licensed; practitioners to comply with regulations; foreign sites register with the Kansas Secretary of State; and Internet pharmacies to display identification information about the pharmacy, pharmacist, and practitioner		Referred Internet pharmacy(ies) to AG for possible criminal prosecution and filed lawsuits against the unauthorized practice of pharmacy	Referred one physician to the medical board in another state and obtained an injunction against a physician; the Kansas Board of Healing Arts also filed a lawsuit against a physician for the unauthorized practice of medicine.	AG filed lawsuits against 10 online pharmacies and obtained restraining orders against the companies to stop them from doing business in Kansas; filed lawsuits against 7 companies and individuals selling prescription drugs over the Internet.
Kentucky			Required an Internet pharmacy to obtain a state license		

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State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
Louisiana		Dispensing medication without physical examination represents conduct that is inconsistent with the prevailing and usually accepted standards of care and may be indicative of professional or medical incompetence.		Referred two physicians to the medical boards in other states	
Maine	Introduced bill making it illegal to sell any drug, medicine, or pharmaceutical or medical preparation on the Internet		Issued monetary fines		
Maryland		Warned licensed doctors that online prescribing is subject to peer review and that physicians not licensed in the state providing consultations or prescribing online to residents may be fined $50,000			
Michigan					AG filed notices of intended action against 10 Internet pharmacies for illegally dispensing prescription drugs.
Missouri			Referred Internet pharmacy(ies) to AG for possible criminal prosecution.		AG filed suit and obtained permanent injunctions against two online pharmacies and physicians for practicing without state licenses.

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State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
Nevada		Interpreted its laws to define malpractice to include prescribing a specific drug for a new patient without conducting a physical examination; proposed regulation to require pharmacists to verify that a bona fide physician/patient relationship exists before filling prescriptions for out-of-state patients from out-of-state doctors	Internet pharmacy(ies) agreed to discontinue business following investigation	Interviewed two physicians and suggested they stop prescribing over the Internet; they complied.	
New Hampshire	Introduced bill requiring mail-order pharmacies to be licensed and obtain permit				
New Jersey					AG filed suits charging nine Internet pharmacies with consumer fraud violations for selling prescription drugs over the Internet without a state license.
New York	Introduced bill prohibiting the dispensing of controlled substances through an Internet consultation or sale	Recommended registration of out-of-state pharmacies; views the failure to conduct a physical examination of a patient prior to prescribing medications as a violation of state law that defines appropriate medical conduct	Referred Internet pharmacy(ies) to AG and other state boards		

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State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
North Carolina		Adopted the position that prescribing drugs over the Internet solely on the basis of an online questionnaire is inappropriate and unprofessional	Referred Internet pharmacy(ies) to a federal agency		
North Dakota			Referred four pharmacies to pharmacy and medical boards in other states		
Ohio		Adopted regulations prohibiting physicians from prescribing or dispensing controlled substances or dangerous drugs to patients they have not examined and diagnosed in person; pharmacy board adopted rules for the sale of drugs online, requiring licensure or registration of pharmacy and disclosure.			An Ohio doctor was indicted on 64 felony counts of selling dangerous drugs and drug trafficking over the Internet. The Medical Board may have his license revoked.
Oregon			Referred Internet pharmacy(ies) to state medical board, FDA, and U.S. Customs Service		
Pennsylvania					AG filed lawsuits against three online companies and various pharmacies and physicians for practicing without proper licensing.
Rhode Island	Introduced bill making it illegal to sell prescription drugs over the Internet				

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State	Legislative actions	Policy clarifications	Pharmacy board actions	Medical board actions	Legal actions
Texas		Established that prescribing controlled substances without a physician/patient relationship is unprofessional conduct			
Washington			Referred three physicians to the state medical board	Placed one physician on probation and charged him with monetary fines	
Wisconsin		Regards prescribing of a specific drug via the Internet without examining the patient as unprofessional conduct		Placed one physician on probation and suspended another	

Note: State pharmacy and medical boards' actions obtained from surveys (see apps. III and IV).

Survey of State Pharmacy Boards

U.S. GENERAL ACCOUNTING OFFICE

SURVEY OF STATE PHARMACY BOARDS

Introduction:

At the request of the U.S. Congress, the General Accounting Office is studying states' efforts to oversee the distribution of prescription drugs over the Internet. Through surveying state pharmacy board executive directors in all 50 states, we hope to learn how states are overseeing online pharmacy practices.

This questionnaire focuses on obtaining a description of online pharmacies and identifying efforts of state boards of pharmacy to oversee online pharmacies, and coordinate with other government agencies. The questionnaire should take about 15 minutes to complete. Most of the questions can be answered quickly and easily by checking boxes.

Instructions:

For the purpose of this survey, we define online pharmacies as pharmacies that use the Internet as the primary access point for patients as well as mail-order and "brick and mortar" pharmacies which utilize the Internet to supplement their direct public access.

This questionnaire should be completed by the person or persons most familiar with your state's efforts to oversee online pharmacy practices. Please provide the name, title, telephone number, and email address of the person mainly responsible for completing the questionnaire so that we may consult with him or her if necessary.

Name of person to call: _____

Title: _____

Telephone number: ( ) _____

Email address: _____

If you have any questions about this questionnaire, please call Claude Hayeck at (202) 512-7143 or Darryl Joyce at (202) 512-7276.

Please return the completed questionnaire in the enclosed self-addressed envelope within 10 days of receipt. In the event the envelope is misplaced, please send your questionnaire to:

Darryl Joyce
U.S. General Accounting Office
HEHS/HF&PH, Room 5A14
441 G Street, N.W.
Washington, D.C. 20548

A final report will be sent to you once it is issued. Thank you for your help.

Note: Forty-nine states and the District of Columbia returned the questionnaire. The "N" for each question is the number of respondents who answered that question.

Section I: Regulation of Online Pharmacies

1. Does your state require resident pharmacies or other businesses that provide prescription drugs over the Internet (online pharmacies) to be licensed or registered? ***(Check one)*** (N = 50)

   a. [50] Yes

   b. [0] No → ***(Skip to Question 3)***

2. Must resident online pharmacies or other businesses that provide prescription drugs over the Internet obtain a mail order pharmacy license in your state? ***(Check one)*** (N = 48)

   a. [11] Yes

   b. [37] No ***(Please specify the license that must be obtained)*** _____
   _____

3. Does your state require out of state pharmacies or other businesses that provide prescription drugs over the Internet to be licensed or registered? ***(Check one)*** (N = 50)

   a. [39] Yes

   b. [11] No →***(Skip to Question 5)***

4. Must out of state online pharmacies or other business that provide prescription drugs over the Internet obtain a mail order pharmacy license in your state? ***(Check one)*** (N = 39)

   a. [25] Yes

   c. [14] No ***(Please specify the license that must be obtained)*** _____
   _____

5. Does your state pharmacy law or regulations include specific language on online pharmacy practices in your state? (N = 50)

   a. [5] Yes → ***Please provide a copy of these laws or regulations.***

   b. [45] No

6. Does your state board currently have plans to revise its state pharmacy law or regulations to include specific language on online pharmacy practices in your state? (N = 46)

   a. [15] Yes. → Please describe your plans

   _____
   _____
   _____
   _____

   b. [31] No

Section II: Description of Online Pharmacies

The following questions ask for information about the pharmacy industry in your state.

7. Can your state board identify the number of online pharmacies that were licensed/registered with your state board as of December 1, 1999? (N = 49)

   a. [13] Yes

   b. [36] No → ***(Skip to Section III, Question 10)***

8. As of December 1, 1999, how many online pharmacies were licensed/registered with your state? ***(If none or data are not available, check the appropriate boxes below.)***

   __85__Total [None] Zero → ***(Skip to Section III, Question 10)***

   (N=13) Range Average [None] Data not available → ***(Skip to Section III, Question 10)***
   1-15 7

9. Of the total number of online pharmacies provided in question 8, how many are located in or located outside your state? (N = 9)

   __7__Number located in your state

   __59__Number located outside your state

Section III: Resources for Overseeing Pharmacy Practices

10. How many staff of your state board are responsible for inspecting/investigating the practices of pharmacies (brick and mortar, mail order, and online pharmacies) in your state? (N = 49)

_396_ Total number of staff

11. From January 1, 1999 through December 1, 1999, how many staff of your state board, if any, have inspected/investigated online pharmacy practices in your state? ***(If zero or not available, check the appropriate box below.)***

_35_ Total number of staff (N = 15)

[19] Zero (N = 19)

[15] Not available (N = 15)

Section IV: Efforts to Oversee Pharmacy Practices

The following questions ask for information about your state's efforts to monitor the compliance of online pharmacies with state pharmacy laws.

12. What methods, if any, does your state board use to ensure that online pharmacies distributing prescription drugs in your state (regardless of location in the United States) are complying with state pharmacy laws? ***(Check all that apply)*** (N=48)

a. [19] Conduct periodic inspections
b. [23] Review inspection reports from other state boards of pharmacy
c. [37] Require proof of licensure from state where non-resident pharmacy is located
d. [38] Follow up on complaints
e. [13] Order medication over the Internet
f. [5] Other ***(Please specify)*** _____
g. [3] None

13. Has your state board experienced any problems with online pharmacies (regardless of location in the United States) complying with your state pharmacy laws? (N=49)

a. [24] Yes → Please describe the problems that your state has experienced with online pharmacies complying with your state pharmacy laws. _____

b. [25] No

14. Next, we would like to ask you about your state board's efforts to identify online pharmacies that may be practicing without a valid license or registration in your state. In what way(s), if any, does your state board attempt to identify online pharmacies (regardless of location in the United States) that are practicing without a valid license or registration in your state? ***(Check all that apply)*** (N=47)

a. [20] Search the Internet
b. [39] Respond to complaints
c. [35] Respond to referrals from other government agencies
d. [36] Respond to referrals from NABP (National Association of Boards of Pharmacy)
e. [9] Order medication over the Internet
f. [4] Other ***(Please specify)*** _____

g. [4] None → ***(Skip to Question 17)***

15. Listed below are activities a state board might perform in order to identify online pharmacies that practice in their state without a valid license or registration. For each of the following activities, how difficult, if at all, has it been for your state board to obtain information about online pharmacies? ***(Check one for each activity)***

Activity	Very difficult	Moderately difficult	Slightly difficult	Not difficult
1. Determining the location of the online Pharmacy affiliated with the Internet web site (N=38)	14	14	6	4
2. Identifying the corporate Officers of the online pharmacy (N=37)	20	12	5	0
3. Determining if online pharmacies located in the United States are selling prescription drugs to consumers in your state (N=38)	17	13	7	1
4. Determining if online pharmacies located Outside of the United States are selling Prescription drugs to consumers in your State (N=37)	28	5	3	1
5. Other ***(Please specify)*** _____(N=3)	1	1	0	1

16. From January 1, 1999 through December 1, 1999, did your state board identify any online pharmacies that were practicing in your state without a valid license or registration? ***(Check one)*** (N=40)

a. [18] Yes → How many online pharmacies were practicing without a valid license or registration? 46
b. [22] No

17. Next, we would like to ask you about online pharmacies located outside the United States. From January 1, 1999 through December 1, 1999, did your state board identify any online pharmacies located outside of the United States that were selling prescription drugs to consumers in your state? ***(Check one)*** (N=50)

    a. [8] Yes
    b. [32] No → ***(Skip to Question 19)***
    c. [10] Don't know → ***(Skip to Question 19)***

18. For each country listed below, please indicate the number of foreign online pharmacies that you determined were selling prescription drugs in your state as of December 1, 1999. ***(Enter number of online pharmacies. If none, enter "0".)***

a. United Kingdom	N=2	[ ] Don't know
b. Germany	N=1	[ ] Don't know
c. New Zealand	N=1	[ ] Don't know
d. Thailand	N=2	[ ] Don't know
f. Other ***(Please specify)***		
France	N=1	
Mexico	N=3	

19. Now, we would like to ask you about any complaints that your state board may have received concerning the practices of online pharmacies in your state.

    Did your state board receive any complaints about online pharmacies from January 1, 1999 through December 1, 1999? If you are unable to disclose information on the number of complaints about online pharmacies due to concerns of confidentiality, check the appropriate box below. ***(Check one. If you are unable to disclose this information, check the box below.)*** (N=50)

    a. [20] Yes → How many complaints were received? 78 Range 1-15 Median 5

    b. [21] No → ***(Skip to Question 21)***

    [9] Unable to disclose. Please explain →_____

    ↓ ↓
    (Skip to Question 21)

20. What type(s) of complaints did your state receive about online pharmacies during this time period? ***(Check all that apply)***

    a. [11] Medication was dispensed without a prescription
    b. [4] Medication received was not correct
    c. [0] Price was not as quoted
    d. [2] Medication was not delivered
    e. [0] Health plan did not reimburse drug costs
    f. [7] Other ***(Please specify)*** _____
    g. [1] Not available

21. Next, we would like to ask you about any inspections/investigations that your state board may have conducted concerning the practices of online pharmacies in your state. Did your state board conduct any inspections/investigations of online pharmacies from January 1, 1999 through December 1, 1999? ***(Check one)*** (N=50)

    a. [24] Yes → How many inspections/investigations were conducted?__45__

    b. [26] No → ***(Skip to Question 23)***

22. About how many work days in total did your staff spend identifying and inspecting/investigating online pharmacy practices from January 1, 1999 through December 1, 1999? (N=24)

		Range	Median
__61__	Total	0.3-15	4
[15]	Data not available		

23. Now, we would like to ask you about actions that your state board may have taken against online pharmacies that were practicing in your state. From January 1, 1999 through December 1, 1999, did your state board take any actions, including referrals to other agencies, against any online pharmacies? ***(Check one)*** (N=48)

    a. [13] Yes

    b. [35] No → ***(Skip to Section V, question 25)***

24. What type(s) of actions has your state board taken against online pharmacies during this time period? ***(Check all that apply)***

    a. [0] Probation—a restriction of pharmacy practice for a specified period of time
    b. [0] Surrendered—a license is relinquished by the licensee and is void
    c. [0] Suspension—the withdrawal of the license for a specified period of time
    d. [0] Revocation—the withdrawal of the license
    e. [2] Monetary fines
    f. [0] Letters of reprimand
    g. [4] Referral to the state Attorney General for possible criminal prosecution
    h. [3] Referral to state medical board
    i. [2] Referral to a federal government agency ***(Please specify)*** _____
    j. [5] Other ***(Please specify)*** _____
    k. [3] Not available

Section V: Other Issues

25. In what way(s), if any, has your state board attempted to educate consumers about purchasing prescription drugs over the Internet? ***(Check all that apply)***

    a. [8] Media events
    b. [3] Public meetings
    c. [2] Announcements on the Interne
    d. [8] Other ***(Please specify)*** _____
    e. [31] None

26. Does your state board of pharmacy have any initiatives planned for 2000 to identify and monitor online pharmacies practicing in your state? (N=48)

    a. [22] Yes → Please explain _____
    _____
    _____
    _____
    _____

    b. [26] No

27. Please discuss below any resources such as personnel, computer equipment, and training that you believe your state needs to assist its efforts to monitor online pharmacy practices in your state. (N=31)

31 respondents provided comments
19 respondents did not provide comments

28. Please describe below any recommendations that would improve your state's oversight of online pharmacy practices? (N=31)

31 respondents provided comments
19 respondents did not provide comments

29. Thank you for participating in this study. If you have any additional comments about online pharmacies or any questions asked in this questionnaire, please write them in the space provided below. (N=14)

14 respondents provided comments
36 respondents provided no comments

Survey of State Medical Boards

U.S. GENERAL ACCOUNTING OFFICE

SURVEY OF STATE MEDICAL BOARDS

Introduction:

At the request of the U.S. Congress, the General Accounting Office is studying the growing incidence of physicians prescribing drugs over the Internet. Through surveying state medical board executive directors in all 50 states, we hope to learn how state boards are regulating Internet prescribing practices under existing state laws.

This questionnaire focuses on obtaining information on state medical boards efforts to oversee online prescribing practices. The questionnaire should take about 15 minutes to complete. Most of the questions can be answered quickly and easily by checking boxes.

Instructions:

This questionnaire should be completed by the person or persons most familiar with your state's efforts to oversee online prescribing practices. Please provide the name, title, and telephone number, and email address of the person mainly responsible for completing the questionnaire so that we may consult with him or her if necessary.

Name of person to call: _____

Title: _____

Telephone number: _____

Email address: _____

If you have any questions about this questionnaire, please call Renalyn Cuadro (202) 512-6129 or Gloria Taylor (202) 512-7160. Please return the completed questionnaire in the enclosed self-addressed envelope by January 5, 2000. In the event the envelope is misplaced, please send your questionnaire to:

Renalyn Cuadro
U.S. General Accounting Office
HEHS/HF&PH, Room 5A14
441 G Street, N.W.
Washington, D.C. 20548

A copy of our final report will be sent to you once it is issued. Thank you for your help.

Note: We received 45 surveys from the medical boards in 39 states. The "N" for each question is the number of respondents who answered that question.

Section I: Regulation of Online Prescribing Practices of Physicians

The following questions ask for information about online prescribing practices in your state.

1. Does your state have the authority to regulate prescribing practices over the Internet? (If state law is unclear on this issue please explain in the space provided below) *(N=40)*

   a. [37] Yes

   b. [2] No

   [1] State law is unclear on this issue ***(Please explain)***_____
   _____
   _____
   _____

2. When obtaining a prescription over the Internet some web sites ask that a patient complete a questionnaire online. Then, a prescription is issued based on a physician's review of the questionnaire. The questionnaire is the first contact with the physician and there is no anticipation of future contact. This situation is commonly referred to as an "online consultation."

   Would your board conclude that an online consultation satisfies the standard of good medical practice under your state's medical practice act? *(N=39)*

   a. [0] Yes

   b. [39] No

3. Listed below are the minimum standards of medical care that the AMA and other professional organizations believe physicians should adhere to when prescribing medications to patients over the Internet. For each standard, please indicate whether or not your board has determined that each is required for physicians prescribing medications. ***(Check "Yes" or "No" for each standard)***

	YES	NO
a. Patient diagnosis established through appropriate patient examination	[38]	[1]
b. Treatment alternatives discussed with the patient	[36]	[2]
c. Reliable medical history accessible to physician	[36]	[2]
d. Documentation of a medical record	[37]	[1]
e. Benefits and risks of prescribed medication discussed with the patient	[34]	[3]
f. Follow up, when necessary, with the patient to assess therapeutic outcome	[34]	[3]
g. Other ***(please specify)*** _____	[5]	

Section II: Efforts to Oversee Physicians that Prescribe Drugs Online

The following questions ask for information about your state's efforts to identify physicians that prescribe over the Internet in your state.

4. From **January 1, 1999 through December 1, 1999**, did your state board identify any physicians licensed in your state that were prescribing drugs to patients in your state based on an online consultation? *(N=45)*

   a. [17] Yes → How many physicians did your board identify? __36__ Range 1-10 Median 1

   b. [28] No

5. From **January 1, 1999 through December 1, 1999**, did your state board identify any physicians not licensed in your state that were prescribing drugs to patients in your state based on an online consultation? *(N=45)*

   a. [18] Yes → How many physicians did your board identify? __36__ Range 1-8 Median I

   b. [27] No

6. What methods, if any, has your state board used to identify physicians that prescribe drugs over the Internet? ***(Check all that apply)***

   a. [14] Conduct searches over the Internet
   b. [8] Order medications over the Internet
   c. [29] Follow up on complaints
   d. [21] Review media reports
   e. [8] Other ***(please specify)***_____
   f. [9] None

7. What difficulties, if any, has your state board experienced in identifying physicians that prescribe drugs to patients over the Internet? ***(Check all that apply)***

   a. [25] Determining the identity of the physician
   b. [25] Determining the location of the physician
   c. [16] Determining whether the physician is licensed in another state
   d. [6] Other ***(Please specify)***_____
   e. [10] No Difficulties

Now, we would like to ask about any complaints that your board may have received concerning physician online prescribing practices in your state.

8. From **January 1, 1999 through December 1, 1999**, did your state board receive any complaints about physicians prescribing over the Internet? *(N=44)*

   a. [20] Yes

   b. [24] No → ***Go to question 11***

9. From **January 1, 1999 through December 1, 1999**, how many complaints did your state board receive about physicians prescribing over the Internet? *(N=20)*

		Range	Median
33	Number of complaints	1-5	1

   [3] Not available

10. What type(s) of complaints did your state board receive about physicians prescribing over the Internet? ***(Check all that apply)***

   a. [5] Inappropriate patient diagnosis
   b. [16] No patient examination
   c. [11] Patient did not have a previous relationship with the physician
   d. [1] Patient had adverse reaction to prescribed drug
   e. [5] Patient could not contact physician for follow up information about prescribed drug
   f. [5] Other ***(please specify)*** _____

Next, we would like to ask you about any investigations and actions that your state board may have initiated against physicians prescribing over the Internet.

11. From **January 1, 1999 to December 1, 1999** did your state board initiate any investigations concerning physicians prescribing over the Internet? *(N=45)*

    a. [26] Yes

    b. [19] No → ***Go to question 13***

12. From **January 1, 1999 to December 1, 1999**, how many investigations did your state board initiate concerning physicians prescribing over the Internet? *(N=24)*

    __32__ Number of investigations

    [4] Not available

13. From **January 1, 1999 through December 1, 1999**, has your state board taken any actions against physicians for prescribing over the Internet? *(N=44)*

    a. [11] Yes

    b. [33] No → ***Go to question 15***

14. Listed below is a list of actions that may be taken against a physician for prescribing over the Internet. From **January 1, 1999 through December 1, 1999** indicate the total number of physicians that your state took each type of action against. ***(Please provide a number for each)***

    a. __5__ Probation—a restriction of medical practice for a specified period of time
    b. __0__ Surrendered—a license is relinquished by the licensee and is void
    c. __2__ Suspension—the withdrawal of the license for s specified period of time
    d. __0__ Revocation—the withdrawal of the license
    e. __2__ Monetary fines
    f. __0__ Letters of concern
    g. __0__ Referral to the state Attorney General for possible criminal prosecution
    h. __4__ Referral to the medical board in another state
    i. __7__ Other ***(Please specify)***_____

Section III: Other Issues

15. In what way(s), if any, has your state board attempted to raise public awareness about obtaining a physician's prescription over the Internet. ***(Check all that apply)***

    a. [12] Newsletter to physicians
    b. [15] Interviews with the media
    c. [7] Press releases
    d. [5] Announcements on the board's web site
    e. [9] Other ***(Please specify)*** _____
    f. [20] None

16. Has your state board worked with state agencies or professional organizations to improve the oversight of physicians prescribing over the Internet? *(N=45)*

    a. [27] Yes ***(Please explain)***_____
    _____
    _____
    _____

    b. [18] No

17. Are there any initiatives needed to improve your state's oversight of physicians that prescribe over the Internet? *(N=38)*

    a. [22] Yes ***(Please explain)***_____
    _____
    _____
    _____

    b. [16] No

18. To what extent do you believe that prescribing prescription drugs over the Internet is a problem? *(N=38)*

    a. [26] Major problem
    b. [12] Minor problem
    c. [0] Not a problem

19. Are there any additional efforts underway or planned by your state to address issues related to physicians prescribing over the Internet that were not addressed by this survey? *(N=43)*

a. [13] Yes ***(Please explain)***_____

b. [30] No

20. Thank you for participating in this study. If you have any questions or comments about this questionnaire, please write them in the space provided below. *(N=6)*

6 respondents provided comments
39 respondents provided no comments

_____

GAO Contact and Staff Acknowledgments

GAO Contact

Gloria E. Taylor, (202) 512-7160

Staff Acknowledgments

The following individuals made important contributions to this report: John C. Hansen directed the work; Claude B. Hayeck collected information on federal efforts and, along with Darryl Joyce, surveyed state pharmacy boards; Renalyn A. Cuadro assisted in the surveys of Internet pharmacies and state medical boards; Susan Lawes guided survey development; Joan Vogel compiled and analyzed state pharmacy and medical board survey data; and Julian Klazkin served as attorney adviser.

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