

business on June 13, 2001. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

LIST OF SUBJECTS: Chile, tariffs, and imports.

By order of the Commission.

Issued: April 24, 2001.

Donna R. Koehnke,

Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA-191N]

Dispensing and Purchasing Controlled Substances over the Internet

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Guidance.

SUMMARY: This notice is intended to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public concerning the application of current laws and regulations as they relate to the use of the Internet for

dispensing, purchasing, or importing controlled substances. This guidance document explains when controlled substances can be legally purchased from U.S.-based Internet sites. This notice clarifies that consumers must have valid prescriptions to obtain controlled substances legally and that consumers cannot legally purchase controlled substances from foreign supplier Internet sites and have them shipped to the U.S., unless the consumers are registered with DEA as controlled substances importers and are in compliance with all DEA requirements.

FOR FURTHER INFORMATION CONTACT:

Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

Why is This Notice Necessary?

With the advent of Internet pharmacies, DEA registrants and the public have asked how these Internet pharmacies fit into the requirements that currently exist for the prescribing and dispensing of controlled substances. DEA is issuing this notice to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public about the application of current laws and regulations to the use of the Internet for prescribing, dispensing, purchasing, or importing controlled substances.

This document is in the format of questions and answers. The first section provides the context for this notice. The next two sections address issues that apply to DEA registrants and consumers.

General Questions

What are Controlled Substances?

Most drugs that require a prescription from a doctor are not controlled substances. The Controlled Substances Act and its implementing regulations, however, assign certain substances to one of five "schedules." These substances are placed in a schedule based on their potential for abuse, which may lead to physical or psychological dependency. Schedule I substances have no accepted medical use for treatment in the United States and are not available by prescription. Schedule II through V substances have accepted medical use and varying potentials for abuse and dependency. Practitioners (e.g., doctors, dentists, veterinarians, physician assistants, advance practice nurses) who are licensed by a State and registered with DEA may prescribe these substances. Controlled substances include narcotics (pain relievers), stimulants, depressants, hallucinogens, and anabolic steroids. A complete list of controlled substances can be found in Title 21 of the Code of Federal Regulations (CFR) part 1308. Examples of controlled substances are shown below.

Schedule	Example of controlled substances
Schedule I	Heroin, marijuana, mescaline, methcathinone,
Schedule II	Amphetamine, codeine, fentanyl, Hydromorphone, meperidine, methadone, Methylphenidate (Ritalin), morphine, oxycodone, pentobarbital, phenylcyclidine (PCP), secobarbital
Schedule III	Anabolic steroids, phendimetrazine, and products that contain small quantities of certain schedule II controlled substances, such as codeine, in combination with noncontrolled ingredients, such as aspirin.
Schedule IV	Alprazolam (Xanax), chlordiazepoxide (Librium), diazepam (Valium), lorazepam (Ativan), phenobarbital, phentermine
Schedule V	Buprenorphine and many cough Preparations that contain a limited amount of codeine

What are the Basic Requirements for Prescribing, Dispensing, and Importing Controlled Substances?

Only practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate. Pharmacies filling prescriptions for controlled substances must also be registered with DEA and licensed to dispense controlled substances by the State(s) in which they operate. A prescription not issued in the usual course of professional practice or

not for legitimate and authorized research is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled.

Pharmacists must receive written and manually signed prescriptions for Schedule II substances. They may receive oral or faxed prescriptions for Schedules III-V substances provided they confirm the legitimacy of the prescription and the practitioner. Prescriptions for Schedule II substances may not be refilled. Prescriptions for Schedules III-V controlled substances

may be refilled five times, but no prescription may be filled or refilled more than six months after the date on which the prescription was issued. Only those people who are registered with DEA as importers and who are in compliance with DEA requirements may have controlled substances shipped into the customs territory or jurisdiction of the U.S. from a foreign country.

DEA regulations covering prescriptions can be found in Title 21 of the Code of Federal Regulations, part 1306; rules on importation are found in 21 CFR 1312.

Why are Internet Sales an Issue?

The Internet is primarily a communications tool that can be used to facilitate any type of business. On-line pharmacies are currently providing access to a full range of pharmaceuticals, including prescription drugs and controlled substances. Many people view the Internet as changing the way in which business is conducted. For controlled substances, however, the Controlled Substances Act and DEA's regulations continue to determine when and how these substances may be obtained. Internet sales must be in accordance with these requirements.

DEA rules affect how controlled substances may be ordered from an Internet pharmacy and the conditions under which such orders are legal. DEA is currently working on a revision to its regulations that will define the conditions under which prescribers may electronically sign and transmit to any pharmacy (retail, mail order, or Internet) prescriptions for controlled substances. Until these revisions are complete, however, use of the Internet for dispensing controlled substances is governed by existing DEA rules, described above.

DEA is issuing this notice to answer questions that legitimate pharmacies and practitioners have about using the Internet as part of their business. DEA is also aware that some Internet sites are engaged in the illegal sale of controlled substances. Consumers may be illegally purchasing controlled substances from these Internet sites without realizing that they are committing a crime. This notice provides information for consumers to help them understand when they may legally purchase controlled substances.

DEA Registrant Questions About Internet Pharmacies

Must my Internet Pharmacy be Registered with DEA?

The actual physical location of the pharmacy which purchases, stores and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with DEA. The web site itself would not require a separate registration unless it is the same physical location, since the web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse site and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances

from a local pharmacy; these local pharmacies must be registered with DEA. In this case, the Internet "pharmacy" has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations rests with the actual pharmacy where the controlled substances are dispensed.

Your pharmacy must have a license from the State in which the controlled substances are stored and dispensed and, in most instances, from any state in which you plan to conduct business with customers. You should also be aware that many States require licenses for the web site itself since these sites often provide services like patient counseling.

Does the Label on a Prescription I Fill Indicate the Internet Pharmacy or the Registered Location that Filled the Prescription?

The label must list the registered location that dispensed the controlled substance.

Does Being an Internet Pharmacy Change my Responsibilities Under DEA Regulations?

No, you are still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule II Substances?

You may fill valid prescriptions for Schedule II substances if the patient or prescriber provides you with the signed original prescriptions prior to dispensing. Practically, it is unlikely that most patients will want to wait the time required for such a transaction.

Is it Possible for my Internet Pharmacy to Fill Prescriptions for Schedule III-V Substances?

You may receive an original signed prescription or a facsimile of the original signed prescription, or an oral prescription, where allowed, which you verify and immediately reduce to writing. You have the responsibility to ensure the legitimacy of the prescription and the prescriber. At this time, DEA does not permit a prescription received via the Internet to be filled. If you receive prescription information transmitted via the Internet, you must contact the prescriber via telephone and receive an oral prescription for the controlled substance, including the full name and address of the patient, the drug name, strength, dosage form,

quantity prescribed, directions for use and the name, address and registration number of the practitioner (21 CFR 1306.05(a)). You must immediately reduce this oral prescription to writing (21 CFR 1306.21(a)).

Does DEA Intend to Allow Electronic Transmission of Prescriptions in the Future?

DEA is currently engaged in a project to determine the requirements for secure electronic transmission of all controlled substance prescriptions between the practitioner and the pharmacy. When completed, these requirements will automatically certify the authenticity of the prescriber, protect the content of the prescription from alteration, and bind the digital signature on the prescription to the actual prescriber and no one else. These requirements will be subject to rulemaking, and you will have an opportunity to comment on them before they are finalized. You can find more information on this project on the DEA web site at <http://www.deadiversion.usdoj.gov/ecommm/index.html>.

Can Patients Request a Refill of a Controlled Substance Prescription From my Pharmacy by Sending me an email Instead of Calling me on the Telephone?

Yes, the Internet can be used to facilitate communication between you and your patient when your patient is requesting a permissible refill of an existing Schedule III-V controlled substance prescription.

Some Internet Pharmacies have Doctors who Prescribe Substances Based on an on-line Questionnaire. Is this Legal?

Federal law requires that "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" (21 CFR 1306.04(a)). Every state separately imposes the same requirement under its laws. Under Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established:

- A patient has a medical complaint;
- A medical history has been taken;
- A physical examination has been performed; and

- Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Completing a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship. A consumer can more easily provide false information in a questionnaire than in a face-to-face meeting with a doctor. It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone. However, as discussed later in this document, this circumstance is not intended to limit the ability of practitioners to engage in telemedicine. For purposes of this guidance document, telemedicine refers to the provision of health care using telecommunication networks to transmit and receive information including voice communications, images, and patient records.

Some sites recommend to the patient that they not take a new drug before they have a complete physical performed by a doctor. These sites then ask the patient to waive the requirement for a physical and to agree to have a physical before taking the drug they purchase via the Internet. An after-the-fact physical does not take the place of establishing a doctor/patient relationship. The physical exam should take place before the prescription is written. These types of activities by Internet pharmacies can subject the operators of the Internet site and any pharmacies or doctors who participate in the activity to criminal, civil, or administrative actions. For DEA registrants administrative action may include the loss of their DEA registration. Additionally, providing false material information to obtain controlled substances could be considered obtaining a controlled substance by fraud and deceit, which is subject to Federal and State penalties.

I am a Practitioner who is Considering Starting an Internet Practice. Can I use the Internet to Facilitate the Prescribing of Controlled Substances?

You may use the Internet to provide information and to communicate with the patient, but it cannot be the sole basis for authorizing prescriptions. If a doctor/patient relationship exists, you can use the Internet to communicate with patients. Where a doctor/patient relationship exists, you may use the Internet to receive requests for treatment. DEA cautions, however, that

such requests for treatment should be logical based on your knowledge of the patient's medical history and the medical complaint. You may also use the Internet to receive requests for refills of prescriptions from patients.

I am a Physician. Does the need for a Physical Exam Mean that I Cannot Engage in Telemedicine and Prescribe Controlled Substances?

No, DEA does not intend to limit the ability of doctors to engage in telemedicine. If the patient cannot travel to your office, but you supervise an exam given by a nurse or other professional, you can then prescribe the needed medications based on the results, to the extent that State law allows. In this case, your decision on the appropriateness of the medication is based on facts (symptoms, blood pressure, etc.) that have been verified by a qualified third party and observed by you electronically.

I have Read in the Controlled Substances Act (CSA) that it is a Violation of the law to use a Communications Facility to Facilitate the Illegal sale of a Controlled Substance. Does this Apply to the use of the Internet to Obtain Pharmaceutical Controlled Substances?

Yes, Title 21, United States Code, section 843(b) defines a communication facility as "any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication." Anyone who uses the Internet to facilitate the illegal sale of a controlled substance would be in violation of 21 U.S.C. 843(b), which is punishable by a term of imprisonment of not more than four years and a fine of not more than \$30,000. This provision could apply to owners of Internet sites, prescribers, pharmacists, and patients.

Questions for Consumers

Are Internet Pharmacy Sites Legitimate?

Many Internet pharmacy sites are legitimate. These Internet pharmacy sites may vary in the services they provide, but they may fill a prescription for a controlled substance which was issued to you by an authorized practitioner for a legitimate medical purpose. They should confirm the legitimacy of the prescription for a Schedule III-V controlled substance before filling it by contacting the prescriber. They are not authorized to fill a prescription for a Schedule II

controlled substance unless they have first received the original signed prescription.

Some Internet sites for pharmacies advertise local pharmacies and usually list the name, address, and telephone number of the local pharmacy closest to you. Many of these sites provide a great deal of information concerning specific diseases or medical conditions, and drug information. Many Internet sites operated by local pharmacies or mail order pharmacies serve as a communication link so that you can request refills of prescriptions, check the status of your prescription, or ask the pharmacist a question. These are appropriate uses of the Internet by pharmacies.

Some sites simply provide information about specific drugs and medical conditions. After obtaining some general information from you, this type of "Internet Pharmacy" will refer you to a specific local pharmacy or a mail order pharmacy to have the prescription that you obtained from your physician filled. These are appropriate uses of the Internet by pharmacies.

Are There Internet Pharmacy Sites That are Not Legitimate?

Some Internet pharmacy sites do not require that you have a prescription from your doctor. These "Internet Pharmacies" require the customer to complete a medical questionnaire. This type of site advises that the information will be reviewed by a doctor, and the drug will be prescribed and sent to you, if appropriate. The medical questionnaire often has most of the questions set so that if the default answers are not changed, the questions are answered in an appropriate manner to obtain the desired drug. Questionnaire sites often require that the customer waive certain rights. This type of pharmacy usually does not name the doctor who will be reviewing the medical questionnaire or provide any information about the qualifications of the doctor. These sites operate in a manner that is not consistent with state laws regarding standards of medical practice and may be engaging in illegal sales of controlled substances (see discussion above).

Some Internet Pharmacy sites are operating in a foreign country and often do not require any prescription before sending controlled substances to you. These sites often advise that there have been changes to the U.S. law that authorize the customer to import a controlled substance into the United States without benefit of a prescription. These types of sites may be engaging in

illegal sales of controlled substances (see discussion below).

Is it Legal to Buy Controlled Substances From Foreign Internet Sites and Have Them Shipped to the U.S.?

No, having controlled substances shipped to the U.S. is illegal unless you are registered with DEA as an importer and you are in compliance with 21 U.S.C. 952, 953, and 954 and 21 CFR part 1312. Some foreign Internet sites claim they can legally sell these controlled substances; other sites, knowing that such shipments are illegal, advise consumers of ways to avoid having the packages seized by U.S. Customs. The Controlled Substances Act prohibits any person from importing into the customs territory of the U.S. any controlled substance or List I chemical (21 U.S.C. 971 and 21 CFR part 1313) unless that person maintains a valid, current authorization to import such substances or chemicals (21 U.S.C. 957(a)). DEA regulations further state:

“No person shall import or cause to be imported any controlled substance * * * unless and until such person is properly registered under the Act (or exempt from registration) and the Administrator has issued him a permit to do so pursuant to § 1312.13. * * *” (21 CFR 1312.11(a))

Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960).

The CSA Provides a Personal Use Exemption for Controlled Substances Purchased Abroad. Does the Exemption Apply to Controlled Substances Bought from a Foreign Internet Site?

The Controlled Substances Act and DEA regulations allow you a personal use exemption to bring a limited quantity of controlled substances into the U.S. for your use only when you bring the controlled substances across the U.S. border in your possession (21 U.S.C. 956, 21 CFR 1301.26). It does not apply to controlled substances being shipped into the U.S. Purchasing controlled substances on the Internet and having them shipped to you in the U.S. is not permitted by the personal use exemption. Such purchases and shipments would be considered “imports” of the controlled substance even if the substance is for your personal use. Unless you are registered as an importer and in compliance with the requirements, such shipments are illegal and subject to seizure.

Does it Make a Difference if I Have a Prescription from a U.S. Doctor for Controlled Substances That I Buy From a Foreign Internet Site?

No, the law remains the same. Unless you are registered with DEA as an importer and are in compliance with DEA’s requirements, you may not have controlled substances shipped to you in the U.S. from another country.

What are the Things to Consider in Selecting an Internet Pharmacy?

An “Internet Pharmacy” site should provide a physical address for the pharmacy, in addition to the Internet address, and a telephone number for the pharmacy.

Some indicators that the “Internet Pharmacy” may not be legitimate and should not be used as a source for controlled substances are the following:

- The site is not a participant in any insurance plan and requires that all payments be made with a credit card.
- The site requires that you waive some rights before they send you the drugs.
- The site advises you about the law and why it is permissible for you to obtain pharmaceutical controlled substances from foreign countries via the Internet.
- The site does not ask the name, address, or phone number of your current physician.
- The site advises you to have the drugs sent to post office boxes or other locations to avoid detection by U.S. authorities.

I Have Seen a VIPPS Seal on Some Internet Pharmacy Sites. What Does This Mean?

The National Association of Boards of Pharmacy (NABP) has developed a voluntary program called the Verified Internet Pharmacy Practice Sites (VIPPS). The NABP has begun issuing a “seal of approval” to Internet pharmacies that meet standards regarding State licensing and DEA registration. To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of their State and each State to which they dispense pharmaceuticals. In addition, pharmacies displaying the VIPPS seal have demonstrated to NABP compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The NABP also provides information on whether a pharmacy is

licensed and in good standing (see <http://www.nabp.net>).

Are the Rules Different for “Life Style” Drugs?

Some people have applied the phrase “life style drugs” to certain medications, such as Viagra, weight control medications, and tranquilizers. Many of the so-called life style drugs are not controlled substances. If a “life style” drug is a controlled substance, however, it is still subject to all regulations for controlled substances. You must obtain a prescription from a DEA registered prescriber and have it filled by a DEA registered pharmacy.

I Have a Complaint About an “Internet Pharmacy” Site on the Internet That Appears to be Illegally Selling Drugs. Where Should I Send the Complaint?

If the complaint involves a pharmaceutical controlled substance, contact the DEA, Office of Diversion Control, Drug Operations Section, Washington, DC 20537, telephone (202) 307-7194 or your local DEA office (for a list of contacts, see <http://www.dea.gov/agency/domestic.htm>).

If the complaint involves any pharmaceutical drug other than a controlled substance, contact the U.S. Food and Drug Administration, HFC-230, 5600 Fishers Lane, Rockville, MD 20857, or file a report on the FDA’s web site at <http://www.fda.gov/oc/buyonline/buyonlineform.htm>.

If the complaint involves a pharmacist or a physician, you may contact the State Board of Pharmacy or the State Board of Medicine where the doctor or pharmacist is located.

Additionally, you may wish to view other sites on the Internet that are for registering complaints such as the NABP (<http://www.nabp.net>).

Dated: March 19, 2001.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study