U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JUL 31 2007

Dear Pharmacy Registrant:

The illegal sale of controlled substances via the Internet poses a serious threat to the public health and safety. The Drug Enforcement Administration (DEA) is extremely concerned about this problem. Many people view the Internet as changing the way in which business is conducted. For controlled substances, however, the Controlled Substances Act (CSA) and DEA regulations continue to determine when and how controlled substances may be obtained.

DEA is charged with enforcing the CSA and the Controlled Substances Import and Export Act (21 U.S.C. 801 et seq.). Regulations implementing these laws may be found in Title 21, Code of Federal Regulations (CFR), Parts 1300-1316. Regardless of how a patient obtains controlled substances, the patient must have a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner must be registered with DEA and licensed by the state(s) in which he or she engages in professional practice (21 CFR 1306.03). 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 practice (21 CFR 1306.06). Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled (21 CFR 1306.04, 1306.05). Only those persons 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 United States from a foreign country (21 CFR 1312.11).

Enclosed for your information is a Notice on Diversion Trends via the Internet. This document will provide guidance to you and your staff in preventing the illegal diversion of pharmaceutical controlled substances via the Internet. This situation will only be solved through a cooperative effort between practitioners, pharmacies, distributors, state and local law enforcement, regulatory agencies, and DEA. Should you have questions, please visit our website at www.deadiversion.usdoj.gov or contact the Liaison and Policy Section at (202) 307-7297. Your support and cooperation in this matter is greatly appreciated.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

NOTICE: DIVERSION TRENDS VIA THE INTERNET

According to the 2005 National Survey of Drug Use and Health, approximately 6.4 million Americans used psychotherapeutic drugs nonmedically and of those, 4.7 million used pain relievers. The nonmedical use of these types of drugs is second only to the illegal use of marijuana.

Over the last several years, the Internet has increasingly been used by drug seekers to illegally obtain controlled substance pharmaceuticals. The Drug Enforcement Administration (DEA) regards this as a critical issue. To address this problem, DEA has had to utilize its administrative authority to suspend or revoke the DEA registrations of pharmacies, practitioners, and distributors who were involved in the illegal distribution of controlled substances via the Internet. Additionally, DEA has used traditional criminal investigative approaches to arrest doctors, pharmacists, and web site operators who were involved in the illegal sale of controlled substances over the Internet.

DEA is aware of the increase in the number of Internet web sites that solicit orders from "customers" who are interested in obtaining controlled substances without a valid prescription or legitimate medical purpose. The operators of these web sites often collaborate, either directly or indirectly, with DEA-registered practitioners and pharmacies to fill the orders placed by customers. It is commonplace to find that the practitioners, the pharmacies, and the customers looking to obtain controlled substances are all located in different states. Typically, drugs such as hydrocodone combination products, benzodiazepines, or phentermine are those most sought after by these customers. DEA recognizes that while some Internet web sites facilitate legitimate prescribing and dispensing, other web sites facilitate the illegal sale of controlled substances.

The process by which a controlled substance is illegally obtained usually starts with a "customer" making online contact with an Internet website. Typically, the customer selects the drug that they want and is required to complete a medical questionnaire and possibly fax recent medical records to the web site. An online consultation fee is typically charged by the web site and paid by the customer with a credit card. Insurance is not an accepted form of payment. Often, within a few hours, a practitioner or physician's assistant affiliated with this web site may contact the customer by phone and provide a "consult." The practitioner or physician's assistant will ask the customer a number of medical-related questions and then authorize a "prescription" via the web site. An Internet pharmacy affiliated with the website subsequently receives, fills, and ships the drug order to the customer.

Title 21, Code of Federal Regulations, Section 1306.04 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." Every state separately imposes similar requirement under its laws. Under Federal and state law, for a practitioner to be acting in the usual course of professional practice, there must be a bona fide doctor/ patient relationship.

Medical authorities 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.

An individual completing a medical questionnaire that is reviewed by a practitioner hired by an Internet web site does not establish a doctor/patient relationship. It is illegal to receive a prescription for a controlled substance without a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.

However, this is not intended to limit the ability of practitioners to engage in telemedicine. Telemedicine refers to the provision of health care using telecommunication networks to transmit and receive information including voice communications, images, and patient records.

Recently, in response to DEA initiatives that have effectively shut down pharmacies supplying large quantities of controlled substances over the Internet, new web sites have started advertising "Direct Script" programs. Under this program, the process for a customer to obtain a controlled substance via an Internet web site is the same except that controlled substance prescriptions are no longer filled by an affiliated Internet pharmacy. The controlled substance prescription is either faxed to the customer's local pharmacy or is sent directly to the customer for presentation at a local pharmacy. The initial consultation fee is increased; however, the customer now has the option of using insurance to cover the cost of the controlled substance prescription. Initial indications from various sources are that controlled substance prescriptions illegally obtained via the Internet have successfully been filled in the retail pharmacy environment.

It is important that pharmacies take the proper action to ensure that controlled substance prescriptions obtained illegally over the Internet are not filled. Pharmacy personnel should exercise caution and due diligence when presented with a controlled substance prescription, received via fax or in person, bearing an address of a practitioner located in another state. While not all prescriptions authorized by a physician located in a state other than the pharmacy are illegal, every effort should be made to verify the authenticity of the controlled substance prescription especially those written by practitioners unfamiliar to the pharmacist or for "patients" unfamiliar to the pharmacist.

If a prescription is presented at the pharmacy that is suspicious, the pharmacist should not fill the prescription until the legitimacy of the prescription is determined. If a prescription is presented at the pharmacy that is suspected as being from an illegal Internet pharmacy, it is requested that the pharmacy contact the DEA office in their local area. The contact information for the local DEA offices is available at www.DEAdiversion.usdoj.gov. Alternately, any information concerning illegal Internet activities can be reported to DEA via the Internet at www.DEAdiversion.usdoj.gov and clicking on the icon in the lower right entitled "Report Suspicious Internet Pharmacies," or by calling the DEA drug abuse hotline toll free at 877-792-2873.

The illegal sales of controlled substances, via the Internet, poses a serious threat to the public health and safety. The situation will only be solved through a cooperative effort between practitioners, pharmacies, distributors, state and local law enforcement, regulatory agencies, and the DEA.

DEA appreciates your continued support and cooperation.