



Wisconsin Briefs

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INTERNET PHARMACIES

INTRODUCTION

States are searching for ways to assist citizens in coping with the rising cost of prescription drugs, an expense not covered by Medicare. Some states have banded together to establish multi-state prescription drug pools or have investigated dealing directly with drug manufacturers to negotiate discounts for citizens. Other states, including Wisconsin, have attempted to make it easier for citizens to take advantage of lower drug prices in Canada by providing links to Canadian pharmacies via the Internet. The cost of prescription drugs is considerably lower in Canada under a national health care system which regulates drug pricing. The practice of instituting state-sponsored websites to provide links to Internet pharmacies, however, has met with opposition from the U.S. Food and Drug Administration (FDA) and its legality may be challenged. The Wisconsin Pharmacy Examining Board has also expressed concern over the safety of drugs ordered on the Internet from Canadian pharmacies.

STATE OF WISCONSIN DRUG PRESCRIPTION CENTER

In his January 2004 "State of the State Message", Governor Jim Doyle announced plans for a website to assist Wisconsin residents in finding lower-priced prescription drugs through Canadian Internet pharmacies. After a delay of several weeks to allow for the inspection of the pharmacies by the Wisconsin Department of Health and Family Services, direct links to three Canadian

pharmacies' websites were added on February 25, 2004.

Identified as the "State of Wisconsin Prescription Drug Resource Center", the website (www.drugsavings.wi.gov) is an informational and educational site for Wisconsin citizens. The site provides links to Medicare information, Canada Internet drug prices, health information, and a helpline. The site includes a detailed disclaimer of liability on the part of the state.

The website provides links to three pharmacies: CanadaDrugs.com, Granville Pharmacy, and Total Care Pharmacy. All three suppliers are licensed and inspected by the Canadian government. It lists 83 maintenance drugs only; generic drugs and those that require refrigeration are not included.

To use the website, a patient must first fill a prescription at a local pharmacy to monitor any negative reactions to the drug. If there are no negative reactions, the patient may order refills from Canada using a form downloaded from the state's website. The patient sends the filled-out form and prescription to the Canadian pharmacy that the patient chooses.

The FDA has indicated that it will not prosecute individual patients who buy Canadian drugs. However, it opposes any efforts by governments or businesses to expedite the purchase of drugs from foreign locations, especially through Internet sites.

Representatives Mark Pocan and Frank Boyle have also posted a direct link on www.markpocan.net to both Wisconsin's and Minnesota's websites.

MINNESOTA WEBSITE

Minnesota. Minnesota was the first state to launch a website that allows individuals to order prescribed drugs from approved Canadian pharmacies that have websites. The website, www.minnesotarx-connect.com, began operating on January 30, 2004. The Minnesota website provides order forms, lists of approved drugs, and addresses of the Canadian pharmacies that are considered safe. Consumers must still purchase by mail or by fax. In addition, it provides information on prescription medicine safety, offers cost-savings tips, and describes programs to help low-income Minnesotans pay for prescription medications.

On February 23, 2004, the FDA sent a warning letter to Minnesota Governor Tim Pawlenty calling the state's plan "unsafe, unsound and ill-considered". Despite warnings, the FDA has not yet taken any enforcement action against Minnesota.

NATIONAL GOVERNORS ASSOCIATION

At the National Governors Association 2004 Winter Meeting in Washington, D.C., Governor Jim Doyle and other governors organized a summit to build political support for importing low-cost prescription drugs from Canada. States besides Wisconsin that have expressed an interest in reimportation are: Alabama, California, Delaware, Illinois, Iowa, Louisiana, Massachusetts, New Hampshire, New York, North Carolina, Ohio, Oklahoma, Vermont, and West Virginia.

TYPES OF INTERNET PHARMACIES

Three types of Internet pharmacies that sell drugs directly to consumers have emerged:

1. Ones operating like traditional drug stores and mail-order pharmacies that dispense drugs only after receiving prescriptions from consumers or their physicians.
2. Ones that provide consumers medication without a physical examination by a physician. In place of the traditional face-to-face physician/patient consultation, the consumer fills out an online questionnaire that is reportedly evaluated by a physician affiliated with the pharmacy.
3. Ones that dispense medication without a prescription.

The first type receives certification from private organization watchdogs and licenses from the states in which they operate. The other two types raise public safety concerns.

INTERNET PHARMACY ISSUES

For various reasons and with increased frequency, consumers are using the Internet to access health related information and products. The online sale of consumer products has increased rapidly, including the sale of drugs.

The Internet offers a convenient and often less expensive alternative for purchasing prescription drugs to the traditional "bricks and mortar" drugstore. The first Internet pharmacies began online service in early 1999, and federal officials have estimated that between 200 and 400 businesses were selling prescription drugs on the Internet by July 1999. During this period, federal officials reported that approximately 10 million Americans used the Internet to shop for health products, spending an estimated \$160 million on prescription drugs. Although there are benefits of online drug sales, there are also concerns about safety and regulation.

Public health officials concur that state-licensed Internet pharmacies offer consum-

ers an alternative to the traditional drug-store. 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.

For those on Medicare, for individuals without prescription drug insurance, and for those looking to buy drugs their doctors won't prescribe, online pharmacies appears to offer an alternative. Internet users order potentially harmful and addictive prescription drugs from what the FDA considers "renegade" websites. These sites write, fill, and sell prescriptions for hundreds of medications. It is difficult to monitor these websites or find the prescribing doctor and pharmacy that filled the order. These website operations are frequently cloaked in secrecy, often shutting down one day and reemerging the next under a different name.

By using Internet pharmacy websites, consumers eliminate their doctors from the health care equation. Individuals in medical need have turned to medical websites for self-diagnosis, and, in theory, can buy drugs online to heal themselves. On the other hand, before prescribing a medication, a physician will weigh why a patient needs it against possible risks or side effects. A physician also considers possible drug interactions and inquires about allergies to any medications.

CANADIAN DRUG CONCERNS

Health Canada's Therapeutic Products Directorate is the Canadian authority that regulates pharmaceutical drugs and medical devices for human use. This agency is comparable to the FDA.

Because of the pressure from U.S. governors to allow citizens to obtain prescription drugs from Canada, several Canadian groups, including the "Coalition for Manitoba Pharmacy," have expressed concern

over the impact on the country's national health system.

The coalition fears Internet pharmacies harm the Canadian health care system by increasing health care system costs and making it harder for Canadian pharmacists to offer quality care to patients. The rapid and unpredictable growth of cross-border drug sales is causing disruptions in the supply of needed medicines to Canadian community pharmacies.

FEDERAL REGULATION

At the federal level, the FDA, U.S. Federal Trade Commission (FTC), U.S. Customs, Drug Enforcement Agency, and U.S. Department of Justice have increased their investigation and prosecution of Internet pharmacies and physicians that illegally dispense and prescribe prescription drugs. The major player on the federal level is the FDA.

U.S. Food and Drug Administration. Under the federal Food, Drug, and Cosmetic Act, the FDA has the legal authority to take action against the importation, sale, or distribution of an adulterated or misbranded drug; the importation, sale, or distribution of an unapproved new drug; illegal promotion of a drug; the sale or dispensing of a prescription drug without a valid prescription; and counterfeit drugs. In conjunction with this authority, the FDA has established priorities for taking enforcement actions involving online sales, and expanded its capability to monitor sites operating illegally through advanced technology search tools.

As part of its outreach activities, the FDA, in 2000, launched "cyber" letters – letters sent electronically via the Internet – to operators of foreign-based Internet sites who sell online prescription drugs that may be illegal. The agency also sends hard copies of each "cyber" letter to the website operator, the U.S. Customs Service, and regulatory officials in the country in which the operator

is based. The FDA may also use “cyber” letters to prevent illegal sales of prescription drugs by domestic websites.

U.S. Congress – 108th Congress. H.R. 2652, introduced on June 26, 2003, amends the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet. H.R. 2652, known as the “Internet Pharmacy Consumer Protection Act”, was referred to the Subcommittee on Health of the House Committee on Energy and Commerce.

H.R. 2652 prohibits any person from selling prescription drugs through an Internet site unless the site meets specified requirements. These requirements include a page with proper links that identify the seller, persons who serve as pharmaceutical or medical consultants to the seller, and the states in which the seller and medical or pharmaceutical consultant are licensed to prescribe and dispense medications. H.R. 2652 would allow a state that has requirements in effect for Internet sites that are no less stringent and that has adequate procedures for their enforcement to have primary enforcement responsibility for any violation involving such a purchase made within that state.

VERIFIED INTERNET PHARMACY PRACTICE SITES PROGRAM (VIPPS)

The National Association of Boards of Pharmacy (NABP) created the VIPPS program in 1999 to verify and certify Internet pharmacies. A coalition of state and federal regulatory associations, professional associations, and consumer advocacy groups provided their expertise in developing the criteria which VIPPS-certified pharmacies follow. VIPPS pharmacy sites are identified

by the VIPPS hyperlink seal displayed on their website.

To be certified, a pharmacy must:

1. Comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals;
2. Demonstrate to NABP compliance with VIPPS criteria including patient rights to privacy, authorization and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

Currently, 14 Internet pharmacies operating dispensing facilities in 21 states have been certified by NABP through its VIPPS program.

STATE LAWS TO REGULATE ONLINE PHARMACIES

All states have enacted laws to protect patients from harm resulting from the use of unsafe drugs and the improper practice of medicine and pharmacy. Under these state laws, to receive a prescription drug, a licensed health care practitioner must examine a patient to determine the appropriate treatment and issue a prescription for an FDA-approved drug. A registered pharmacist working in a licensed pharmacy fills the patient’s prescription.

With the advent of Internet pharmacies, some states are amending their pharmacy laws to include online pharmacies. Currently, seven states regulate Internet pharmacies (Arkansas, Illinois, Indiana, Nevada, New Hampshire, New York, and Texas).