



# Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## Internet Pharmacy

It is illegal to purchase or sell prescription drugs over the Internet without a valid prescription from a prescriber. The following four elements are useful in determining the validity of a prescription and/or a doctor-patient relationship:

- ◆ A patient has a medical complaint
- ◆ A medical history has been taken
- ◆ A physical examination has been performed
- ◆ Some logical connection exists between the medical complaint, the medical history, the examination, and the drug prescribed

A patient completing a questionnaire that is reviewed by a physician working on behalf of an Internet pharmacy does not constitute a bona fide doctor-patient relationship, and any prescriptions generated as a result of the questionnaire are not valid. This type of activity by Internet pharmacies can subject the site and participating pharmacists and physicians to criminal, civil, or administrative penalties. Additionally, if controlled substances (CS) are involved, federal and state penalties may be imposed. This is not intended to limit the ability of practitioners to engage in telemedicine, which utilizes telecommunication networks to transmit and receive health care information including voice, images, and patient records.

The National Association of Boards of Pharmacy® (NABP®) has developed a voluntary program called Verified Internet Pharmacy Practice Sites™ (VIPPS®). NABP issues a VIPPS seal of approval to Internet pharmacies that meet standards regarding state licensure, Drug Enforcement Administration (DEA) registration, inspection requirements, patient privacy, authentication and security of prescription orders, and patient counseling requirements. NABP also provides information on whether a pharmacy is licensed and in good standing at [www.nabp.net](http://www.nabp.net).

Common indicators that an Internet pharmacy site is not legitimate include:

- ◆ The site does not provide a physical address and/or phone number

- ◆ The site does not require a prescription
- ◆ The site does not ask for the name, address, and phone number of the treating physician
- ◆ The site prominently advertises CS and lifestyle drugs
- ◆ The site is not a participant in any insurance plans and requires that all payments be made with a credit card

Complaints regarding an Internet pharmacy site that appears to be selling non-controlled drugs illegally can be reported online to the United States Food and Drug Administration (FDA) at [www.fda.gov/oc/buyonline/buy-onlineform.htm](http://www.fda.gov/oc/buyonline/buy-onlineform.htm). If CS are involved, the complaint should be reported to DEA, Office of Diversion Control, Drug Operations Section, Washington, DC 20537, telephone 202/307-7194, online at [www.dea.gov](http://www.dea.gov), or to the Montana DEA office at 406/657-6020.

## Electronic Signature for Controlled Substance Prescriptions

Computer-generated prescriptions, electronic prescribing, and e-signatures are now a reality in daily pharmacy practice. The Board of Pharmacy has adopted rules (24.174.523) that allow for secure electronic signature and transmission of prescriptions for non-CS; however, DEA does not allow electronic signature of prescriptions for CS. DEA has said that electronically signed prescriptions for CS in Schedules III-V can only be accepted if the information is verified with the prescriber prior to dispensing. Prescriptions for Schedule II CS may not be electronically signed under any circumstance. Electronic transmission of Schedule II prescriptions is only allowed for hospice, nursing home, or hospitalized patients.

DEA is working in earnest to write rules to address electronic signature of CS prescriptions, which is required by the Electronic Signatures in Global and National Commerce (ESIGN) Act signed by President Bill Clinton in June 2000. The purpose of the ESIGN law is to spur the growth of electronic commerce by ensuring electronic contracts, signatures, and records have the same legal status and effect as their ink and paper counterparts.



## **FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips**

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- ◆ One Touch Basic®/Profile®
  - ◆ Lot Numbers 272894A, 2619932, or 2606340
  - ◆ Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - ◆ Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- ◆ One Touch Ultra®
  - ◆ Lot Number 2691191
  - ◆ Multiple Languages – English and French text on the outer carton
  - ◆ Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit [www.GenuineOneTouch.com](http://www.GenuineOneTouch.com).

## **New DEA Number Assignments; Updated DEA Practitioner's Manual Released**

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit [www.deadiversion.usdoj.gov/drugreg/reg\\_apps/new\\_reg\\_number110906.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm).

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at [www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual090506.pdf](http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf).

## **Optimizing Computer Systems for Medication Safety**



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- ◆ Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

# Compliance News

Compliance News to a particular state or jurisdiction should not be assumed (the law of such state or jurisdiction.)



- ◆ Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to “overload” the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- ◆ Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- ◆ Maximize a system’s capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- ◆ Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- ◆ Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- ◆ Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print “Topical or External Use Only” warnings on drug labels for all drugs that can be administered safely only by this route.
- ◆ Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer’s alert system and the response to the alert.

## **Revised Coumadin Labeling and Medication Guide**

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin<sup>®</sup>, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at [www.fda.gov/cder/Offices/ODS/medication\\_guides.htm](http://www.fda.gov/cder/Offices/ODS/medication_guides.htm).

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit [www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin](http://www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin).

## **FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments**

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for “hidden traps” by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to “Be smart, be skeptical!” and will be available in English, Spanish, and French. One component is a “teaser” Web site available at <http://wemarket4u.net/glucobate/index.html>. At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

## **FDA Implements Strategy for Phony Dietary Supplement Claims**

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency’s counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes ([www.fda.gov/diabetes/](http://www.fda.gov/diabetes/); [www.fda.gov/diabetes/pills.html](http://www.fda.gov/diabetes/pills.html); [www.fda.gov/opacom/lowlit/diabetes.html](http://www.fda.gov/opacom/lowlit/diabetes.html); [www.fda.gov/opacom/lowlit/sdiabetes.html](http://www.fda.gov/opacom/lowlit/sdiabetes.html)), as well as more general health care information.

## **Inspector's Corner**

By Bill Sybrant

We receive numerous questions at the Montana Board of Pharmacy regarding the conspicuous display of license or registration in the place of business. A review of statute and administrative rule should help clarify any questions.

**Pharmacists:** MCA 37-7-302 (2) Each person licensed and registered under this chapter must receive from the department an appropriate license. The license must be conspicuously displayed at all times in the place of business.

**Pharmacies:** MCA 37-7-321 The license must be displayed in a conspicuous place in the pharmacy for which it is issued.

**DEA registrants:** ARM 24.174.1402 (4) The registrant shall prominently display the certificate of registration to be visible to the public.

**Technicians:** ARM 24.174.704(3) Verification of completion of training, by test or otherwise, shall be recorded by the supervising pharmacist, and shall be available for inspection with the training record.

Since Pharmacy Technician Certification Board (PTCB) certification is required to be a certified pharmacy technician (24.174.702 1d), proof of certification must be available for inspection. The inspector will always ask for both current state registration (displayed) and PTCB certification (displayed or with records) every time he or she visits a pharmacy. For those who work multiple locations, the Board expects that originals are displayed at the primary place of employment and a photo copy of current registration or certification is displayed at each additional place of employment. Every registrant is responsible for maintaining current licensure and certification; however, it is the responsibility of the pharmacist-in-charge to verify that licensure for every individual working in the pharmacy is current and properly displayed.

### **\$4 Prescriptions in Montana**

The recent media attention about the expansion of the \$4 prescription programs into Montana by some retail chain pharmacies has resulted in numerous phone calls to the Board of Pharmacy office. Because of a state law that prohibits sales at less than cost, some of the prescriptions must be priced higher than \$4 in Montana. The law is a Trade and Commerce statute, which reads as follows:

30-14-209. Sales at less than cost forbidden. It is unlawful for a vendor to sell, offer for sale, or advertise for sale any article of commerce at less than the cost thereof to the vendor or to give, offer to give, or advertise the intent to give away any article of commerce for the purpose of injuring competitors and destroying competition.

### **Proposed Prescription Monitoring Program in Montana**

The Board of Pharmacy is working in collaboration with a diverse group of stakeholders to implement a prescription monitoring program (PMP) in Montana. A bill authorizing the establishment of a PMP and giving

rule-making authority to the Board of Pharmacy will be presented to the Montana Legislature during the 2007 session.

A PMP utilizes a centralized database to collect and analyze CS prescription information that is submitted electronically by resident and nonresident pharmacies that fill prescriptions for Montana residents. Practitioners, pharmacists, licensing boards, law enforcement, and patients can request a report from the PMP, which lists all CS prescriptions filled for a patient during a specified time period including the prescriber and the pharmacy. A PMP is intended to be a source of information for practitioners and pharmacists in the care of their patients. A PMP is also a tool to help deter drug abuse and diversion. It is not intended to prevent patients from obtaining needed drugs.

Twenty-four states have implemented PMPs, nine states have enacted enabling legislation, and three states, including Montana, have PMP legislation pending. The Board of Pharmacy is applying for federal grant monies, which are available to assist states in establishing or enhancing PMPs. The PMP would be sustained by creating a CS registration fee paid by prescribers, dispensers, and distributors of CS.

Articles about the progress of the PMP will be published in future editions of this *Newsletter*. If you would like more information, please contact the Board of Pharmacy office at 406/841-2371.

### **OTC Plan B Raises Logistical and Administrative Challenges**

The August 24, 2006, FDA approval of the over-the-counter (OTC) sale of Plan B<sup>®</sup> to women 18 years of age and older was intended to make the drug more easily available within the narrow window of effectiveness; however, its new dual status as both a prescription and OTC drug raises a number of challenges for pharmacists, patients, and regulators. How will the issue of conscientious objection be affected by Plan B's increased availability? How will authorities monitor age verification and record keeping? How will pharmacists receive training on the medication and its distribution? NABP published an article addressing the challenges associated with Plan B in its November/December 2006 *Newsletter*. The article can be downloaded from the NABP Web site at [www.nabp.net](http://www.nabp.net). Just click on Newsletters, NABP Newsletter, and then select November/December 2006 from the drop-down menu.

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