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Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Do You Have Your New Terminal Distributor's License?

Please check the terminal distributor of dangerous drugs (TDDD) license at your facility to be sure you have received your 2007 TDDD license from the Ohio State Board of Pharmacy. The TDDD license is the license required for all pharmacies, hospitals, clinics, emergency medical service squads, etc. If you have not renewed or received your 2007 TDDD license, please call the Board office immediately. The 2006 TDDD licenses expired on December 31, 2006.

Continuing Pharmacy Education Note

The Board's annual Jurisprudence Quiz is included as part of this *Newsletter*. The questions in the quiz relate to the topics covered in this *Newsletter* as well as the May, August, and November 2006 issues. If you need them, copies of the previous *Newsletters* can be found on the Ohio State Board of Pharmacy Web site at www.pharmacy.ohio.gov by clicking on "C.P.E. News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2007**. Any answer sheets postmarked after March 31, 2007, will not be accepted.

Final CPE Reminder

This is a final reminder to those pharmacists whose license number begins with 03-1. This is the year for you to report your continuing education (CE). It will be due in the Pharmacy Board office **no later than May 15, 2007**. The continuing pharmacy education (CPE) report forms should be arriving in your mail sometime early in March while your renewal forms will not be arriving until midsummer. If you have not received your CPE reporting form by the end of March, please notify us at the Board office so we can get you a replacement. The CPE reporting form is also available on the Board's Web site under "**Forms.**" The Web site form can be filled out online and then you can print it, sign it, and mail it to the Board office.

You will need to show a total of six continuing education units (CEUs) (60 hours of CE credit); 0.3 CEUs (three hours) of those must be in Board approved jurisprudence. (Please make sure that the jurisprudence courses are Board approved. There are a lot of courses coded as law that are not approved by the Board for use in meeting this requirement.) The other 57 hours may be in any category (01, 02, 03, or 04) that you wish.

You may use certificates dated on or after March 1, 2004, that you did not use when reporting in 2004. In addition, please

be sure that you have the certificates in hand before you enter the number on the form. Every year, we have a few pharmacists who put numbers down before they receive their certificates from the CE provider. Sometimes, that certificate then fails to arrive because they did not pass the examination. Falsifying the CPE reporting form is not something that the Board takes lightly. As long as you have the originals in your possession when you complete the reporting form, you should have no problem with this reporting period. If you fail to submit a CPE form in a timely manner, your renewal form will not be mailed to you until your CPE form is received.

Is Filling Internet Prescriptions a Good Idea?

All pharmacists are aware of the ready availability of Web sites where people can purchase prescription drugs, including controlled substances, without a prescription from their own physicians. Many of these sites require the patient to complete a questionnaire (one that often starts off with entering a credit card number) that is allegedly reviewed by a physician who then authorizes the dispensing of the drug. Sometimes, the prescriber, or a "representative" of the prescriber, calls the person to discuss the request. The person requesting the drug usually ends up with the drug appearing in the mailbox within a few days. No physical examination is conducted by the prescriber, nor is it possible, since the prescriber is often very far away from the patient. In the past, the order was usually filled by one pharmacy, which was run by the people who organized the scheme. Many Web sites fed back to just one pharmacy, which might have been located outside of the United States. It was well recognized by most pharmacists that this was an illegal scheme that should not be allowed to continue. The federal government agreed and some action has been taken by Drug Enforcement Administration and other federal agencies against organizations that did this.

Recently, we have become aware that the scheme is changing. Now the Web sites have recruiters who look for retail pharmacies who are willing to fill the prescriptions and mail them out. These recruiters are sometimes offering a fee of \$10 to \$20 per prescription, a sum that is catching the eye of some pharmacists. The companies may even offer to put in a computer to specifically handle the business. These computers are then used to receive prescriptions electronically and document the provision of drugs to patients on a system other than the pharmacy's usual computer system. Note that the electronic prescriptions never come from a Board approved prescribing system, which every pharmacist

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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.

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.

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.

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) 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.

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®, 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.

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit 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/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html), as well as more general health care information.

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should know makes them not valid. It should go without saying, but be aware that pharmacists and pharmacies who agree to participate in a scheme of this sort are putting themselves in the place of the original central pharmacies that have been the target of federal action in the past and are making themselves liable for both administrative and criminal action, federally or locally. If a pharmacist does not receive a valid prescription issued by a prescriber in the usual course of practice, the prescription is illegal and the pharmacist could be charged with both possessing a false prescription and making an illegal sale of a drug (both of which are felonies in the state of Ohio) in addition to action the Board may take on the pharmacist's license to practice.

When pharmacists in Ohio are considering the phrase "usual course of practice" to determine whether a prescription has been issued legitimately, they need to be aware of the State Medical Board of Ohio's rule on prescribing to persons not seen by the prescriber (4731-11-09 Ohio Administrative Code). The full text of the rule is included in the "Drug Laws of Ohio" book (in Section F) as well as on the Medical Board's Web site: www.med.ohio.gov. The most important paragraphs that pharmacists need to remember are as follows:

4731-11-09 Prescribing to persons not seen by the physician.

(A) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.

(B) Except in institutional settings, on call situations, cross coverage situations, situations involving new patients, protocol situations, situations involving nurses practicing in accordance with standard care arrangements, and hospice settings, as described in paragraphs (D) and (E) of this rule, a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any dangerous drug which is not a controlled substance to a person who the physician has never personally physically examined and diagnosed, except in accordance with the following requirements:

(1) The physician is providing care in consultation with another physician who has an ongoing professional relationship

with the patient, and who has agreed to supervise the patient's use of the drug or drugs to be provided; and

(2) The physician's care of the patient meets all applicable standards of care and all applicable statutory and regulatory requirements.

All pharmacists should be able to see that a scheme where the physician, "patient," and pharmacy are all separated by large distances will have difficulty meeting this standard.

If you are approached by one of these recruiters offering you this kind of a deal, please use good judgment. Contact the Board office if you have any questions. If you keep in mind the fact that a deal that seems too good to be true probably is not true, you should be able to avoid dealing with the criminal and administrative repercussions that could result.

Disciplinary Actions

Anyone with a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Professional Licensing Agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, www.dental.ohio.gov

State Medical Board – 614/466-3934, www.med.ohio.gov

State Nursing Board – 614/466-3947, www.nursing.ohio.gov

State Optometry Board – 614/466-5115,
www.optometry.ohio.gov

State Pharmacy Board – 614/466-4143, www.pharmacy.ohio.gov

State Veterinary Medical Board – 614/644-5281,
www.ovmlb.ohio.gov

Drug Enforcement Administration – 800/230-6844,
www.deadiversion.usdoj.gov

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