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Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Terminal Distributor Renewals

By the time this *Newsletter* is published, renewal notices for terminal distributor licenses will have been sent out by the Ohio State Board of Pharmacy and should have been received by all licensees. If you have not yet received yours, please contact the Board office as soon as possible. If you are the responsible person on the license, please remember that you are responsible for seeing that the license is renewed before January 1, 2010.

This year's process for renewal has changed. For the first time, we will be accepting online terminal distributor renewal applications with payment by credit card for most licensed sites. Please note that only terminal distributors with **unlimited** licenses will be able to renew online this year. Also, a terminal distributor license cannot be renewed online if any one of the following applies: change of address, change of responsible person, change of business name, change of business ownership, and/or change of drug category of the license. This is all explained on both the renewal application and the online renewal screens, which give directions on how to handle these situations. For ordinary renewals, however, the process should be as easy and painless as the pharmacists' renewal process has been the last two years **if** you read and follow the directions contained in your renewal packet and on the renewal screens. Please also note – **do not hit the "back" button after you authorize payment with your credit card!** Each time you hit the back button, this will cause your credit card to be charged again. The last two years we have had several pharmacists whose cards were charged up to six times because they were not patient enough to wait for the card processing to occur. In other words, if that happens, it is your fault, not the system's. We try to catch those mistakes before they get posted to your card, but we are not always successful. If it does occur, please contact the Board office so we can reverse the extra charges.

Proposed New and Changed Rules Filed

On September 28, 2009, the Board filed several proposed new and changed rules for public notice. The public hearing

on these rules is scheduled for November 2, 2009, at 1:30 PM. Pharmacists interested in reviewing the rule changes proposed by the Board may view them on the Board's Web site under "What's New" prior to the Board making a final determination on their status. After the Public Rules Hearing, there will also be a hearing before the Joint Committee on Agency Rule Review. After that hearing, the Board will make a final determination on implementation and on the effective date of those rules that are given final approval. Notice of that decision and copies of all new and changed rules will be placed on the Board's Web site and, on the effective date, the changes will be incorporated into the Administrative Code rules posted on the Web site.

'Accidental' Drug Poisonings in Ohio

The Ohio Department of Health (ODH) compiles statistics on many different health-related topics every year and tries to monitor trends so that action can be taken when needed. Just recently, ODH noticed an alarming trend. In 2008, the number of deaths from "accidental" drug overdoses exceeded the number of traffic fatalities in Ohio. While traffic fatalities have remained fairly consistent from year to year, the drug overdose deaths have risen at an alarming rate. A large majority of those overdoses involve prescription opiates, often combined with other drugs or alcohol; however, opiates are appearing as a primary cause in most of these deaths. ODH has become so alarmed by this trend that they have started holding local planning meetings around the state. The first of these meetings was held on October 21, in Portsmouth, OH, where there were more than 120 people present, including doctors, addiction specialists, law enforcement, nurses, pharmacists, and other interested parties. More meetings are being planned.

Pharmacists can, and must, play a role in addressing this epidemic. We have a requirement in our rules (4729-5-20 OAC) that pharmacists must perform prospective drug utilization review on **every** prescription filled. One part of that prospective review involves detecting and resolving issues relating to overuse and underuse of medications. When a pharmacist determines that a patient is receiving

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Pharmacy Security and Safety Prove Necessary Component in Pharmacists' Training

Pharmacy robbery – no one ever thinks it will happen to them, but those who have experienced it know it **can** happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin®. They left with bags filled with OxyContin and Percocet®, having a retail value of nearly \$10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university's college of pharmacy alumni e-Newsletter. In the article Bryan states, "I crouched down hoping they hadn't seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery," he explains. "I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal."

In December 2008, a safety DVD, *Pharmacy Security – Robbery*, accompanied the shipments of the National Association of Boards of Pharmacy® 2009 Survey of Pharmacy Law that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management

course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

"One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber's appearance – clothes, height, weight – and not just focusing on the gun," states Cisneros. He was glad to have received the DVD, explaining that, "it was just the right length, added a lot to the class, and led to great discussions." Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol® Web site at www.rxpathrol.org. RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at www.partnersagainstpain.com under Pain Education Center.

Concerns with Patients' Use of More than One Pharmacy



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified Patient Safety Organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy

Compliance News

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



locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient's pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM's computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through Surescripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the \$4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbals, nutritional supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

CDC Launches Get Smart Web Site to Help Decrease Antibiotic Resistance

Centers for Disease Control and Prevention (CDC) launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it. Because antibiotic resistance is one of the world's most pressing public health problems, CDC also held Get Smart Week on October 5-11 to emphasize its public health effort to decrease antibiotic resistance, including how pharmacists can become involved.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at www.cdc.gov/getsmart/.

FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements.

ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

FDA Takes Actions on Pain Medications Containing Propoxyphene

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite "serious concerns . . . , the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time." Additional information can be found at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm.

opiates from multiple prescribers, the pharmacist should take steps to make sure the treatment is legitimate **before** dispensing the prescription. Often, a patient who is seeing multiple prescribers is doing so just to obtain the drugs. That is defined in law as deception (doctor shopping) and that is a felony in Ohio. On the other hand, a patient who is being treated at a major cancer center clinic may really see multiple prescribers due to the clinical rotations of the hospital's house staff physicians. In other words, do not automatically assume that a patient is doctor shopping until you do some checking.

One valuable tool in verifying the legitimacy of a patient (particularly a new patient) who presents a prescription for a controlled substance is to obtain an Ohio Automated Rx Reporting System (OARRS) report on that patient. The OARRS report will give you information (names, addresses, etc) on the prescribers and pharmacies used by that patient. If you find that the patient is receiving controlled substances from one prescriber (or one clinic) only, then your comfort level with the prescription should be better than it would be if you found the patient had visited 10 prescribers and eight emergency rooms in the last six months.

Patient profiles and OARRS reports are only part of the equation, however. In addition, the pharmacists need to know the prescribers and the patients. If the patient lives a long distance away from your pharmacy, it would be prudent to question why the prescription is being presented to you. While most of us think that our pharmacy is the best one around, it helps to be practical every now and then. Why would the patient need to drive from Portsmouth to Marion (or Columbus, or Zanesville, or Dayton) to get a prescription filled? Is your pharmacy **really** that outstanding? Furthermore, if the prescriber's office is also located a long distance from your pharmacy as well as the patient, the question to ask is **why** does the patient need to drive here to fill the prescription.

Often pharmacists are the first to detect a physician who begins to stray from patient care into drug trafficking. We often get complaints from pharmacists when physicians begin to prescribe unusual quantities and unusual combinations of drugs. Pharmacists are often the first in the community (other than the drug abusers, of course) to realize that something is wrong. Please continue to monitor this issue and let us know when someone begins to stray.

Some indicators that there may be a problem with a physician who treats "pain" include patients that all get the same drug(s) in the same quantities (pain is not like an infection where one dose fits all); when most of the patients receive prescriptions for the highest strengths available (most patients do well on hydrocodone/APAP 5/325); when the doctor's parking lot is full of cars from out of state or from several counties away; when you find that the doctor only takes cash; when the patients always pay you cash for their prescriptions (or they pay cash for the second prescription after Medicaid or another insurer paid for the first); or when the patients appear in van loads rather than individually, etc.

Even though the workload in most pharmacies is high and difficult to deal with on a daily basis, pharmacists must use good judgment when filling prescriptions. Pharmacists

have a duty to the patients and to society to ensure that the drug therapy is appropriate and reasonable. Blindly filling a prescription without proper thought because you are too busy to spend the time to think before you act is a disservice to the patient, society, and the profession. Pharmacists have always been and still are the gatekeepers in this process. Legitimate patients should have their prescriptions filled in a timely and accurate method without being subjected to harassment or delay. Patients who are trying to obtain drugs to support a habit or to sell should **not** have their prescriptions filled. Determining which category an individual patient fits into is difficult at best, but both the prescriber and the pharmacist have an equal responsibility to make that call.

Pharmacy Technician Issues

We have been receiving a large number of calls from or about technicians. Please remember that in Ohio, technicians are **not** required to be licensed, registered, or certified. However, employers must ensure that technicians are qualified to compound drugs or to package or label any drug. In order to be a qualified pharmacy technician, a person must be 18 years of age or older, a high school graduate (exceptions for the age and graduation requirements are made for technical school students), must have cleared a Board-defined background check, and must have passed a Board-approved examination. Technicians who were employed on or before April 8, 2009, have 18 months to meet those criteria. Technicians hired after April 8, 2009, have 12 months from the date of hire to meet the criteria. The rules for the background checks and the approved examinations may be found on the Board's Web site under "What's New" if you need more information. As always, if you have specific questions that are not answered on the Web site, please call the Board office.

Disciplinary Actions

Anyone with a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The 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 – 800/882-9539; www.dea diversion.usdoj.gov

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