



Oklahoma State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Oklahoma City, OK 73105-3488

Physician Dispensing

Physicians are authorized to dispense prescription medications by their practice acts. A dispensing machine may be utilized based upon the following regulations and rules:

1. The medications in the machine are the sole responsibility of the physician whose name, address, and Drug Enforcement Administration (DEA) number for controlled dangerous substances are noted on the invoice as the recipient.
2. The machine must be located in the physician's office.
3. All medications dispensed from the machine must be dispensed under the physician's name that is responsible for the medications.
4. A valid physician-patient relationship must exist for a medication to be dispensed to a patient under the physician's name and authority.
5. The label on the medication container must list the physician's name that is responsible for the medications, as well as all other information required by law.

OS 355.1.A Only a licensed practitioner may dispense dangerous drugs to such practitioner's patients and only for the expressed purpose of serving the best interests and promoting the welfare of such patients. The dangerous drugs shall be dispensed in an appropriate container to which a label has been affixed, such label to include the name and office address of the licensed practitioner, date dispensed, name of patient, directions for administration, prescription number, the trade or generic name and the quantity and strength, not meaning ingredients, of the drug therein contained; provided, this requirement shall not apply to compounded medicines. The licensed practitioner shall keep a suitable book, file or record in which shall be preserved for a period of not less than five (5) years a record of every dangerous drug compounded or dispensed by the licensed practitioner.

Note: In most cases an appropriate container must be child-resistant by Consumer Product Safety Commission regulations. See the Board's Web site for additional information at www.pharmacy.ok.gov.

6. The responsible physician must keep appropriate logs, invoices, and records as required by law, including DEA and Oklahoma Bureau of Narcotics and Dangerous Drugs Control, and physician licensing boards.
7. If the physician dispenses controlled drug substances, whether from a machine or in another way, the physician is responsible for assuring an approved ID is presented and that Prescription Monitoring Program data is submitted to the appropriate agencies.

8. A physician assistant may **not** dispense medications for a patient to take home, whether from a machine or any other form, with the only exception being sample medications in the original manufacturer's sample packaging.
9. An advance practice nurse may **not** dispense medications for a patient to take home, whether from a machine or any other way, with the only exception being sample medications in the original manufacturer's sample packaging.
10. Use due diligence in billing insurance plans for medications dispensed by a physician. Utilization of a licensed pharmacy to bill insurance plans for physician-dispensed medications may not be within the insurance company's contract specifications and may violate state regulations.

Have You Mailed Your Renewal?

The Oklahoma State Board of Pharmacy mails renewal applications 60 days in advance of expiration. If you do not receive a renewal, it is your responsibility to obtain one (visit www.pharmacy.ok.gov and click on "Download Forms"). Please allow a **minimum of 15 business days** from the date of receipt for your application to be processed. Renewals are processed in the order they are received. Please do not call the Board office before the 15-day period has passed.

Board Statement on Flavoring Prescriptions

A pharmacist may add flavoring agents, up to a maximum of 5% of the total volume, to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use date that shall be no longer than 14 days if stored in a refrigerator, unless otherwise documented. Documentation of beyond-use dates longer than 14 days shall be maintained by the pharmacy electronically or manually and made available to agents of the Board upon request. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's agent unless the pharmacist obtains a prescription for the over-the-counter product from the patient's practitioner.

Information on "Swapping"

Provision of reduced cost or "free" products, equipment, software, or other items may constitute a violation of swapping rules. The term *swapping* refers to discounts on services paid for by a nursing facility (eg, a service covered by consolidated billing requirements under Medicare Part A and therefore considered to be an "out of pocket" expense for the nursing facility) in exchange for referrals of services paid for by a governmental payor directly (eg, a service paid directly by Medicare Part B).

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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.rxpatrol.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



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 Announces Get Smart Week to Help Decrease Antibiotic Resistance

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

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.

Some items to consider:

1. The size of the discount does not matter; linkage to swapping matters.
2. Below-cost or below-market deals are suspect.
3. Discounts tied to “exclusives” or to implicit or explicit swap agreements are suspect.

Based upon 73 FR 56832 at 56844 (September 30, 2008):

Nursing facilities often obtain discounts from suppliers and providers on items and services that the nursing facilities purchase for their own account. In negotiating arrangements with suppliers and providers, a nursing facility should be careful that there is no link or connection, explicit or implicit, between discounts offered or solicited for business that the nursing facility pays for and the nursing facility’s referral of business billable by the supplier or provider directly to Medicare or another federal health care program. An example could be a nursing facility that received a discounted, or free, service or item in exchange for explicit or implicit guiding of business to a vendor such as a pharmacy. Such swapping arrangements implicate the anti-kickback statute and are not protected by the discount safe harbor. When evaluating whether an improper connection exists, suspect arrangements include below-cost arrangements or arrangements at prices lower than the prices offered by the supplier or provider to other customers with similar volumes of business. Other suspect practices include, but are not limited to, discounts that are coupled with exclusive provider agreements and discounts or other pricing schemes made in conjunction with explicit or implicit agreements to refer other facility business. If any direct or indirect link exists between a price (including provision of a free service or item) offered by a supplier or provider to a nursing facility for items or services that the nursing facility pays for out-of-pocket and referrals of federal business for which the supplier or provider can bill a federal health care program, the anti-kickback statute is implicated.

Disciplinary Actions – June 17, 2009

For more information you may view hearing minutes at www.pharmacy.ok.gov.

Sandra K. Decker, Tech #1102 – Case 914: Revoked

Impaired Pharmacist #13774 – Case 916: License suspended indefinitely. Respondent must abide by Oklahoma Pharmacists Helping Pharmacists (OPHP) contract and must attend additional continuing education (CE). Respondent fined \$9,000.

Impaired Pharmacist #12619 – Case 924: Respondent license suspended for 10 years until June 17, 2019. Suspension stayed immediately and respondent placed on probation. Respondent must abide by a 10-year contract with OPHP, and respondent must attend additional CE. Respondent fined \$4,000.

Tonia Morris, DPh #9795 – Case 921: Respondent ordered to watch a medical error video. Respondent must attend additional CE. Respondent fined \$750.

Cardinal Health, Wholesale #88-W-116 – Case 926: Respondent will maintain a compliance program designed to detect and prevent diversion of controlled substances, and inform the Board of suspicious orders in the same manner as DEA. Respondent fined \$47,000.

Cardinal Health, Wholesale #88-W-116 – Case 927: Respondent will maintain a compliance program designed to detect and prevent diversion of controlled substances, and inform the Board of suspicious orders in the same manner as DEA. Respondent fined \$64,000.

Edward Everett Hildebrand, DPh #7494 – Case 927: Respondent license reprimanded for two years. Respondent will attend additional CE. Respondent fined \$32,000.

Terrell Moorhead, DPh #8615 – Case 926: Respondent license reprimanded for two years. Respondent will attend additional CE. Respondent fined \$23,500.

Cardinal Health Solutions, Inc dba Oklahoma State University Medical Center Pharmacy License #2-5190 – Case 926: Respondent fined \$60,000.

Cardinal Health Solutions, Inc dba Hillcrest Medical Center Pharmacy #2-5007 and #2-5189 – Case 927: Respondent fined \$129,000.

Disciplinary Actions – July 15, 2009

For more information visit www.pharmacy.ok.gov.

Naomi Goldberg, Tech #10213 – Case 925: Revoked.

Christopher W. Nash II, Tech #10010 – Case 929: Revoked.

Ahmed Ahmed, Tech #12201 – Case 931: Revoked.

Tammy Kay Allen, Tech #10512 – Case 932: Revoked.

Adam Burnett, Tech #9580 – Case 930: Revoked.

Impaired Pharmacist #9370 – Case 649: Request for probation of license granted. Respondent must maintain OPHP contract. Respondent must attend additional CE. Respondent must work under the supervision of another pharmacist for 320 hours.

Impaired Pharmacist #11290 – Case 745: Request for probation of license is granted. Respondent must maintain OPHP contract. Respondent must attend additional CE. Respondent must work under the supervision of another pharmacist for 160 hours.

Impaired Pharmacist #9706 – Case 922: Respondent’s license suspended for five years. Suspension is stayed and respondent is placed on probation. Respondent must continue his contract with OPHP. Respondent must attend eight hours of live CE each year through 2014. Respondent must develop a personal final review process to check prescriptions.

Colte Lee Utley, DPh #14012 – Case 928: Respondent must watch medical error video. Respondent must attend additional CE. Respondent fined \$750.

Don Gepner, DPh #11246 – Case 934: Respondent placed on probation until July 15, 2010. Respondent must attend additional CE. Respondent fined \$1,000.

From the Compliance Officers

New rules addressing compounding and United States Pharmacopeia Chapter 797 can be found on the Board’s Web site.

Immunization rules and statutes have been changed. A patient-specific order is no longer required after November 1, 2009. See the Board’s Web site for more information.

Be diligent about placing the correct prescriber on prescription labels. This is important for many reasons, one being prescription monitoring program submission information. The Board of Pharmacy is checking for compliance in this area.

Let Us Hear From You

The Board welcomes your comments and questions. You may mail them to the Oklahoma State Board of Pharmacy, 4545 Lincoln Blvd, Suite 112, Oklahoma City, OK 73105, fax us at 405/521-3758, or e-mail us at pharmacy@pharmacy.ok.gov.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency Web site. Two printout copies have been deposited with the Publications Clearinghouse of the Oklahoma Department of Libraries. [74 O.S. 2001 § 3105(B)]