



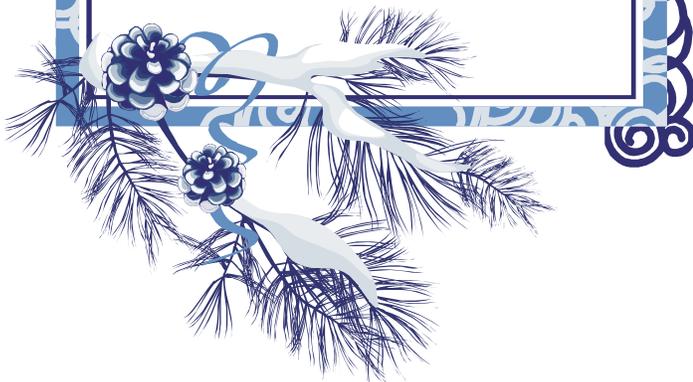
# Oklahoma State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Season's Greetings

*The members and staff of the Oklahoma State Board of Pharmacy would like to join in wishing everyone happiness and all the best for the coming year.*



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### 15.01. Continuing Education Networking

*By Dorothy Gourley, DPh*

Having been an Oklahoma State Board of Pharmacy member for almost 10 years, I have a deep appreciation of the importance of pharmacists staying connected with each other. During our time on the Board, every Board member has the unique opportunity to speak with pharmacy students or new graduates about the profession. While each of us may have a little different way of expressing ourselves, the message is clear: **Pharmacists are the medication experts on the health care team, and the importance of remaining an expert depends on continual learning.**

I have been practicing hospital pharmacy for over 40 years. The importance of staying connected is just as important for me today as it was in the beginning. During a recent meeting with directors of pharmacy in hospitals, our connection and learning from each other was apparent and comfortable. In today's changing health care environment, one of the most important things you can do is to stay connected professionally.

The position of director of pharmacy in hospitals has changed a bit from when I first began practice as a hospital pharmacist. Many directors do not actually have their hands in the day-to-day operations of the hospital pharmacy, and some directors may not even be pharmacists, but the importance of the director staying connected to the profession has not changed. Continual learning and being current with all of the professional expectations can best be accomplished through attending meetings with other pharmacists. I belong to and support both state and national pharmacy associations. Obtaining live continuing education through attendance at these meetings has been very important to me throughout my career. It is hard for me to believe that the person who

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## DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at [www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances](http://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances).

## System-Based Causes of Vaccine Errors

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter ([www.ismp.org/sc?id=307](http://www.ismp.org/sc?id=307)), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

**Practice Recommendations.** Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

## FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm).

## **PTCB Implements Changes to CE Requirements**

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at [www.ptcb.org](http://www.ptcb.org).

## **Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern**

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at [www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf](http://www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf). In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at [www.njconsumeraffairs.gov/press/05012013.pdf](http://www.njconsumeraffairs.gov/press/05012013.pdf).

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, [www.rxpatrol.com](http://www.rxpatrol.com), provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

## **Assured Brand Naproxen Tablets Recalled Due to Packaging Error**

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm).

## **Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations**

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/Recalls/ucm412431.htm](http://www.fda.gov/Safety/Recalls/ucm412431.htm).

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sets the direction of one of the most important departments of the hospital, the hospital pharmacy, can be a good leader without being intimately connected to the profession of pharmacy. I encourage all hospital directors of pharmacy to become members of and regularly attend both state and national pharmacy organization and association meetings, and take the information they learn at those meetings back to their staffs. I consider it one of the responsibilities of a hospital director of pharmacy.

### 15.02. Phantom PICs

The Board has received several questions from Oklahoma-licensed pharmacists who have been approached by out-of-state pharmacies asking them to be employed as their pharmacist-in-charge (PIC) for their Oklahoma license, and suggesting to the pharmacists that they do not have to actually work at the pharmacy. A term for this might be an “absent” or “phantom” PIC. This situation is no doubt occurring more frequently due to the new requirement that nonresident pharmacies that do sterile compounding must have an Oklahoma-licensed PIC. In one case, the Oklahoma-licensed pharmacist was not even living in the United States at the time of the employment offer; the pharmacy just wanted a pharmacist with an Oklahoma license to sign its application or renewal in a fraudulent attempt to meet the legal requirement. The required PIC duties for an Oklahoma-licensed pharmacist include accepting the full responsibility of all aspects of the pharmacy’s operation, responsibility for controlled and non-controlled drugs in the pharmacy, as well as

- (A) supervision of all employees as they relate to the practice of pharmacy;
- (B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;
- (C) maintaining a proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;
- (D) proper display of all licenses;
- (E) annual controlled drug inventory; and
- (F) maintenance of prescription files.

Notably, **OAC 535:15-3-2(b)(4) states:** “A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager.”

**OAC 535:15-3-2(c)(1) states:** “Where the actual identity of the filler of a prescription is not determinable, the manager of the pharmacy and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board of Pharmacy.” And **OAC 535:15-3-2(c)(4) states** that the pharmacy manager must “[e]stablish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.”

It would not be possible for a PIC to exercise and fulfill these responsibilities without being physically present in the pharmacy a substantial amount of time. Keep in mind the legal aspects of the responsibilities that are assumed if you

are approached by a pharmacy for a position as “phantom” or “absent” PIC.

### 15.03. Clinical Drug Studies

The federal government has very specific regulations that deal with drug studies involving human patients. These regulations include requirements and documentation for informed consent by the study participants. In most cases, each clinical trial in the US must be approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are minimal and are worth any potential benefits. An IRB is an independent committee that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of participants are protected. Federal regulation requires all institutions in the US that conduct or support biomedical research involving people to have an IRB initially approve and periodically review the research. A clinical study is led by a principal investigator, who is often a doctor. Members of the research team regularly monitor the participants’ health to determine the study’s safety and effectiveness. Charging patients for medications in a clinical trial is governed by 21 CFR 312.8(a) and (b). In most cases, a study sponsor must obtain **prior written authorization** from Food and Drug Administration to charge for drugs used in an investigational drug study, and under 21 CFR 312.8(d)(1), a sponsor may recover only the direct costs of making its investigational drug available.

Pharmacies and pharmacists must exercise caution in their involvement in a business model that purports to be a “study” or “survey” involving human patients, and ensure that if they are involved in such a study, they have followed all applicable federal regulations. In the absence of a real “study,” a pharmacist or pharmacy that pays a prescriber to write prescriptions as a study director or medical advisor may be in violation of Board regulations and rules as well as both state and federal anti-kickback statutes. Additionally, prescribers who are requested to be participants in a drug “study” should request and review a copy of the official IRB study protocols and applicable federal study approvals before accepting a role in the study. In the absence of following the federal regulations that apply to human drug studies, prescribers may also be charged with state and federal law violations.

### Disciplinary Actions

For more information, you may view hearing minutes at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov).

#### 15.04. October 01, 2014 Board Hearing

**Candice Smith, Technician #13885 – Case No. 1284:** Admitted to guilt on four counts, including possession of a controlled dangerous substance (CDS) without a valid prescription, and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.**

**Devin Denton, Technician #16618 – Case No. 1289:** Admitted to guilt on four counts, including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

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**Dustan Conway, Technician #4343 – Case No. 1293:**

Admitted to guilt on four counts including possession of a CDS without a valid prescription and theft while working as a registrant. **Revoked.**

**Guy Sheneman, DPh #9806 – Case No. 1295:**

Admitted to guilt on 45 counts, including making or filing a report or record that he knew or should have known to be false; billing or charging for quantities greater than delivered or for a brand when a generic or a compounded product is dispensed; and submitting fraudulent billing or reports to a third-party payer of prescription drugs (for example, intentional billing for Aggrenox® name brand when aspirin 81 mg was dispensed; billing for Flovent® HFA when Ventolin® HFA was dispensed; billing for Abilify® when n-acetylcysteine was dispensed; billing for Lunesta® when zolpidem was dispensed). During the partial period audited by the Board, there was an aggregate overbilling of about \$351,496.85. Respondent agrees that he will never again own a pharmacy, an interest in a pharmacy, or an interest in an entity that owns a pharmacy. Respondent agrees to never work in a pharmacy again in any position, whether paid or unpaid. **Revoked.**

**Med-Econ Drug, Inc, #51-5055 – Case No. 1297:**

Admitted to guilt of 46 counts, including filing a report or record that the registrant knows to be false; billing or charging for quantities greater than delivered or for a brand when a generic is dispensed; providing fraudulent billing or reports to a third-party payer of prescription drugs; and failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy. **Pharmacy PIC/owner was revoked and agrees to sell all pharmacies owned by him and all ownership interests in any pharmacies, including respondent pharmacy, within 30 days from the date of the order with up to 30 days additional time possible.**

**15.05. November 19, 2014 Board Hearing**

**Impaired Pharmacist #9893 – Case No. 1298:**

Admitted to guilt on four counts, including practicing pharmacy without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition; committing theft while practicing pharmacy; and violating a voluntary or Board-ordered rehabilitation program for the impaired contract. **Registrant's license is placed on suspension for 10 years until November 19, 2024. Must enter into and abide by a 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP). Registrant may request probation after he completes a fit-for-duty evaluation.**

**Goffrey Jenson, Technician #17802 – Case No. 1299:**

Found guilty on three counts, including failing to conduct himself at all times in a manner that will entitle him to the respect and confidence of the community in which he practices and failing to notify the Board, in writing, within 10 days of a change of employment. **Revoked.**

**Andrew Clary, Technician #13442 – Case No. 1300:**

Found guilty on six counts, including possession of a CDS without a valid prescription; abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or

its metabolite; committing theft while practicing pharmacy; failing to notify the Board, in writing, within 10 days of a change of employment; and attempting diagnosis or treatment that is the legally constituted right or obligation of any practitioner of the healing arts. **Revoked.**

**Shawn Hughes, Technician #17116 – Case No. 1301:**

Admitted to guilt on three counts, including performing duties that may not be performed by supportive personnel; performing tasks while not under the immediate and direct supervision of a pharmacist currently licensed by the Board; and failing to stop dispensing functions whenever the pharmacist is not in the prescription department. **Revoked.**

**Calendar Notes**

The Board will meet on **January 14**, and **February 25, 2015**. The Board will be closed Thursday, **January 1**, for New Year's Day; Monday, **January 19**, for Martin Luther King, Jr, Day; and Monday, **February 16**, for Presidents' Day. Future Board dates will be available at [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov) and will be noted in the April Newsletter.

**Change of Address or Employment?**

**Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem, and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.**

**Special Notice About the Newsletter**

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

**Oklahoma Pharmacists Helping Pharmacists**

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext. 5773. All calls are confidential.

“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 website.”

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