



Oklahoma State Board of Pharmacy

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This special newsletter is published by OSBP in addition to the quarterly electronic newsletter which is published in conjunction with the National Association of Boards of Pharmacy Foundation, Inc. (January, April, June and July) available at <http://www.nabp.net/publications/oklahoma-state-board-of-pharmacy-newsletters/>

“The Bryan H. Potter Oklahoma State Board of Pharmacy Building”



The new Bryan H. Potter Oklahoma State Board of Pharmacy Building at 2920 North Lincoln Boulevard, just north of the State Capitol, was dedicated in September 2013. The Board offices were moved into the new building last August. Working closely through the Office of Management and Enterprise Services, and utilizing a building site on the state capitol complex which was provided without charge, the Board achieved the goal of a permanent home after renting office space for over a century. By thoughtful and frugal operation of the agency for over a quarter-century and through savings from the non-appropriated budget each year, the Board saved the building funds in advance of construction and the project was entirely paid for upon completion. This is an amazing accomplishment considering the fact that license fees charged by other states are often more than 50% higher than the fees charged by the Oklahoma Board of Pharmacy.

The Board pays the maintenance, utilities, insurance and housekeeping costs and has a 75-year lease agreement with state. The building was constructed as a 100 year expected use building and includes office space for future board expansions if needed. Currently, the Oklahoma State Dental Board and the Oklahoma State Veterinary Board lease the additional office space. The funds from those leases are applied toward the Pharmacy Board expenses, making current Pharmacy Board office costs lower than they were at the old Board offices. All three agencies share the entry foyer, common areas and board room to achieve outstanding value for the funds expended. The Board exercised a far-sighted approach to the building by investing in energy conservation engineering including high-efficiency and LED lighting, low emissivity thermal pane glass, R-30 insulation value walls and roof, and a SEER 30 rated geothermal HVAC system utilizing wells drilled 325 feet deep under the parking lot. In addition, the Board authorized funds for a 25% reserve geothermal well capacity for the building to assure efficient operation of the building for decades to come. The Board office operation has moved substantially to an electronic office, utilizing shared OMES computer server services, internet, VOIP telephones, and electronic file storage by scanning technology. Over 300 linear feet of file cabinet space, including archive and pharmacist historical license files back to 1907, have been scanned for digital storage which eliminated the need for an entire 500 square foot room which would have been dedicated to paper file storage.

OSBP-ISMP SAFETY CONFERENCE

In June, the Board hosted the ISMP-OSBP Pharmacist Safety Conference at the Oklahoma Sports Hall of Fame Event Center in Oklahoma City. The conference was provided free-of-charge as a public service to pharmacists in the interest of public health and safety and was attended by over 240 pharmacists.

Institute of Safe Medication Practices (ISMP) staff Dr. Donna Horn, R.Ph., D.Ph., the Director of Patient Safety - Community Pharmacy and Matthew P. Fricker, Jr., M.S., R.Ph., FASHP, ISMP Program Director. presented four (4) hours of ACPE accredited continuing education on the topics of:

- 1) Improving Medication Safety with High Alert Drugs,
- 2) Human Factors in Medication Safety, and
- 3) Targeted Medication Safety Best Practices.

In October 2014, the Board is hosting a free DEA Update & Drug Diversion Seminar at the Events Center. Mr. Joe Rannazzisi will present a 2 hour program on DEA regulations and enforcement and OSBP staff will provide an additional hour of CE on drug diversion detection and prevention. Seminar registration information was emailed to Oklahoma pharmacists in late August and can be found on the OSBP webpage under “Announcements”. The Board hopes to hold more pharmacy events in the future.

“COMPLIANCE WATCH LIST”

This list reflects SOME of the most commonly observed inspection violations and does not represent a comprehensive list. Registrants should review all applicable laws to ensure compliance. (This list is random and not in any specific order.)

- **Physician Name & Address:** The correct physician and physician’s office address listed on the prescription must be selected when inputting prescription prescriber information. This is required for all prescriptions, non-controlled and controlled drugs. When the incorrect physician’s office address is inputted, prescription refill faxes may be routed to the wrong office and allow protected patient information to be viewed by people at the other office who are not authorized to see it. This is an important HIPAA compliance issue. Pharmacists-in-charge and pharmacies are responsible for educational training of data entry personnel to understand the high importance of selecting the correct physician’s name and address, and assure that all pharmacists are

reviewing this information when certifying the prescription.

- **IV Fluids mixed by Nurses:** Nurses are not allowed to mix IV fluids for administration by another nurse. The nurse who mixes an IV fluid must be the nurse who administers it. Mixing and labeling IV fluids for someone else to administer is considered “dispensing” by law, and under state law only pharmacists and doctors are authorized to “dispense.” Pharmacists who practice in hospitals and as consultant pharmacists for hospital drug rooms should include this information in nursing education during orientation training and as ongoing continuing education.
- **Gabapentin Abuse Concerns:** Anecdotal reports and social media indicate that there is cause for concern regarding the increasing abuse of gabapentin. Gabapentin is not a Controlled Substance. However, gabapentin shares many characteristics of addictive drugs in that it often produces a withdrawal syndrome and has psychoactive effects. Pregabalin, a close relative of gabapentin, is a Controlled Substance. Pharmacists should consider the abuse potential of gabapentin when patients continuously request “early refills” or offer to pay cash for the medication when insurance carriers deny payment due to an early refill.
- **No “Pharmacy Technicians” in Hospital Drug Rooms:** Oklahoma permitted pharmacy technicians may only work in licensed pharmacies under the supervision of a pharmacist. This does NOT include licensed hospital drug rooms. If they are working in a hospital drug room, they may no longer renew their permit nor call themselves a “pharmacy” technician. They may perform only those duties allowed to drug room technicians. Please review the law book for more information.
- **Sterile & Hazardous drug compounding:** Oklahoma resident and non-resident pharmacies “compounding and dispensing sterile therapeutic preparations” must obtain a Parenteral Permit from the Board in addition to their pharmacy license. Pharmacies which provide sterile compounding services must have a sterile compounding hood and meet <USP 797> standards.

Pharmacies which compound hazardous drugs must have a Biological Safety Cabinet (BSC) in which to compound the medications. Annual documentation of pharmacist and technician training is required.

Biological Safety Cabinets (powder hoods) and sterile compounding hoods must be inspected, tested and certified to assure they are working properly BEFORE initial use and on a regular schedule thereafter. The schedule of retesting is dependent upon the use of the hood. For sterile compounding, the requirement is every 6 months. Many companies provide this service.

Pharmacies must keep documentation of the inspection and test results for review by the Board. Review both the non-sterile and sterile compounding rules for guidance on the recertification schedule.

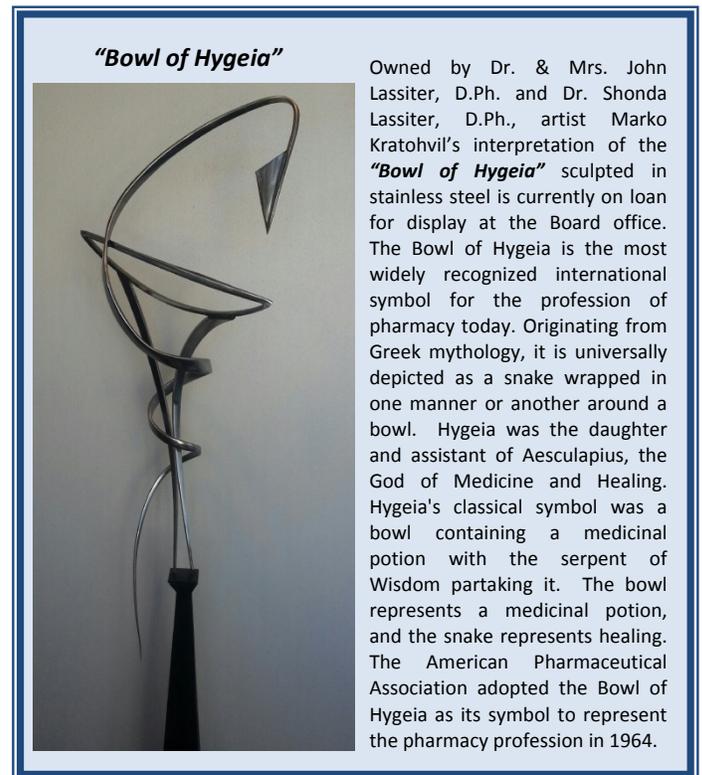
- **Sale of medications to physicians or other pharmacies:** Oklahoma resident Retail pharmacies which “supply legend drugs to licensed practitioners for their office administration and/or to hospitals and other licensed pharmacies for their dispensing” (medications which are not filled on a patient-specific prescription) must obtain a Drug Supplier permit in addition to their pharmacy license. Records of sales must be documented by invoice.
- **Immunizations:** Pharmacists must have a current Immunization Permit to provide influenza and other vaccine immunizations. Pharmacists who immunize must maintain ongoing competency through required training such as CPR and continuing education. The immunization permit and current CPR certification must be displayed with the pharmacist license. Floating pharmacists should carry a copy of their immunization permit and current CPR certification with them at all times. Check the Board website for immunization permit requirements and applications.
- **Technician Training Phase II:** If a pharmacy technician fails to complete Phase II of training (on-the-job training) within 90 days of the date their technician permit was issued, the pharmacy manager MUST notify the Board in writing. The technician permit is automatically VOID and the permit MUST be returned to the Board (535:15-13-13). It is the responsibility of the pharmacy manager and the pharmacy documented on the original technician permit application to notify the Board. Failure to notify the Board in writing is a violation of Board rules and regulations and may result in Board action.
- **Technician Training File:** Educational training of technicians must be documented in their training file. Technicians who compound medications must have documented training in the type of compounding they do. Technicians who do sterile compounding must have sterile compounding training that includes requirements such as glove fingertip sampling included in 535:16-10-52(d)(f).
- **PMP submissions:** Don’t strip off the first letter before the Driver’s License number prior to PMP submission. Always use the patient’s legal name on PMP submission. Closely watch any notations in fields that may get inadvertently transmitted. (i.e. “don’t fill again,” “sex offender,” etc.).
- **Compounding pharmacies and Beyond Use Dates:** Compounding pharmacies should review USP 795 and USP 797 beyond use date (BUD) assignments for compliance. PICs should determine the risk level of the compounding they practice in their pharmacies, and verify that the

BUDs assigned to products in their pharmacies meet the standards. There are very specific BUDs in the FDA and OSBP regulations, as well as the methods which may be used to test for and determine an extended BUD for a compounded medication.

- **Technicians Cannot Counsel:** Counseling patients regarding their medications is a hallmark of a pharmacist's practice of pharmacy and is encoded in rule and law. The requirement that a pharmacist provide counseling is stated in OSBP rules in section 535:10-9-2. OSBP rules 535:15-5-7.5.(6) and 535:15-13-7(7) and some federal statutes specifically forbid pharmacy technicians from counseling patients. PICs should review this with technician staff. Technicians who counsel are subject to board action.
- **Old prescription labels:** Do not place a new prescription label over an old prescription label on a bottle that was filled but not picked up by the patient. Always remove the old label. Blacking out the patient name and information on the label with a marking pen is not sufficient as alcohol can be used to wash out most marking pen ink, allowing HIPAA protected patient information to be viewed. Pharmacies may mark out the patient information when the prescription is "returned to stock" awaiting use in a future prescription. Prescription labels on bottles should be removed and shredded before being placed in the trash. "Marking out" a prescription label does not prevent a person from using alcohol or another solvent to remove the mark-out ink and exposing protected HIPAA information.
- **Verification of licensure before purchase:** Pharmacists-in-Charge must assure that any company or wholesaler their pharmacy purchases drugs from is licensed by the Board of Pharmacy. You may check the status of any Board licensee on the Board website. If you are unfamiliar with the company or wholesaler, ask them to fax you their Oklahoma Board license AND their license from their resident state. PICs should also check the company's resident state website to verify current licensure. Inspectors often find medications and bulk compounding drugs from "Canadian" or other suppliers which are not FDA approved and are not licensed in the US or in Oklahoma. Drug suppliers cannot ship drugs into the US without FDA approval. Sometimes, the drug has been approved by the European Union's equivalent of the FDA, but this is not accepted by the FDA. And at times, the drug has no approval at all and may be counterfeit.
- **Pharmacies providing filled prescriptions to patients in other states:** Oklahoma licensed pharmacies who mail or ship filled prescriptions to patients in other states must review the licensing requirements of the state into which they are sending medications to assure compliance with

that state's laws. Nearly all states require that out of state pharmacies shipping products into their state must be licensed by the state into which they are shipping. Many states also require that the pharmacist-in-charge be licensed to practice pharmacy in that state. In addition, state laws should be reviewed on a regular basis to determine if there have been changes in licensing requirements. Many states are implementing more stringent regulations and rules regarding prescriptions shipped across state lines.

- **APRN's dispensing:** The Oklahoma Board of Nursing has determined that APRN's may not dispense prescription medications from hospital emergency rooms. Physicians may dispense as long as all applicable regulations and rules are followed.



Drug Diversion Detection & Prevention

Pharmacies are required to have a written Drug Diversion Detection and Prevention Policy. The Policy must outline the procedures that the pharmacy uses to control diversion of all drugs from the point of ordering the drug through delivery of the prescription to a patient. The policy does not need to be a lengthy document. The policy should address the ordering, receiving, and check-in processes as well as the dispensing process. Other items which should be included in the policy are persons who are authorized to be in the pharmacy and/or have key access, review of invoices, inventory controls, and use of electronic equipment such as video.

The Board recommends that a perpetual inventory be kept of all Schedule II drugs plus alprazolam products. A minimum policy might include a perpetual inventory of Schedule II drugs and at least counting full bottles of

alprazolam products as often several dozen stock bottles of 500 tablets have been stolen before the pharmacist-in-charge discovers the diversion is occurring.

The policy should also address such items as bringing large purses, backpacks and coats into the pharmacy, and large drink containers which have been used to slip large stock bottles out of the pharmacy. Spilled tablets and capsules should never be left on the floor, but should be picked up immediately to keep them from being diverted. The policy should include restrictions or procedures for employees entering, filling or checking out their own prescriptions. Routine bag checks and video surveillance camera reviews often result in discovery of theft. Random drug screens should also be considered as part of a diversion control plan.

How Could I Make That Error?

Ever hear of “inattentional blindness”? It refers to the failure to see something that is not expected to be seen, like a drug utilization review alert, and it tends to be involuntary. A verifying pharmacist is not expecting a dose to be wrong and consequently is “inattentively blinded” and does not “see” the high dose alert, overrides it, and dispenses an overdose. The pharmacist saw what he or she expected to see as they looked at an order on the computer screen and mentally filled in the missing dose as it is typically ordered, even though it was incorrect.

Pharmacists must be aware of what factors contribute to inattentional blindness, those being one’s capacity to pay attention (altered by lack of sleep and fatigue); one’s expectation (confirmation bias); and one’s mental workload (distractions, multitasking). Advice: get ample rest, focus on one task at a time, and expect the unexpected!

Cell Phone Use by Pharmacy Staff

Pharmacists-In-Charge should monitor cell phone use by their pharmacy staff to ensure that they are not taking pictures which have identifiable protected patient information in them such as prescription labels or patients at the counter. This is a HIPAA compliance issue. The Board has investigated cases which involved pharmacy staff using cell phones to text information to an accomplice that a CDS prescription had been filled and that they should come through the drive-through window and they would “sell” it to them rather than the patient. The Board has also investigated cases involving pharmacy staff that “tweeted,” texted, or sent social media posts that included protected information about patients which violates HIPAA regulations.

Prescription Errors and Distractions

Many prescription error reports received by the Board cite “excessive noise” and “telephones ringing” causing distractions as the root causes of the error. Airlines have addressed some of their distraction problems with a term they call the “Sterile Cockpit Rule.” Pilots are required to refrain from non-essential activities during

critical times such as take-offs and landings. In the same manner, PICs should review the working environment of their pharmacies to find ways to help decrease such distractions and establish them in their policy and procedures. For example, while we all enjoy music, a reasonable volume should be established by the PIC as well as selecting non-distracting music. Songs with words are more likely to cause distractions because we tend to “sing along” with them, causing our attention to wander from the important tasks at hand. Oftentimes, many of the distracting telephone calls are not business related, but are instead technicians and clerks receiving numerous personal cell phone calls, texts, tweets, and social media updates while they are working on critical prescription input and filling tasks.

Hospitals and compounded medications

Hospital pharmacies and drug rooms which purchase compounded medications from out-of-state pharmacies must review the pharmacy’s resident state regulations to assure that it is permissible for them to compound non-patient specific medications. While Oklahoma currently allows pharmacies to compound non-patient specific medications for administration in hospitals and physician offices, many states do NOT allow this practice. It has been reported that some out-of-state pharmacies will use one patient name, often not a real patient’s name, on an entire order of hundreds of doses in an attempt to circumvent their state’s laws. PICs must review the state laws of the compounding pharmacy’s resident state before purchasing products to assure they are in compliance with their regulations on this issue.

Prescription Drug Bottle Recycling

There have been reports nationwide where pharmacy employees have been contacted and requested to “save” empty name-brand prescription drug bottles for a plastic recycling company. The amount paid per empty bottle varies. But rather than recycling the plastic bottles, the bottle is refilled with counterfeit medication and resealed to look like an original unopened bottle. The counterfeit is then resold outside the normal distribution channel in a manner such as when a pharmacy receives a fax from an unknown wholesaler or other company offering a drug that is in short supply or at a substantial price reduction.

No doubt there are legitimate plastic recycling companies who do recycle prescription drug bottles. However, the Board strongly recommends that if you do send plastic bottles for recycling, please obliterate the bar code and lot number information on the bottle to stop it from being used to allow counterfeit medication to enter the nation’s drug supply. In addition, always do “due diligence” to assure that any drugs you purchase come from legitimate companies who are licensed by the Board to ship into Oklahoma.

Director’s Commentary

Common Sense Directions — In the medical world, we often take for granted that everyone knows the basic mathematic, metric and common medical abbreviations.

Using the 1 mL equals 1 cc equivalent, or 0.25 teaspoons means 1/4th teaspoon is second-nature to prescribers and pharmacists. However, this is not the case with many of our patients.

For example, a prescriber may write a prescription for an IM injectable solution with directions of “1 cc every 14 days”. While it might be absolutely correct for the pharmacist to dispense the prescription with directions written exactly like that, syringes are labeled in mL increments and we often do not know if the patient understands that 1 cc = 1 mL. Most pharmacists would clarify the labeling to read “Inject 1 mL intramuscularly every 14 days” to help the patient better understand the directions. The same situation occurs when a prescriber writes “give 0.25 teaspoons every 4 hours” and the dropper that comes with the medication is labeled in mL increments rather than teaspoons. Most pharmacists would clarify the labeling to read “give 1/4th teaspoon (1.25 mL) every 4 hours” to help the patient utilize the dose dropper correctly.

The challenge we have today with the situations above is that in most cases technicians are inputting the prescription data and they input it exactly as the prescriber has written it. And their job performance often depends on accuracy metrics which are calculated using the number of times the pharmacist sends the prescription back for correction or **clarification** of the directions. Thus, when the pharmacist sends a prescription back for clarification of the directions, the correction is counted “against” the technician in both job performance evaluations and sometimes their paycheck. I’ve seen “error lists” in some pharmacies where the technicians with the highest number of “clarifications” are posted for everyone to see. This puts the pharmacist in the awkward position of either dispensing a prescription with directions that, while absolutely correct, may increase the chances of a medication dose error OR sending the prescription back for clarification of the directions which then causes the technician that inputted the information to be fearful of becoming targeted by their employer for input errors. This often creates a tense situation between the pharmacist and technician.

Pharmacists “practice” pharmacy and part of the responsibility of the pharmacist “practicing” pharmacy is to assure that the directions on the prescriptions they dispense are accurate, clear and understandable for their patients. We have all seen the consequences of dosing errors caused by directions such as “give .50 mg daily” and the decimal was missed and 50 mg was given. Or the medication was in liquid form and the 0.5 mg dose was interpreted as 0.5 mL—but the medication strength was 10 mg/mL—a ten-fold error. My point to this commentary is that pharmacy management policies must NOT create situations in pharmacies whereby pharmacists are discouraged from sending prescriptions back to technicians for clarification of the dose directions due to the fear of adverse impact on the technicians resulting in a tense environment in the pharmacy.

While dispensing a prescription written for ibuprofen liquid with the directions of “0.5 cc every 4 hours prn”

may be exactly what the prescriber wrote, common sense and professional practice standards give the pharmacist the motivation that if the syringe or dropper is marked in mL increment designations the label directions should be clarified to state the route of administration and the dose unit of measure to help the patient receive the correct medication and dose. Some clarification language such as “0.5 cc (0.5 mL or ½ mL) by mouth” is much easier for the patient to understand when the dropper or oral syringe is labeled in mL increments. In any event, the pharmacist is responsible for “interpreting” the wording on a prescription. There should be no impediment for a pharmacist to return a prescription to a technician for clarification or clarify the wording themselves due to company “policies” which create a dis-incentive for application of pharmacist professional judgment by penalizing the input technician when the prescription directions need a professional judgment decision.

