



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/>.

Rules Changes & Reminders

- Compounding pharmacies may not compound sterile products for office-use. If a facility wishes to compound sterile products for office use, they must register with the FDA and the Board of Pharmacy as a 503(b) outsourcing facility and abide by CGMP standards rather than USP 797 standards in Oklahoma. A compounding pharmacy is permitted to compound non-sterile products for office-use.
- All licensed facilities must have a written drug diversion detection and prevention policy. If you have questions regarding a policy, a guide may be found at:
https://www.ok.gov/pharmacy/documents/DRUG%20DIVERSION%20D%26P_GUIDE.pdf
- Pharmacies may not sell prescription drugs to wholesalers and wholesalers cannot buy from pharmacies. This does not prohibit the return of medications purchased from the wholesaler or the return of outdated or unsaleable merchandise.
- Technicians may take refill authorizations from prescriber's office when no changes have been made to non-controlled prescriptions. The pharmacist must take a refill authorization when changes have been made to the strength or directions for a non-controlled prescription. The pharmacist must take any refill authorization for a controlled prescription as OBND defines this as a new prescription.
- Technician training must be updated and documented on an annual basis. The PIC and pharmacy may determine the type of technician training based on the pharmacy practice (i.e. test, in-services, web-based, conferences, etc.) The documentation must be available in the pharmacy.
- There may be no arrangements between any registrant and prescriber in which fees are divided or there are private formulas. There also may not be any agreements between any registrant and prescriber to require prescriptions to be sent only to a particular business. There may not be automatic refills of prescriptions without patient consent.

Pharmacy Law Update

An important change in the Pharmacy Act which goes into effect on November 1st allows a pharmacy to deliver or ship patient-specific filled prescriptions to a prescriber's office or clinic, in certain situations where it is in the best interest of the patient. These include:

- a. patient-specific filled prescriptions may be delivered or shipped to a prescriber's clinic for pick-up by those patients who the prescriber has individually determined and documented do not have a permanent or secure mailing address,
- b. patient-specific filled prescriptions for drugs which require special handling written by a prescriber may be delivered or shipped to the prescriber's clinic for administration or pick-up at the prescriber's office,
- c. patient-specific filled prescriptions, including sterile compounded drugs, may be delivered or shipped to a prescriber's clinic where they shall be administered,
- d. patient-specific filled prescriptions for patients under Medicare and/or Medicaid for End Stage Renal Disease (ESRD) may be delivered or shipped to a prescriber's clinic for administration or final delivery to the patient, or
- e. patient-specific filled prescriptions for radiopharmaceuticals may be delivered or shipped to a prescriber's clinic for administration or pick-up.

Examples of an insecure mailing address might include a situation where the medication might be stolen or lost if sent to a mailbox; or if a patient lives at a shelter or other temporary housing. The prescriber should document the problem in the patient's chart and the pharmacy is responsible to monitor requests to ship to the prescriber's office. It would not be likely that all of the prescriber's patients would have an insecure mailing address.

Examples of special handling might include situations where the medications must be kept at specific temperatures or the prescription must be administered by the prescriber. The prescriber may also determine that it is in the best interest of the patient to receive part of the prescription at a time rather than the full quantity. This might be especially appropriate for a mental health patient.

Non-Resident Pharmacy Inspections

Effective November 2015, all non-resident pharmacies are required to have had an inspection by their resident state board of pharmacy or a company approved by the Oklahoma State Board of Pharmacy (OSBP) within the last 2 years of their initial application or last renewal. (OSBP inspects all resident pharmacies, manufacturers, wholesalers, hospital pharmacies and drug rooms, and medical gas suppliers on the average of once each year. Some states do not inspect regularly, if at all.)

The date of the last inspection is required on both a new pharmacy license application and a renewal application. Failure to do so may result in the application being returned and not being renewed before the license expiration. Pharmacies are not allowed to ship prescriptions into Oklahoma without an active non-resident pharmacy license.

It is the responsibility of the pharmacist-in-charge (PIC) to assure that the pharmacy has been inspected within the past two years. If they have not, the PIC should contact their resident state board and if they do not plan to inspect every two years, then the PIC should contact the OSBP for information on companies which have been approved to provide non-resident pharmacy inspections.

FDA Draft Guidance Document

FDA has released a draft guidance document for industry on a hospital pharmacy compounding drug products for associated hospitals under the same ownership and control. A draft guidance document represents the current thinking of FDA on an issue and, while it does not have the force of law, it does often represent the track that FDA plans to take on an issue.

The draft document includes guidelines which health systems may want to review as they configure their business models to conform to future regulations and rules. In general, pharmacies are not allowed to compound sterile drugs for transfer to another pharmacy for dispensing as this would probably be considered manufacturing.

Keep in mind that an FDA registered outsourcing facility must comply with current Good Manufacturing Practices which are more stringent than USP<797> standards.

The entire draft guidance document is available at the FDA website.

[Excerpt from the FDA draft guidance document]

However, FDA does not intend to take action if a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription or order provided that:

(1) The drug products are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy;

(2) The drug products are only administered within the healthcare facilities to patients within the healthcare facilities⁸, pursuant to a patient specific prescription or order; and

(3) The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions (section 501(a)(2)(A)) or misbranded (e.g., section 502(g)).

The 1-mile radius in our (FDA) policy is intended to distinguish a hospital campus from a larger health system. As explained in section II.B of this guidance, certain characteristics of hospital pharmacies distinguish them from conventional manufacturers. However, a health system pharmacy that compounds drug products without patient-specific prescriptions for facilities within its health system across a broader geographic area could function as a large manufacturing operation, but without the necessary standards to assure drug quality. If such a pharmacy contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the potential to harm many patients. Outsourcing facilities, which are subject to CGMP requirements and other conditions that help to assure drug quality, can compound and distribute drug products to healthcare facilities nationwide without first receiving prescriptions for identified individual patients.

B. Hospital or Health System Compounding Under Section 503B of the FD&C Act

A compounder can register as an outsourcing facility if it intends to provide compounded drugs to facilities such as other hospitals or clinics outside the 1 mile radius of the pharmacy in which the drug is compounded without first obtaining a prescription for an identified individual patient.

Registering as an Authorized Collector with DEA

In September 2014, the DEA passed legislation allowing pharmacies to dispose of patient's controlled substances if they were properly registered as an authorized collector with the DEA. At that time the OK Bureau of Narcotics and Dangerous Drugs (OBND) did not allow pharmacies to take possession of controlled substances from patients. They have since changed their rules and Oklahoma pharmacies may register with the DEA as an authorized collector. They may use collection receptacles or participate in mail-back programs.

It is very important to understand that pharmacies may only dispose of medications that have been dispensed to patients through this program. All expired or unusable controlled substances that belong to registrants (i.e. pharmacies, prescribers) must be disposed of and accounted for properly through a reverse distributor or wholesaler.

More information regarding registration with the DEA may be found at:
http://www.deadiversion.usdoj.gov/drug_disposal/index.html

You may also refer patients to the nearest OBNDD take-back location for destruction of medications. They do not take liquids, inhalers, or syringes. Locations may be found at: <https://portal.obn.ok.gov/takeback/default.aspx>

Immunizations / Storage of Vaccines

Pharmacists who are administering vaccines must have an immunization permit from the Board of Pharmacy. They must also maintain current CPR certification and keep it available for compliance officers upon inspection.

The CDC has published best practices for the proper storage of vaccines. It is essential for pharmacists to maintain the “cold chain” of vaccines. CDC does not recommend and Vaccines For Children (VFC) does not allow storage of any vaccine in a dormitory-style refrigerator under any circumstances. CDC discourages the use of combination refrigerator/freezer units because they have a single refrigeration condenser and the freezer compartments in these units have demonstrated that they are not capable of maintaining correct temperatures for frozen vaccines.

It is recommended to remove the crisper bins and place water bottles in the bottom to help maintain a consistent temperature. Have a centrally-located certified, calibrated thermometer in both the refrigerator and the freezer. Record temperatures twice daily and initial the log.

You must be complying with all aspects of proper storage if you are participating in the VFC program in Oklahoma. There is much more information located at either of these two websites:

https://www.ok.gov/health/Disease_Prevention_Preparedness/Immunizations/Vaccines_for_Children_Program/

<http://www.cdc.gov/vaccines/recs/storage/default.htm>

Absentee PICs

With the new requirement that non-resident pharmacies must have an Oklahoma licensed pharmacist-in-charge (PIC), the Board has noted a disturbing trend whereby some non-resident pharmacies are attempting to employ an “absentee” or “phantom” PIC. We have discovered pharmacies who have “hired” a pharmacist with an Oklahoma license to sign the applications or renewals for the pharmacy license and sterile drug permit without the pharmacist ever setting foot in the pharmacy. In many cases, the pharmacist is also not licensed in the state where the non-resident pharmacy is located and thus they would not be allowed to practice in the pharmacy at all. And in some cases, the pharmacist is already the PIC of an Oklahoma resident pharmacy and is violating the regulations by signing documents that represent he is PIC of more than one pharmacy.

Board rule **535:15-3-2. Pharmacy responsibilities** clearly outlines the duties of a pharmacy manager or PIC. Section (b)(4) states: *“A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager.”*

It has come to the Board’s attention that there are some staffing companies that have a business model whereby pharmacists are contracted to be the PIC of a pharmacy during the license application period, and even after licensing. In one case reported to the Board, the Oklahoma licensed pharmacist was living in another country 8,000 miles from the location of the pharmacy that the staffing company was trying to hire him as the PIC. There is not a way for a pharmacist to fulfill the responsibilities of being a PIC without actually working in the pharmacy.

It is vital that pharmacists understand the significant responsibilities and liabilities they are accepting when they become a PIC. The Board does not take lightly the violation of regulations which occur when a pharmacist becomes a “phantom” or “absentee” PIC. Several pharmacists and pharmacies have been disciplined for these violations. Do not allow your license and good name as a pharmacist to be put at risk by non-resident pharmacy owners who appear to be attempting to violate the law which requires non-resident pharmacies to have an Oklahoma licensed PIC.

Changes/Additions that may be made to C-II Prescriptions

According to OBNDD regulations, if an error is made in filling out a C-II prescription, a new prescription must be written by the prescriber.

However, if the following items have been omitted from a C-II prescription, a pharmacist may add them to the prescription:

- Patient address,
- Patient age, and
- Generic name of drug.

After consulting with the prescriber, the following may be added and documentation of contacting the prescriber must be noted on the back of the prescription:

- Dosage form, and/or whether it is to be compounded,
- Directions for use,
- Quantity, and
- Prescriber’s DEA number *

** A recent letter from the DEA dated May 2, 2016 allows the pharmacist to add the DEA number to a prescription after confirmation with the prescriber.*

Items that may NOT be added to a C-II prescription are:

- Prescriber name,
- Drug name,
- Date of issuance, and
- Patient name.

Do not erase, use white-out, or mark-out anything on a C-II prescription.

Clarifications may be made for things such as a drug name being misspelled, a patient’s name being misspelled or changing a maiden name to a married name, but the name of the patient may not be changed if it is the wrong patient.

Controlled Electronic Prescriptions And Transfers

Electronic prescriptions are becoming more commonplace. If your software is certified, it is permissible by law to fill electronic prescriptions, including C-II's. Electronic prescriptions must be electronically stored and do not need to be printed out, but can be printed if you choose. Electronic signatures are only valid for electronic prescriptions. Faxed and original controlled drug prescriptions must have a manual, written signature. CIII-V prescriptions that have a computer generated signature must be verified by phone and documented as a verbal order.

According to DEA regulations, if a controlled prescription is electronically transmitted to a pharmacy and cannot be originally filled at that pharmacy for any reason, it may NOT be transferred to another pharmacy by the original pharmacy. The prescriber must be contacted and the prescriber must re-transmit the prescription to another pharmacy.

Once an electronic prescription has been initially filled, it is permissible for a patient to transfer remaining refills to another pharmacy.

Continuing Education Audits

When a pharmacist graduates from pharmacy school, they have some of the most up-to-date education available in the profession. After graduation, continuing education becomes the tool that professionals use to hone their education, stay up-to-date in the profession, and develop new skills. As former board member Dr. Gordon Richards, Jr., often said, your education is like a tool box and it is your responsibility as a professional to add new tools to that tool box to take care of your patients.

In this light, pharmacists should view continuing education as an opportunity to stay current in their scope of practice. If you are a medical center pharmacist at a pediatric hospital, it is common sense that you would take some CE courses in pediatric pharmacy. If you are a community pharmacist, it is common sense that you would take courses such as the ISMP Community Pharmacy Risk Assessment program to help you develop new skills to decrease errors. In other words, it is important to take some courses in the areas of your practice and not just "whatever is easiest to get."

Oklahoma was one of the first states to require CE for a pharmacist to renew their license. The Board is proud of the fact that Board CE audits find very few Oklahoma pharmacists who have failed in meeting the requirement for CE. Some states have a very different experience. A recent story in the Idaho State Board of Pharmacy newsletter noted that "more than 30% of all audited Idaho pharmacists did not complete the minimum legal requirements." This is disappointing. Pharmacists are professionals and our patients expect and deserve us to be compliant with our continuing education requirements and be up-to-date on our drug information.

Last year, the Board provided several free continuing education programs around the state. The ISMP Safety Conference lunch programs sponsored in Oklahoma City and Tulsa in 2015 are noteworthy in that Oklahoma is the only pharmacy Board in the country that designates the extensive funding required to present such high-quality, nationally known speakers without cost. In 2014, the Board sponsored both an ISMP Safety Conference, and a DEA Conference featuring Dr. Joe Rannazzisi. The Board also sponsored four 3-hour Board Approved CE regional law seminars in 2015 provided free of charge. These were held in Oklahoma City, Tulsa, McAlester and Lawton.

On June 23rd, the Board plans to host a major 3-hour ACPE approved CE event in Oklahoma City on USP <797> Compounding Requirements. Contact the Board if you are interested as availability is limited!

In addition, this fall we will host four law CE seminars in Oklahoma City, Tulsa, and two other new locations to encourage attendance. These events showcase the Board's outreach to provide quality education as a service to the profession. Make sure you are signed up for emails on our website to get updates for events such as this.

Error Reduction Ideas

A recent article in the Wyoming State Board of Pharmacy newsletter highlighted a pharmacy which has created a novel way to assure patients are counseled properly when the dispensing pharmacist determines the need. The pharmacy enacted a policy where the pharmacist affixes a caution label over the checkout barcode stating that counseling is required.

Clerks and technicians are told that they are never permitted to remove the caution label. The policy allows only a pharmacist to remove the label after the counseling is completed. The label covers the barcode preventing the completion of the checkout process. When the prescription is picked up, the clerk simply informs the patient that "the pharmacist will be performing the prescription's final check" and the pharmacist comes to the counter to counsel the patient. If the patient refuses counseling, the pharmacist asks them to sign the refused counseling log. This type of process developed by a pharmacy manager to assure proper patient counseling is only one of a number of ways that pharmacists across the country are developing their own "best practices" for their patients.

The Board also considers counseling to be one of the best error-prevention ideas available. The high majority of prescription misfills that are reviewed by the Board would have been easily detected if the pharmacist had counseled the patient. Some examples of this include a 2 oz tube of erythromycin acne ointment dispensed with instructions to use in the eyes, a prescription with the wrong patient name on it, and a prescription labeled with a dose of "7" instead of a "1". Counseling is a vital part of our profession, and our patients trust us to provide them the information they need, even if at times they

may not realize they need it. The Board encourages pharmacies to develop ways to implement required patient counseling as a part of their error prevention procedures, and then assure that technicians and clerks follow the policies on counseling. This is just one more way to provide our patients the best of what the profession of pharmacy has to offer.

USP <800> Hazardous Drugs

The revised chapter of USP <800> regarding hazardous drugs (HD) was published on February 1, 2016. It will not be implemented until July 1, 2018 but do not wait until 2018 to prepare. This relates to all places where HDs are prepared, stored, transported and administered. It applies to both sterile and non-sterile compounding.

Most pharmacies will need significant renovations if they intend to continue to compound HD. Identify all HD in your facility and store them separately from all other drugs in a negative pressure room with at least 12 air changes per hour. HDs include, but are not limited to, those listed by the National Institute for Occupational Safety and Health (NIOSH). Your staff will need to be properly trained to receive, handle, compound, and transport HD as well as handle spills. Competencies must be documented for all staff and appropriate equipment must be installed correctly and certified. You may purchase a copy of USP <800> at www.usp.org.

Loperamide Abuse

The Board has received reports of at least three overdose deaths of Loperamide in the State of Oklahoma from the Medical Examiners' office. It is used in extremely high doses to combat opiate withdrawal and can be habit forming according to some sources. High doses of Loperamide can prolong the QT interval and cause heart arrhythmias. Please educate your pharmacy staff and be wary of large purchases.

Beyond Use Dates for Non-Sterile Compounded Preparations

For water containing or aqueous based topical/dermal and mucosal liquid and semisolid formulations the BUD may be no longer than 30 days.

For water containing or aqueous based oral formulations the BUD may not be longer than 14 days when stored under refrigeration. Even when you add an active pharmaceutical ingredient (API) to an already manufactured liquid that has a water or aqueous component, the BUD should not exceed 14 days when refrigerated.

For non-aqueous formulations the BUD may not be longer than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.

Watch the expiration dates for all ingredients used including the non-active ingredients. The BUD cannot exceed the expiration date of any ingredient used in compounding the preparation.

The USP-NF standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (e.g., the same drug concentration range, pH, excipients, vehicle, water content, etc.).

Director's Commentary: Counseling

Recently I was at a pharmacy and observed the check-out area for several minutes. Probably a dozen patients came to pick up their medications during the time I was observing. During that time, not a single patient was counseled on their medications. Each time a patient came to the checkout to get their prescription, the clerk or technician pushed a document to them and said "please sign this." Not one time was a patient asked if they wanted to speak to the pharmacist nor did the pharmacist come to the counter to counsel the patient. I happen to know that the pharmacy (one of many under a corporate ownership) has a policy and procedure that requires the pharmacist to counsel the patients on many prescriptions—but the clerk and technician staff have obviously been allowed or trained to ignore that policy.

When the Board investigates misfilled prescriptions, it is evident that the vast majority of misfills would not have made it to the patient if counseling had been provided to the patient. This fact alone should be enough to encourage pharmacists to assure that patients are counseled.

It is vital that pharmacists-in-charge understand that THEY are personally responsible to ensure that the policies and procedures of the pharmacy are followed, and that the technicians and clerks are trained properly and follow the policies and procedures. The pharmacy itself may also be held accountable, but in most cases the primary responsibility for compliance will fall on the pharmacist-in-charge. Pharmacists-in-charge should not take their responsibility lightly. Failure to counsel is a primary principle of pharmacy and will be enforced by the Board.

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