



Oklahoma State Board of Pharmacy

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“TOP 10 COMPLIANCE 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.)

- **Telephoned prescriptions:** Pharmacists must take new telephoned prescriptions from a physician's office. Technicians are prohibited by law from receiving telephoned prescriptions. [OAC 535:15-5-7.5.]
- **Transferred prescriptions:** Prescription transfers must be between two pharmacists or interns. Technicians are prohibited from taking prescription transfers. [OAC 535:15-3-12.]
- **Invoice Files:** Three (3) files for invoices must be maintained. Schedule II, Schedule III-V, and unscheduled. [OBN 475:25-1-4.]
- **CII Orders:** DEA 222 forms must be completed when received.
- **Documentation:** A new telephoned prescription should be immediately reduced to writing immediately by the pharmacist with documentation of the pharmacist who took the prescription. Pharmacy policy and procedure should address this, and the PIC is responsible for assuring accurate documentation policies and procedures are followed. If the pharmacist who took the prescription cannot be identified, responsibility for the prescription is assigned to the PIC.
- **Signed Logs:** Prescription logs must be signed on a daily basis by each pharmacist who was involved in dispensing prescriptions that day. [OAC 535:15-3-21 and CFR 1306.22]
- **Employee Identification:** Technicians must not work as clerks while wearing a “TECH” name badge. [OAC 535:15-3-2(e)]
- **New Telephoned Prescriptions:** A new telephoned prescription MUST be entered into the computer system as a new prescription. If the pharmacy scans new prescriptions, then the new telephoned prescription must be scanned and entered as a new prescription. Retrieving a patient's old prescription information from the computer and creating a new one from that data,

even if it is by the same physician and for the same medication and directions, is not permissible. The new telephoned prescription which is reduced to writing will have the receiving pharmacist's identification and thus MUST be filed for documentation of responsibility.

- **Document Invoices:** All CIII-V invoices must be dated when received. [21 CFR 1304.21(d)]
- **Electronic Prescriptions (e-prescribing):** Electronic prescriptions are becoming more and more common. A pharmacy may receive an electronic prescription via computer or fax machine. But beware, not all electronic prescriptions are legal. The prescription is valid ONLY for medications that are not controlled. An electronically prescribed CDS prescription is not valid for dispensing since there is no manual physician signature. Pharmacists must contact the prescriber for a valid phone prescription. For an electronically prescribed CDS prescription to be legal it MUST be transmitted on a software system certified by the DEA or a DEA approved certification provider. Software vendors must provide pharmacies and physicians with a copy of the certification upon request. If this type of prescription is received, it must still be printed off and filed as a written prescription. As always, faxed prescriptions for CDS signed manually by the physician before faxing are valid, but must be printed by the receiving pharmacy and filed as a written prescription. [21 CFR 1311.170]

One CDS Drug Allowed per Written Prescription

OBN regulations require that each prescription for a CDS must be written on a separate prescription. The following regulation is specific to written prescriptions for CDS.

Title 475 – Oklahoma State Bureau of Narcotics and Dangerous Drug Control

475:30-1-4(c)(3). Manner of issuance of prescriptions
(3) Each scheduled drug shall be written on a single prescription form, and no other prescriptions (controlled or non-controlled) shall be written on the same prescription form.

New Technician Application Includes Exam

Beginning April 1, 2012 the application for a new pharmacy technician will include an exam containing law and conversion questions. This exam is to be used as a training tool. A pharmacist shall administer this exam as a prerequisite before approving an Oklahoma State Board of Pharmacy technician application. The pharmacist shall **correct** the exam, **review** incorrect answers with the technician applicant, and **keep the original exam in the technician's training file** for review by Board staff during inspections. The pharmacy policy and procedure training manual should reference this examination. The Board will rely on the pharmacy to determine a successful exam score. The exam may be administered as an open book exam if desired by the pharmacist conducting the technician training. Answers are not provided for the exam as pharmacists should know the answers, **but the law book reference which provides the answer is noted by each question. Please destroy all previous copies of the pharmacy technician application and use the new technician application available at www.pharmacy.ok.gov.**

Information Regarding Disposal of Controlled Substances

DEA regulations do not allow a registrant to accept controlled drug substances (CDS) from anyone except a registrant. DEA regulations also do not allow a registrant to destroy medications in any manner except by a reverse distributor.

Some frequently encountered situations:

1. If a prescription for a CDS has been dispensed, a DEA registrant shall never accept it back under any circumstance. Registrants include any person or entity that holds a DEA license including pharmacies and practitioners.
2. A DEA registrant shall always dispose of unwanted CDS in their inventory through a Reverse Distribution Service (RDS).
3. A CDS in a pharmacy or a physician's office that is not in the original manufacturer's packaging, such as a prescription in a vial that was not picked up by a patient OR a compounded CDS prescription medication, must be disposed of through a DEA approved Reverse Distribution Service. Some RDS may not accept medications that are not in the original manufacturer's package or compounded medications by company policy. In all cases, it is the responsibility of the pharmacy (or practitioner) to locate a RDS which will accept the product. If you are unable to find a RDS which will accept compounded products, contact DEA for a list of RDS which will provide the service. Pharmacies are required by state law to send expired/unwanted CDS to a RDS within 6 months after expiration.
4. CDS prescription medications brought into a hospital by a patient must be returned to that patient or that patient's family. A CDS

prescription may not be disposed of by the hospital. Note: Law enforcement must be contacted in the event of attempted suicide.

5. CDS prescription medications dispensed to a hospice patient who dies must be left with the responsible family member upon the death of the patient. Hospice employees do not have authority under federal law to accept or take the patient's prescriptions from the possession of the patient or the patient's responsible family member for any reason.
6. CDS prescription medications dispensed to a nursing home patient must be given to the responsible family member upon the death of the patient. The nursing home may not destroy them or accept them for transfer to someone else for destruction.

Notes:

- A. You may encourage a family member to destroy the medication or take it to a law enforcement disposal drop box.
- B. You may request a police officer to come to a nursing home or assisted living facility to accept CDS prescriptions that belonged to a patient IF the patient or the patient's family requests this, but this is an optional service of law enforcement.
- C. The DEA and/or OBN sponsored take-back programs may NOT accept CDS from a registrant of DEA under any circumstances.
- D. Pharmacies and pharmacists should review the requirement of a registrant to obtain ID of the recipient and recipient's agent as set by 475:30-1-15 and report the information as set by title 63§ 2-309C (10).

Printed Name on CDS Prescriptions

Title 475 – Oklahoma State Bureau of Narcotics and Dangerous Drug Control

475:30-1-4(a). Manner of issuance of prescriptions

(a) The practitioner shall sign a written prescription in the same manner as he/she would sign a check or legal document and **shall also type, stamp or print the practitioner's name on the face of each prescription.**

Investigational Drugs

According to a communication dated October 13, 2009, from Stanley Shepperson, PharmD, MS (CDR, USPHS, Regulatory Operations Officer, FDA/Center for Drug Evaluation and Research/Office of Compliance/Division of New Drugs and Labeling Compliance/Compounding Team), “[d]rugs listed as ‘investigational’ by FDA must be prescribed or ordered by a licensed prescriber who has an FDA-sanctioned IND for a recipient/patient who is also part of the IND study.” Pharmacists should ascertain the IND study status of a physician and patient when dispensing investigational drugs.

Drug Diversion Detection & Prevention Policy

Rules and regulations of the Oklahoma State Board of Pharmacy require that all pharmacies have a drug diversion detection and prevention policy. The policy must cover all prescription drugs, not just controlled substances.

535:15-3-2 (c)(4). Pharmacy responsibilities

(c) Pharmacy manager's and pharmacy's responsibilities. The following describe responsibilities of the pharmacy and pharmacy manager.

(4) Establish 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.

Pharmacies must have well-developed, written policies and procedures outlining the steps they are taking to prevent and detect diversion of prescription drugs. There are equivalent requirements for drug rooms, manufacturers, wholesales and medical gas suppliers.

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) specifically forbid pharmacy technicians from counseling patients.** In addition, federal legislation in OBRA 1990 requires that dispensing pharmacists offer to counsel each Medicaid recipient when filling prescriptions for them. The Board has received reports of technicians who are attempting to counsel patients. In some cases, the technicians may have received information in an academic or certificate "technician training program" in which they were led to believe, or they believed, qualified them to provide counseling. **In all cases this is not legal in Oklahoma.** PTCB Certification or any other academic or training programs do NOT qualify a technician to counsel patients. The Board will exercise strict enforcement in situations where technicians have counseled patients. The technician, the pharmacist at the pharmacy when the situation took place, the pharmacist-in-charge, and the pharmacy license are all responsible for, and subject to, discipline action by the Board in these cases. Additional enforcement action by CMS/Medicaid, and/or payment recovery by insurers against the pharmacy, may occur. It is very important that pharmacists-in-charge assure that technicians understand the rules and regulations regarding counseling and all other technician-related rules. Encourage your technicians to READ the law book.

Compliance Thru Education

Prescription Monitoring Program (PMP) Changes Effective January 1, 2012

All controlled prescriptions must be submitted to PMP within 5 minutes of selling (not filling) them to the customer. The pharmacy must submit the ID information of both the recipient and the recipient's agent, if someone other than the patient is picking up the prescription. If a patient is a resident of a nursing home or a hospice patient and does not have an ID card, the pharmacy may use the social security number for the patient. If you have further questions, please call the Bureau of Narcotics at (405) 521-2885.

Transfer of Medications in Hospitals

Hospital directors of pharmacy (PICs) should make sure they are thoroughly familiar with and understand the regulations and rules which govern the transfer of medications to other departments of the hospital and other business entities. An invoice must be used to document controlled drug substances (CDS) in Schedule II-V which are transferred (from one DEA number to another DEA number), sold, or given away to another business entity or to another location. A DEA222 must also be used when a CDS in Schedule II is involved. In some cases, such transfers are also subject to the federal Robison-Patman Act, which, in part, prohibits the transfer of medications purchased under not-for-profit contracts to for-profit business entities. In situations where a hospital pharmacy supplies CDS and other medications to an ambulance service, the PIC should ascertain the DEA status of the ambulance service and transfer medications in the appropriate manner. This is very important in situations where the ambulance service is located at a different address than the hospital pharmacy, is owned or operated by another business entity, and/or has a different DEA number

Fioricet is to be Reported to the PMP

The Uniform Controlled Dangerous Substances Act as set forth in 63 O.S. § 2-208(A)(1) provides that any substance containing any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid is a schedule III controlled substance. A recent opinion of the United States District Court clarified the status of Fioricet (generics) as a controlled drug. Based upon this ruling and the subsequent Oklahoma State Board of Pharmacy interpretation of OAC 535:1-14-4, the Oklahoma Bureau of Narcotics will require all dispensers to report Fioricet as a schedule III controlled substance to the PMP. Fioricet (generics) should be treated as a controlled drug and included on your controlled drug inventory.

Electronic Storage of Prescriptions

Electronic storage of prescriptions is currently not allowed. All prescriptions, regardless of how they are received, must be printed out and filed as hard-copy originals at this time. The Board will notify you if rules change to allow alternative storage methods.

Identifying the Problem

***By Kevin Rich, D.Ph.
Executive Director OPHP***

It is extremely important to be able to identify the disease of chemical dependency in a friend, family member or colleague. Denial is a component of chemical dependency which allows the disease to continue regardless of the consequences. Often family, friends or colleagues express that they knew there was a problem, but weren't aware of the consequences of having chemical dependency. Help arrest the disease of chemical dependency, by trusting your instinct and calling the OPHP helpline if you feel like someone is suffering from chemical dependency. After calling OPHP, the person in need will be handled by a compassionate professional and we will keep your confidence and facilitate the help for your friend or loved one before things progress too far. The call could be the best thing you do for a friend or loved one. If you are a pharmacist or student pharmacist in the active stages of chemical addiction or other mental health issue and you identify with any of these symptoms please call the OPHP Helpline immediately. Rest assured, if you have no legal issues regarding your pharmacy license you will be considered a self-referral to OPHP. With your adherence to OPHP recommendations you will remain anonymous to the Oklahoma State Board of Pharmacy and no disciplinary action will be taken on your pharmacy license. Arresting the disease of chemical dependency, getting your life back, and keeping your pharmacy license in good standing are the main goals of OPHP.

Policy and Procedures

All pharmacies are required to have written "Policies and Procedures". Areas that should be addressed include the safe and efficient distribution of pharmaceuticals, accountability of all employees, compounding procedures, and other pertinent pharmacy activities. The manuals need to be readily available. The Board of Pharmacy will be reviewing the policies upon inspection and some wholesalers are requesting a copy for their records.

Proper Identification

Per state law, the only acceptable identification for the PSE and PMP tracking system are the following: a current driver's license, state issued ID, passport, or military ID. The only exception is if a patient has none of these types of identification such as a nursing home resident. In this situation, a Social Security number may be submitted. If the patient is a minor, a parent's acceptable ID should be used.

For the purpose of acceptable identification, please refer to the following definition: "State" is any state, territory, or possession of the United States, the District of Columbia, or foreign nation. The Oklahoma Bureau of Narcotics does not view tribal IDs as an acceptable form of identification and advise pharmacies to not accept them as such.

Quarterly e-Newsletter

The Oklahoma State Board of Pharmacy quarterly e-Newsletter (January, April, July & October) is available online through the National Association of Boards of Pharmacy (NABP). Board registrants should receive an e-mail alert indicating when a new issue is available. If you do not currently receive e-mail alerts, go to <http://www.nabp.net/publications/oklahoma-state-board-of-pharmacy-newsletters/> and click on the subscribe link or you may send an e-mail with the word "Subscribe" in the subject line to OklahomaBOPNewsletter@nabp.net.

The e-Newsletter is considered an official notification from the Board to anyone registered in Oklahoma (pharmacies, pharmacists, interns, and technicians). Please make it a practice to read and understand the information found in the e-newsletter because you may be held accountable for the content.

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