



# Missouri Board of Pharmacy Inspection Guide

September 2015

## MISSOURI BOARD OF PHARMACY

◆  
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JEFFERSON CITY, MO  
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MissouriBOP@pr.mo.gov

◆  
[www.pr.mo.gov/pharmacists](http://www.pr.mo.gov/pharmacists)

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## Your Inspection Guide:

This guide contains important information regarding your inspection and other resources/updates that may be applicable to your practice. Be sure to visit the Board's website at [www.pr.mo.gov/pharmacists.asp](http://www.pr.mo.gov/pharmacists.asp) for additional information on rule changes, statutory updates and recent news releases from the Board.

## Guide to Inspection Terms:

The inspection is based on the inspector's general review of a pharmacy based on a limited sampling of pharmacy records. Licensees are strongly encouraged to independently review all applicable rules/statutes to ensure compliance with Missouri law. At the end of your inspection, the inspector will issue/initiate one or more of the following:

**Observation Report:** An Observation Report will be issued if no compliance issues are identified at the time of inspection or if compliance issues are noted that may generally be corrected and do not require further review/documentation under the inspection guidelines. A response to an Observation Report is not required. However, licensees are encouraged to review and promptly correct any issues noted.



**Compliance Notice:** A Compliance Notice is issued if the inspection reveals compliance concerns that require official documentation of corrective measures. A compliance notice may also be issued for multiple or repeat compliance issues. A response should be filed by the licensee on or before the date identified by the inspector in the Compliance Notice. Failure to file a response may result in an official investigation or further review by the Board.

**Quality Assurance Report:** A Quality Assurance Report may be issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug. The Board requests that licensees file a response to the Quality Assurance Report on or before the date identified by the inspector.

**Investigation:** Pursuant to Chapter 338, RSMo, in addition to the options listed above, the Board may initiate an investigation if additional factual information may be necessary or will assist the Board in its review.

**Questions/Concerns?** If you have any concerns about your inspection, please feel free to contact Chief Inspector Tom Glenski at (660) 535-4374 or at [tom.glenski@pr.mo.gov](mailto:tom.glenski@pr.mo.gov). Licensees may also contact the Board office.

## QUESTIONS?

MAIN NUMBER: (573) 751-0091

General Questions  
(573) 751-0091  
MissouriBOP@pr.mo.gov

### Specific inquiries regarding:

Complaints  
(573) 751-9056  
compliance@pr.mo.gov

Compliance Questions  
(573) 751-9056  
compliance@pr.mo.gov

Drug Distributors  
(573) 526-6985  
drugdistributor@pr.mo.gov

Intern Pharmacist Licensure  
(573) 751-0092  
intern@pr.mo.gov

Legal Questions  
(573) 751-0093  
lawquestions@pr.mo.gov

Pharmacist Licensure  
(573) 751-0092  
pharmacist@pr.mo.gov

Pharmacy Licensure  
(573) 526-6985  
pharmacy@pr.mo.gov

Tax Compliance/HB 600 Suspensions  
(573) 522-1448  
christa.nilges@pr.mo.gov

Technician Registration  
(573) 522-2425  
technician@pr.mo.gov

## What We'll Need to Review During an Inspection:

Your inspector will ask to review the following documents during the inspection:

### GENERAL RECORDS

- Pharmacy permit
- Pharmacist & technician licenses/registrations
- Copy of pending technician applications
- Technician list
- Invoices for receipt/distribution of legend drugs
- Prescription records
- Policy & procedure manual(s)
- Compounding log
- Investigation documentation for adverse reactions, outcomes and/or complaints regarding compounded products
- Documentation of compounded product recalls
- Required sterile product dispensing records
- Required immunization & drug administration records

### CONTROLLED SUBSTANCE RECORDS:

- Official Order Forms (DEA Form 222) & Power of Attorney authorizations
- Controlled substance receipts & invoices
- Inventory records (initial & annual inventories)
- Dispensing/distribution records (invoices & prescriptions)
- DEA/Missouri BNDD loss reports (i.e.- DEA Form 106)
- Inventory of Drugs Surrendered for Disposal (DEA Form 41)
- Records of controlled substance transfers between pharmacies
- DEA/Missouri BNDD registration certificates

*\* Inspectors may request additional information to review compliance with applicable state/federal law.*

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## Continuing Education:

**IMPORTANT REMINDER:** For the 2016 renewal, all pharmacists must have thirty (30) hours of continuing education (CE) earned between 11/01/14 and 10/31/16. Failure to obtain the required CE will result in a \$1,000 Delinquent CE Fee. Licensees not in compliance may also be subject to discipline by the Board. Please remember all CE must be ACPE or Board-approved. **CME must be pre-approved by the Board.**

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## “Lunch With The Chief” Upcoming Webinars:

The Missouri Board of Pharmacy provides a series of Webinars entitled “**Lunch with the Chief**” from noon to 1:00. The Webinars are hosted by Chief Inspector Tom Glenski, RPh, who discusses a current topic and answers related questions from participants.

October 13, 2015

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[Quick Reminders for Pharmacists-in-Charge](#)

*Are all pharmacy permits and registrations current?*

*Are all your staff pharmacist, intern, and technician licenses current?*

*Is your self-certification for compliance with the Combat Meth Act current?*

*Did you take your annual controlled substance inventory?*

*Are CSOS orders electronically checked in?*

*Do all individuals ordering via CSOS have their own CSOS certificates?*

*Do all pharmacists performing administrations hold the proper training and CPR certifications?*

*Do all immunizing pharmacists have a current protocol?*

*If receiving e-prescribed controlled substance prescriptions, has your software been certified to be DEA compliant?*

**If the answer to any of these questions is “NO” your pharmacy is not in compliance. Please consult with your inspector if you need assistance.**

## Resources On The Board's Website:

### **BOARD NOTICES:**

- Medication Therapy Services Q&A
- HB 412 Implementation FAQ (Veterinary Pharmacies)
- Take Back Programs

### **BOARD PUBLICATIONS:**

- Certification of Medication Therapeutic Plan Authority Q&A
- Compounding Advisory
- Drug Distributor Compliance Guide
- Drug Distributor Compliance Keys
- Immunization/Administration Checklist
- Immunization FAQ
- Internet Practice
- Medication Therapy Services Compliance Guide
- Missouri Law Book
- Missouri Pharmacy Practice Guide
- Pharmacist-in-Charge FAQ
- Pharmacy Compliance Top 10
- Pharmacy Inspection Guide

### **DISPOSING OF UNUSED MEDICATION:**

- Missouri Department of Natural Resources
- Missouri Bureau of Narcotics and Dangerous Drugs
- Food and Drug Administration
  - Disposal by Flushing of Certain Unused Medicines: What You Should Know
  - How to Dispose of Unused Medicine
- SmartRx Disposal (includes video of Safe Medicine Disposal)

### **DRUG ENFORCEMENT ADMINISTRATION (DEA):**

- Controlled Substances Act
- DEA Website
- Electronic Prescribing Rules
- DEA Pharmacist Manual
- DEA Statement on Agents of Prescribers

### **MISSOURI BUREAU OF NARCOTICS AND DANGEROUS DRUGS:**

- BNDD Website
- BNDD Newsletter/Publications
- Controlled Substance Guidelines for Pharmacies
- Mid-level Practitioner & Controlled Substance Guidelines
- Missouri Changes to Prescription Guidelines

### **VIDEOS/WEBINARS:**

- 2015 Legislation and Regulation Update
- 2015 DEA Update With Scott Collier
- 2015 Inspector Tips for Your Next Inspection
- 2014 Pharmacist Administration Regulation Review and Update
- 2014 BNDD Update
- Review of 2014 Legislative/Rule Update and Review of Employment Listings/Waiver Requirements
- 2014 Policies and Procedures Webinar
- 2013 New and Revised Prescription Records and Imaging Regulations (no video-handouts only)
- 2013 Regulatory Update
- 2013 BNDD Regulatory Update
- 2013 Effective Patient Counseling
- 2013 Developing a Patient Safety Culture in Pharmacy Practice Webinar

## LAWBOOK INDEX

Don't know where to find it in the law? A topical index of Chapter 338, RSMo, and the Board's rules is now available at <http://pr.mo.gov/pharmacists-rules-statutes.asp> along with links to the Board's rules and governing statutes.

## ADDITIONAL CONTACT INFORMATION

**MO. Bureau of Narcotics and Dangerous Drugs (BNDD)**  
**(573) 751-6321**  
[bndd@health.mo.gov](mailto:bndd@health.mo.gov)  
<http://www.dhss.mo.gov/BNDD>

◆  
**DEA- Kansas City**  
**(913) 825-4100**  
[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

◆  
**DEA- St. Louis**  
**(314) 538-4600**  
[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

## CONTROLLED SUBSTANCE LOSSES:

- DEA Form 106 (Report of Theft or Loss must be completed and submitted to your local DEA office when there is a controlled substance loss. Forms are available at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)
- Missouri BNDD Report of Loss or Theft of Controlled Substances or Chemicals form must be completed and submitted to BNDD. Forms are available at [www.dhss.mo.gov/BNDD/AppsForms.html](http://www.dhss.mo.gov/BNDD/AppsForms.html)

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## Termination/Discipline Reporting:

### Online Technician Termination/Disciplinary Action Notification Submission

The Board's web site includes an online submission process for notifying the Board of technician termination/disciplinary action as required by Section 338.013.10 and 20 CSR 2220-2.010 (1)(P). The notification web page may be found at <https://renew.pr.mo.gov/pharmacists-tdtf.asp>.

### Online Pharmacist Disciplinary Action Report

Any entity that employs or contracts with a Missouri licensed pharmacist to provide health care services to individuals is required to report to the Board: Any **disciplinary action** against a Missouri licensed pharmacist that would be cause for Board discipline under section 338.055, **OR** the **voluntary resignation** of a Missouri licensed pharmacist against whom any complaints or reports have been made which **might have led to disciplinary action**. Reports must be submitted to the Board within **fifteen days** of the disciplinary action. The notification web page may be found at <https://renew.pr.mo.gov/pharmacists-disciplinary-action-report.asp>.

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## Controlled Substance Issues:

### BNDD Controlled Substance Guidance For Pharmacies

The Bureau of Narcotics and Dangerous Drugs has released *Controlled Substance Guidelines for Missouri Pharmacies*. This helpful guidance tool may be found at: <http://health.mo.gov/safety/bnnd/doc/guidelines.doc>

### BNDD Quarterly Newsletter

Did you know the Bureau of Narcotics and Dangerous Drugs has a quarterly newsletter? The newsletter contains current information and helpful tips related to controlled substances. You may find the newsletter at: <http://health.mo.gov/safety/bnnd/publications.php>

### Do Your Employees Need An Employment Waiver?

Both federal and state controlled substance regulations prohibit a registrant from employing a person who has access to controlled substances who has been found guilty of a controlled substance related offense. Federal regulation applies only to felonies but state regulation applies to both felonies and misdemeanors. Both federal and state regulations allow for a registrant to request a waiver from this prohibition. The waiver request is the responsibility of the registrant. Since federal and state regulations have no time limit on the prohibition, the individual will always require a waiver in order to be employed with access to controlled substances. Since waivers are registrant-specific, the individual will require new waivers if he or she changes employment. More information can be found at: Missouri Bureau of Narcotics and Dangerous Drugs: [Waiver Application](#)

Drug Enforcement Administration Pharmacist's Manual:

[http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.htm#5](http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.htm#5)

### DEA Electronic Prescribing Guidance

The DEA's guidance on laws and regulations pertaining to prescribers and pharmacies using e-prescribing systems for controlled substance prescriptions may be found at: [http://www.deadiversion.usdoj.gov/ecomm/e\\_rx/index.html](http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html)

**SAMPLE FORM**

\_\_\_\_\_  
(Name Of Pharmacy)

**COMPOUNDING LOG**

Name/strength of compound product: \_\_\_\_\_

Person compounding: \_\_\_\_\_ Responsible RPh \_\_\_\_\_

Date Compounded \_\_\_\_\_ Total quantity compounded \_\_\_\_\_

| <i>Ingredient</i> | Manufacturer | Lot number | Expiration date | Quantity |
|-------------------|--------------|------------|-----------------|----------|
|                   |              |            |                 |          |
|                   |              |            |                 |          |
|                   |              |            |                 |          |
|                   |              |            |                 |          |
|                   |              |            |                 |          |
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|                   |              |            |                 |          |
|                   |              |            |                 |          |

If a batch compounded product, batch lot # \_\_\_\_\_ batch exp. date \_\_\_\_\_

Compounding process (or see recipe card):

Prescription number(s) for which compound was dispensed:

(Maintain For Two Years)



# POWER of ATTORNEY for DEA FORM 222 and ELECTRONIC ORDERS

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222. The power of attorney may be revoked at any time by the person who signed the power of attorney. It is necessary to grant a new power of attorney when the pharmacy completes a renewal registration, only if the renewal application is signed by a different person. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA. Suggested formats for granting and revoking power of attorney follow:

## Power of Attorney for DEA Forms 222 and Electronic Orders

\_\_\_\_\_ (Name of registrant)

\_\_\_\_\_ (Address of registrant)

\_\_\_\_\_ (DEA registration number)

I, \_\_\_\_\_ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

\_\_\_\_\_  
(Signature of person granting power)

I, \_\_\_\_\_ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

\_\_\_\_\_  
(Signature of attorney-in-fact)

Witnesses:

1. \_\_\_\_\_ 2. \_\_\_\_\_

Signed and dated on the \_\_\_ day of \_\_\_\_\_ in the year \_\_\_ at \_\_\_\_\_.

## Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact \_\_\_\_\_ this same day.

\_\_\_\_\_  
(Signature of person revoking power)

Witnesses:

1. \_\_\_\_\_ 2. \_\_\_\_\_

Signed and dated on the \_\_\_ day of \_\_\_\_\_ in the year \_\_\_ at \_\_\_\_\_.



# Interim Missouri Schedule II Policy



April 20, 2010

The DEA has published an announcement on their website [www.dea diversion.usdoj.gov](http://www.dea diversion.usdoj.gov) regarding a change in their previous policy regarding Schedule II controlled substance prescriptions. It is under their General Asked Questions section of the website.

The requirements for what is mandated documentation on a controlled substance prescription is set forth in Federal Regulation 21 CFR 1306.05(a), and also in Missouri statute, Section 195, 060.1, RSMo. These laws list the essential parts and requirements. Both laws were enacted in 1971.

Prior to November 2007, if an incomplete controlled substance prescription arrived at a pharmacy, a pharmacist could contact the prescriber by and make limited changes to make the prescription legal for dispensing. The pharmacist had to date and document the changes on the prescription.

The DEA's preamble to a new rule in November 2007 changed this and stated that pharmacists could no longer make changes to Schedule II prescriptions. The DEA stated they are in the process of amending this rule. In the meantime there has been information causing confusion. On April 19<sup>th</sup>, 2010, DEA recently stated that while they are amending their existing rule, they will allow practitioners to make changes to controlled substance prescriptions according to the laws and policies of their individual state.

The Missouri Bureau of Narcotics and Dangerous Drugs conjointly with the Missouri Board of Pharmacy are informing Missouri practitioners to return to the standard of practice prior to November 2007, until such time that the DEA has promulgated a new rule. Until the new DEA rule is effective, Missouri practitioners shall adhere to the following guidelines:

### **Methods of changing prescriptions:**

1. A prescriber may provide a written change to the pharmacy that the pharmacy must attach to the original prescription. The written change shall document the date and name of the person authorizing the change. The change may be mailed, emailed, or faxed.
2. The change may be communicated orally. The pharmacy shall record the date, changes, and person authorizing the changes on the front or back of the prescription.

### **What may be changed/added with permission**

Date written  
 Patient's address (*complete physical address, not P.O. Box*)  
 Drug form  
 Drug strength  
 Quantity to be dispensed  
 Prescriber's address  
 Prescriber's DEA number  
 Directions for use  
 Substitutions permitted  
 Refill information  
 Reasons for extended supplies for Schedule II prescriptions

### **What can never be changed/added**

Patient's name  
 Drug name  
 Prescriber's name  
 Prescriber's signature

**Missouri BNDD**  
 Phone: (573) 751-6321  
 Fax: (573) 526-2569  
[www.dhss.mo.gov/BNDD](http://www.dhss.mo.gov/BNDD)

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