

# MISSOURI BOARD OF PHARMACY

# NEWSLETTER



MAY 2017

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## ASSISTANT PHYSICIANS

The Missouri Board of Registration for the Healing Arts recently began licensing Assistant Physicians. Once licensed, Assistant Physicians (APs) are authorized to prescribe under a supervising agreement with a Missouri licensed physician. BNDD has issued the following guidance:

*APs are recent medical school graduates who have received their medical degrees but have not yet entered a residency program. Some graduates are awaiting the residency program*

*of their choice and waiting for the next cycle. APs obtain a license from the Missouri State Board of Regulation for the Healing Arts, which authorizes them to obtain a BNDD and DEA registration. **They have a supervising agreement with a physician and will have the same controlled substance authority as Physician Assistants** (emphasis added).*

Below is a summary of Missouri's prescribing allowances for mid-level practitioners (with the appropriate supervising/ collaborative practice agreement and controlled substance registrations):

	Advanced Practice Registered Nurses	Physicians' Assistants/ Assistant Physicians
Non-Controlled Substances	<ul style="list-style-type: none"> <li>• Prescription valid for one (1) year</li> <li>• Quantity limits/refills as prescribed</li> </ul>	<ul style="list-style-type: none"> <li>• Prescription valid for one (1) year</li> <li>• Quantity limits/refills as prescribed</li> </ul>
Schedule II	<ul style="list-style-type: none"> <li>• Hydrocodone products only- limited to a 5-day or 120-hour supply. <i>*Includes single ingredient products.</i></li> </ul>	<ul style="list-style-type: none"> <li>• Hydrocodone products only- limited to a 5-day or 120-hour supply. <i>*Includes single ingredient products.</i></li> </ul>
Schedule III (Opiates)	<ul style="list-style-type: none"> <li>• Limited to a 5-day or 120-hour supply</li> <li>• Prescription valid for 6-months from date written.</li> <li>• No refills allowed***</li> </ul>	<ul style="list-style-type: none"> <li>• Limited to a 5-day or 120-hour supply</li> <li>• Prescription valid for 6-months from date written</li> <li>• No refills allowed***</li> </ul>
Schedule III (Non-Opiates)	<ul style="list-style-type: none"> <li>• Full authority to prescribe</li> <li>• 90-Day quantity limits</li> <li>• Prescription valid for 6-months from date written.</li> <li>• Refill as prescribed but no more than five (5) times in six (6) months.</li> </ul>	<ul style="list-style-type: none"> <li>• Limited to a 5-day or 120-hour supply</li> <li>• Prescription valid for 6-months from date written.</li> <li>• <u>No refills allowed</u></li> </ul>
Schedule IV	<ul style="list-style-type: none"> <li>• Full authority to prescribe</li> <li>• 90-day supply limit for a single prescription</li> <li>• Prescription valid for 6-months from date written</li> <li>• Refill as prescribed but no more than five (5) times in six (6) months.</li> </ul>	<ul style="list-style-type: none"> <li>• Full authority to prescribe</li> <li>• 90-day supply limit for a single prescription</li> <li>• Prescription valid for 6-months from date written</li> <li>• Refill as prescribed but no more than five (5) times in six (6) months.</li> </ul>
Schedule V	<ul style="list-style-type: none"> <li>• Full authority to prescribe</li> <li>• 90-day supply limit for a single prescription</li> <li>• Prescription valid one (1) year from date written</li> <li>• Refill as prescribed</li> </ul>	<ul style="list-style-type: none"> <li>• Full authority to prescribe</li> <li>• 90-day supply limit for a single prescription</li> <li>• Prescription valid one (1) year from date written</li> <li>• Refill as prescribed</li> </ul>



## LICENSING NOTES

- All pharmacy technician registrations must be renewed by May 31st. Technicians who do not renew by May 31st are not eligible to work. Visit the Board's website to check registration status.
- Pharmacy and drug distributor renewals will be mailed in August. Renewals are due by October 31st. Renewal applications must be accurate and complete. Licensees using a third party to submit their renewal (e.g., a licensing service or corporate office) should make sure the renewal questions have been answered correctly before filing with the Board.

## BNDD UPDATES

(The following information was published in BNDD's May 2017 newsletter. The full newsletter is available online at: <http://health.mo.gov/safety/bndd/pdf/may17.pdf> )

# Caution

## REMINDER TO PHARMACIES

The new St. Louis County PDMP is scheduled to go live on April 25, 2017 [the program has since gone live]. This creates a PDMP for additional jurisdictions that joined this program such as St. Louis City, St. Charles County, Jackson County, Ste. Genevieve County, Cole County, Lincoln County, Stoddard County, Kansas City and the City of Independence.

Now that these areas have a reportable PDMP, this may lead to drug seekers leaving their area and traveling unusual distances to get prescriptions filled in areas not covered by a PDMP. Watching for seekers who travel unusual distances and bypassing other pharmacies to come to your pharmacy, is an issue where the BNDD, state board and DEA take disciplinary actions. Federal DEA regulations clearly state pharmacies have a secondary and separate responsibility in determining whether to dispense and have the right to decline a prescription.

Any pharmacist who believes a patient may be entering their pharmacy to avoid the PDMP may report this patient to the BNDD. BNDD will then share the information with the PDMP. Pharmacists are given immunity for reporting to BNDD pursuant to Section 195.045, RSMo.

## SUBMIT COMMENTS NOW

Governor Eric R. Greitens recently issued Executive Order 17-03 which requires state agencies to review all rules under their jurisdiction. As part of the review, state agencies are required to hold at least two (2) public hearings to allow citizens and businesses to identify regulations that are ineffective, unnecessary or unduly burdensome.

In compliance with Executive Order 17-03, the Board will be holding public hearings during the following regularly scheduled meetings to receive comments from the public:

- Date: July 12, 2017 @ 9:30 a.m.  
Location: Courtyard Columbia  
3301 Lemone Industrial Blvd.  
Columbia, Missouri
- Date: October 25, 2017 @ 9:30 a.m.  
Location: St. Louis College of Pharmacy  
4588 Parkview Place  
St. Louis, Missouri

Public comments will be accepted on any of the Board's rules. Due to time restraints, comments may be limited to three (3) minutes per person. Comments may also be submitted online at: <https://renew.pr.mo.gov/pharmacists-proposed.asp>.

In addition to the general public comment period, the Board will be reviewing and taking public comments on the following specific rules at the July meeting:

### JULY 2017

20 CSR 2220-2.400	Compounding Standards of Practice
20 CSR 2220-2.600	Standards of Operation for a Class-F: Renal Dialysis Pharmacy
20 CSR 2220-2.675	Standards of Operation/Licensure for Class-L Veterinary Pharmacies
20 CSR 2220-6.100	Pharmacy Standards for Dispensing Blood-Clotting Products
20 CSR 2220-2.500	Nuclear Pharmacy- Minimum standards for Operation

Again, comments on the above rules may be submitted online at: <https://renew.pr.mo.gov/pharmacists-proposed.asp>



## INSPECTION CORNER

Board inspectors frequently noted the following compliance violations during recent board inspections

VIOLATION	COMMENTS
Active name of each active or therapeutic ingredient not included on the prescription container for compounded preparations. [20 CSR 2220-2.400(7)(F)].	Compound names such as “Magic Mouthwash” alone are not compliant. Instead, the actual name of the active or therapeutic ingredients must be listed on either the prescription label or on an auxiliary label. This requirement applies to both sterile and non-sterile preparations. Make sure pharmacy staff has been properly trained on label requirements.
Controlled substance inventories either late or incomplete. [19 CSR 30-1.042]	Controlled substance inventories have to be taken annually and must include Schedule V pseudoephedrine products.
Return-to-stock containers not properly labeled or assigned the wrong expiration date. [20 CSR 2220-3.040]	Return-to-stock containers must be maintained in the patient container with the dispensing date, prescription # and drug name visible on the container. Make sure staff does not black out or remove this information when deleting patient information.  Additionally, return-to-stock medication must be assigned the manufacturer’s original expiration date or an expiration date of one (1) year from the dispensing date on the label, whichever is lesser. [20 CSR 2220-3.040] Remember, return to stock items CANNOT be poured back into the stock bottle.
Insanitary pharmacy conditions [20 CSR 2220-2.010(1)(F)]	Inspectors continue to observe excessive dust/clutter in the pharmacy as well as dirty or soiled reconstitubes. Pharmacies and pharmacy equipment must be clean and sanitary at all times. Violations could result in discipline.
Not verifying the source of a faxed or photocopied prescription/ medication order. [20 CSR 2220-2.085(2)(C)]	Pharmacists are required to take appropriate measures to verify/authenticate a faxed prescription and their origin. Appropriate measures may include: <ul style="list-style-type: none"> <li>• Maintaining a practitioner fax number reference list or an electronic signature file;</li> <li>• Verifying the telephone/fax number; or</li> <li>• Orally verifying the prescription with the prescriber. [20 CSR 2220-2.085(2)(C)]</li> </ul>

Compliance shouldn't start during your inspection. Visit the Board's website for tools and resources to assess your pharmacy's compliance today.

## BOARD OF PHARMACY WEBINARS

Did you miss a live webinar? Recordings of past webinars may be found under the Videos/Webinars section of the [Board's Publications/Resources](#) webpage.



## OPEN INSPECTOR POSITION (MID-MO)

The Board is currently accepting applications from licensed pharmacists for an Inspector position in the Mid-Missouri area which includes Jefferson City, Columbia and Lake Ozark. A full job description and salary information is available on the Board's website.

Interested parties should send a cover letter and resume to [Jennifer.luebbert@pr.mo.gov](mailto:Jennifer.luebbert@pr.mo.gov) or to the Board's address.





# STERILE COMPOUNDING COMPLIANCE NOTES

## PRIMARY ENGINEERING CONTROL & CLEANROOM CERTIFICATION

Sterile Compounding rule 20 CSR 2220-2.200(5) requires certification of all primary engineering controls (PEC) and all ISO classified areas. Certification ensures the pharmacy's facilities and equipment are operating correctly and are able to provide the proper environment for sterile compounding.

When should certification be completed?

- Prior to beginning any sterile compounding activities and every 6 months thereafter.
- Re-certification must also be conducted when:
  1. Any major service or changes occur that may affect the airflow or environmental conditions (ex-new HEPA filters)
  2. The PEC or room is relocated or the physical structure of the ISO classified area has been altered

What tests need to be completed as part of the certification?

- Consult with your certifier to determine which tests need to be conducted in order to maintain proper air quality. Particle counts need to be taken to certify the ISO classification of the PEC or room (see examples below).

What should I do with the certification report?

- Certification results must be reviewed by a pharmacist once they're received.
  - Document the pharmacist review with the identity of the pharmacist and the date
- Maintain all certification reports for a minimum of 2 years.

What actions should be taken if my certification fails?

- Deficiencies or failures must be investigated and corrected.
  - Compounding must STOP until the deficiency/failure is corrected.
  - The affected area may need to be recertified prior to resuming compounding activities.

Location Averages	0.5 µm	No. Samples	User
1	195.56	1	
2	173.25	1	
3	128.47	1	
4	2.16	1	
5	110.58	1	

Mean of Averages	56.50
Standard Deviation	126.35
Standard Error	56.50
95% UCL	175.16
ISO Class 7 Limit	352,000.00
Test Result	PASS

**Overall Test Result: PASSES for ISO Class 7**

### C. PARTICLE COUNT TEST - Data

Status: **PASS**

1-0	2-0	3-0	4-0	5-0

Particle Size Monitored:	0.5
Number of Locations:	5
Number of Samples:	5
Average:	0
Standard Deviation:	0.0
Standard Error:	0.0
95% Upper Confidence Limit:	0
ISO Class Achieved:	5
Condition During Test:	Operational



## DISCIPLINARY ACTIONS

### PHARMACISTS:

**Susan H. Baker**, #042267, Pevely, MO. Two (2) Years Probation. Pharmacist license disciplined by the Colorado State Board of Pharmacy, tested positive for marijuana. Section 338.055.2(8), and (15), RSMo.

**Carolyn V. Cruise**, #042262, Florissant, MO. Public Censure. As Pharmacist, dispensed a non-controlled drug without a prescription, failed to keep a dispensing record for the dispensing, and failed to label the drug prior to dispensing. Section 338.055.2(5), (6), (13), and (15), RSMo.

**Irene Sansoucie**, #2011026615, Fenton, MO. Public Censure. Received prescriptions not lawfully authorized by a physician. Section 338.055.2(5), (6), (13), and (15), RSMo.

### PHARMACIES:

**Dierbergs Fenton Crossing Pharmacy**, #2000158538, Fenton, MO. Three (3) Years Probation. Pharmacist-in-Charge admitted he diverted Fioricet and Oxycodone from the pharmacy. Pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances. Section 338.055.2 (5), (6), (13), and (15), RSMo.

**Stroheckers Pharmacy**, #2011017243, Portland, OR. One (1) Year Probation. Pharmacy was disciplined in Oregon for compounding violations related to compounding of testosterone cypionate, dispensing misbranded sterile preparations, failure to properly compound sterile preparations, failure to follow pharmacy sterile compounding procedures and failure to properly notify patients of a recall. Pharmacy dispensed misbranded testosterone cypionate to nine (9) Missouri patients. Section 338.055.2 (5), (8), (13), and (15), RSMo.

## GOLD CERTIFICATES



The following pharmacists have maintained a Missouri pharmacist license for 50 years. Congratulations to our newest “gold-certificate” pharmacists:

Robert L Bossler

John W Foxworth

James P Hess

John L Keller

Vernon L. Vespa