

**Meeting Notice**  
**Missouri Board of Pharmacy**  
**October 26-27, 2016 (Wednesday - Thursday)**

**Hilton Garden Inn**  
**3300 Vandiver Drive**  
**Columbia, Missouri**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0093 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes, to the extent they relate to the following: Sections 610.021(1), (3), (5), (6), (7), (13), (14), and (17), RSMo, and Section 324.001.8 and .9, RSMo.

The Board may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

**OPEN SESSION**  
**Wednesday, October 26, 2016**

1. 8:00 am Call to Order Christina Lindsay, PharmD, President
2. Roll Call Christina Lindsay, PharmD, President
3. **8:01 am The Board will go immediately into closed meeting pursuant to Section 610.021(1), (3), (5), (6), (7), (13), (14), and (17), and 324.001.8 and .9, RSMo. The Board will remain in closed until 9:00 am**
4. 8:45 am Call to Order Christina Lindsay, PharmD, President
5. 10:00 am 1<sup>st</sup> case, Susan Baker, Disciplinary Hearing, #042267

***Note: The following items will be discussed as time allows during the open meeting. No specific date or time has been assigned to these items.***

6. Agenda Additions/Corrections
7. Board Member Report
8. General Administration Report
  - a. Financial Report
  - b. 2016 Legislative Implementation

- c. 2017 Proposed Legislation
  - d. General Office Update
  - e. New/Pending Rules
  - f. Renewal/Licensing Update
  - g. Joint Patient Safety Conference
  - h. BNDD/BOP Drug Diversion Conference
  - i. December Training/Holiday Lunch
  - j. Employee Recognitions
9. Approval of Minutes
  10. Inspection/Investigation Update
  11. Applications for Intern Training Special Site or Non-Pharmacist Preceptor
  12. STLCOP and UMKC College of Pharmacy
  13. FDA DQSA Guidance/Implementation
  14. Review of 20 CSR 2220-6.040
  15. Review of 20 CSR 2220-6.050
  16. Review of 20 CSR 2220-6.055
  17. Review of 20 CSR 2220-2.650
  18. Review of Strategic Planning Report
  19. 2016 NIOSH Hazardous Drug List
  20. Joint Letter on USP 800
  21. Hospital Advisory Committee Update
  22. Class-B Pharmacy Guidance
  23. 2017 Missouri Pharmacy Practice Guide
  24. Review of NAPLEX/MPJE Pass Rates
  25. Sterile Compounding Survey
  26. Licensees Presently Under Discipline
  27. Board Licensee Statistics
  28. 2016-2017 Legal Contracts
  29. NABP Model Pharmacy Act Revision
  30. NABP Board of Pharmacy Member Manual
  31. Closed meeting pursuant to Section 610.021(1), (3), (5), (6), (7), (13), (14), and (17), and 324.001.8 and .9, RSMo. It is expected that the Board will remain in closed session the remainder of the meeting, except as otherwise noted.

**OPEN SESSION**  
**Thursday, October 27, 2016**

32. 8:15 am Call to Order Christina Lindsay, PharmD, President
33. 8:16 am The Board will go immediately into closed meeting pursuant to Section 610.021(1), (3), (5), (6), (7), (13), (14), and (17), and 324.001.8 and .9, RSMo. The Board will remain in closed until 10:00 am
34. 10:00 am Call to Order Christina Lindsay, PharmD, President
35. 10:00 am 1<sup>st</sup> case, Shannon Krieg, Violation of Disciplinary Order Hearing,  
#200500313
36. Closed meeting pursuant to Section 610.021(1), (3), (5), (6), (7), (13), (14), and (17), and 324.001.8 and .9, RSMo. It is expected that the Board will remain in closed session the remainder of the meeting, except as otherwise noted.

**Missouri Board of Pharmacy  
October 26-27, 2016  
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- #A1 Agenda Additions/Corrections
- #A2 Board Member Reports
- #A3 General Administration Report
- #A4 Approval of Minutes
- #A5 Inspection/Investigation Update (Tom Glenski, Chief Inspector)

**SECTION B- OPEN**

**Wednesday - October 26, 2016**

10:00 AM – 1<sup>st</sup> case

- #B1 Susan Baker, #042267, #2013-006080

**Thursday - October 27, 2016**

10:00 AM – 1<sup>st</sup> case

- #B2 Shannon Krieg, #200500313, #2016-001469

**SECTION C- OPEN**

- #C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor
- #C2 STLCOOP and UMKC College of Pharmacy

**SECTION D- OPEN**

- #D1 FDA DQSA Guidance/Implementation
- #D2 Review of 20 CSR 2220-6.040
- #D3 Review of 20 CSR 2220-6.050
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- #D5 Review of 20 CSR 2220-2.650
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- #D9 Hospital Advisory Committee Update
- #D10 Class-B Pharmacy Guidance
- #D11 2017 Missouri Pharmacy Practice Guide
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- #D13 Sterile Compounding Survey

## **SECTION E- OPEN**

- #E1 Licensees Presently Under Discipline
- #E2 Board Licensee Statistics
- #E3 NABP Model Pharmacy Act Revision
- #E4 NABP Boards of Pharmacy Member Manual

# **SECTION A – OPEN**

**#A1 Agenda Additions/Corrections**

**#A2 Board Member Reports**

- NABP District 6, 7 and 8 Meeting (Portland, Oregon)
- FDA Inter-Governmental Meeting (Sterile Compounding/Drug Outsourcers)
- Other Meeting Updates



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# Agenda

NABP/ACCP Districts VI, VII & VIII

September 11 – 14, 2016 Portland, Oregon



*Come Celebrate With Us!*

**Preliminary Meeting and Lodging Information**

**Sunday, September 11<sup>th</sup>**

- **1:00 pm:** Check-in and registration at the Benson Hotel opens  
*Light refreshments will be available*
- Opening reception on the **Portland Spirit yacht**
- **5:00 pm** Leave hotel & begin boarding **Portland Spirit**  
**Portland Spirit** is in walking distance of the Benson (rides will also be available)
- **6:00 pm** Departure ~ 2 1/2 hour dinner cruise along the Willamette River
- **8:30 pm** Return to hotel

### Monday, September 12<sup>th</sup>

- **7 – 8:00 am:** Continental breakfast in the Crystal Ballroom
- **8:15 am** – Welcome Ceremony ~ Local welcome from dignitaries  
NABP report/AACP report
- **9:45 am** – Morning break
- **10:00 am** – “RPh Contraceptive & Prescriptive Authority, Legislation, Rules & Training” CPE
- **12 noon** – Lunch in the Crystal Ballroom
- **1:30 pm** – “Pharmacy Services Standardization & Centralization & Their Effect on Patient Care & Students Experiential Education” CPE
- **2:30 pm** – District/AACP business meetings
- **3:30 pm** – Afternoon break
- **3:45 pm** – “Evolution of Technicians ~ Duties & Responsibilities” (round table discussion)
- **4:45 pm** – Round Table Discussion Report
- **5:30 pm** – Reception in the London Grill
- *Dinner on your own*

### Tuesday, September 13<sup>th</sup>

- **7 – 8:00 am** – Continental breakfast in the Crystal Ballroom
- **8:15 am** – “Specialty Pharmacy” CPE
- **10:00 am** – Morning break
- **10:15 am** – NABP & AACP Hot Topics Session
- **10:50 am** – Hot Topics Reports
- **11:00 am** – District/AACP Second Business Session

- **12 noon** – Afternoon free time to explore Portland/the surrounding area/special excursions
- *Dinner on your own*

### Wednesday, September 14<sup>th</sup>

- **7 – 8:00 am** Continental breakfast in the Mayfair Ballroom
- **8:15 am** – “Electronic Medical Record Issues”
- **10:15 am** – Morning break
- **10:30 am** – “Internet Fraud / .pharmacy”
- **11:30 am** – Wrap up and plans for 2017
- *Adjourn*

*Online registration is available.*

Make your reservations as soon as possible!

#### **The Benson Hotel**

309 SW Broadway

Portland, OR 97205

Phone: 503-228-2000

Fax: 503-471-3920

*Reference “NABP District 2016 Meeting or BEN-GF591”*

Reserve your room as soon as possible ~ Special pricing not available after August 8

*National Association of Boards of Pharmacy*

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## 2016 Inter-governmental Working Meeting on Pharmacy Compounding

U.S. Food and Drug Administration  
White Oak Campus, Great Room  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

### AGENDA

**Tuesday, September 20, 2016**

**8:00 AM – 4:30 PM**

- 8:00 AM – 9:00 AM     **Registration**
- 9:00 AM – 9:15 AM     **Welcome and Introduction**  
Brian Kehoe, Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation and Analysis, FDA
- Julie Dohm, Senior Science Advisor for Compounding, Center for Drug Evaluation and Research (CDER); Agency Lead for Compounding, FDA
- 9:15 AM – 10:30 AM     **Compounding Regulatory Policy Update**  
Panelists:
- Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA
  - Sara Rothman, Special Assistant, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Panel Topics:
- Where are we now? Overview of regulatory policy documents released since the Fall 2015 Inter-governmental meeting
  - Upcoming high priority policy issues
- 10:30 AM – 10:45 AM     **Break**
- 10:45 AM – 11:00 AM     **Remarks**  
Howard Sklamberg, Deputy Commissioner for Global Regulatory Operations and Policy, FDA
- 11:00 AM – 12:15 PM     **FDA Inspections and Enforcement Update**  
Panelists:
- Ellen Morrison, Assistant Commissioner for Operations, Office of Regulatory Affairs (ORA), FDA
  - Michael Levy, Deputy Director for Policy and Analysis, Office of Compliance, CDER/ FDA
  - Kathleen Anderson, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA

Panel Topics:

- FDA inspections and enforcement update
- Changes in FDA inspectional procedures

12:15 PM – 1:30 PM

**Lunch**

1:30 PM – 3:00 PM

**Oversight of Pharmacies: Prescription Requirements**

Panelists:

- Sara Rothman, Special Assistant, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Daniel Kelber, Acting Director, Division of Professional Regulation, Illinois Department of Financial and Professional Regulation
- Linda Bethman, Assistant Attorney General, Senior Counsel, Maryland Office of the Attorney General
- Sue Mears, Compliance Officer, Iowa Board of Pharmacy

Panel Topics:

- FDA Draft Guidance: Prescription Requirement under Section 503A of the Federal Food, Drug and Cosmetic Act
- State approaches to prescription requirements

Breakout Sessions:

- State laws and policies
- FDA and State enforcement

3:00 PM – 3:15 PM

**Break**

3:15 PM – 4:30 PM

**FDA/State Collaboration and Communication**

Panelists:

- Lauren DiPaola, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA
- Sara Ashton, Testimony Specialist, Office of Policy and Risk Management, ORA/FDA
- Kathleen Anderson, Deputy Director, Office of Unapproved Drugs and Labeling Compliance, CDER/FDA
- Gail Bormel, Supervisory Consumer Safety Officer, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
- Anthony Rubinaccio, Executive Director, New Jersey Board of Pharmacy
- Steven Saxe, Executive Director, Washington State Pharmacy Quality Assurance Commission

Panel Topics:

- State and FDA information needs
- Information sharing agreements

Facilitated open mic discussion

**Wednesday, September 21, 2016**

**8:20 AM – 4:45 PM**

- 8:20 AM – 8:30 AM     **Welcome and Opening Remarks**  
Brian Kehoe, Director of Intergovernmental Affairs, Office of Policy, Planning, Legislation and Analysis, FDA  
  
Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA
- 8:30 AM – 9:45 AM     **Oversight of Pharmacies: Quality Standards & Insanitary Conditions**  
Panelists:  
  - Ian Deveau, Branch Chief, Office of Compliance, CDER/FDA
  - Emily Gebbia, Senior Advisor, Office of Compliance, CDER/FDA
  - Gay Dodson, Executive Director/Secretary, Texas Board of Pharmacy
  - Kimberly Leonard, Acting Executive Secretary; Pharmacy Supervisor, Practice and Registration, New York State Board of Pharmacy
  - Kimberly Gaedeke, Director, Michigan Bureau of Professional Licensing  
Panel Topics:  
  - Insanitary conditions at compounding facilities
  - State-required compounding quality standards and State inspectional approaches  
Facilitated open mic discussion
- 9:45 AM – 10:00 AM   **Break**
- 10:00 AM – 11:30 AM   **Oversight of Outsourcing Facilities: Panel Discussion**  
Panelists:  
  - Gail Bormel, Supervisory Consumer Safety Officer, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
  - Gabrielle Cosel, Policy Analyst, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER/FDA
  - Carmen Catizone, Executive Director, National Association of Boards of Pharmacy
  - Virginia Herold, Executive Officer, California State Board of Pharmacy
  - Caroline Juran, Executive Director, Virginia Board of Pharmacy  
Panel Topics:  
  - Issues related to FDA and State oversight of outsourcing facilities
  - FDA recommendations on State oversight
  - Related updates to NABP Model Act
- 11:30 AM – 11:45 AM   **Remarks**  
Robert M. Califf, Commissioner of Food and Drugs
- 11:45 AM – 1:00 PM    **Lunch**

- 1:00 PM – 3:15 PM      **Oversight of Outsourcing Facilities: Breakout Sessions**
- Licensure – State laws and policies for licensure and outsourcing facility dispensing
  - Regulation – distribution and wholesaling, pharmacist supervision of compounding at outsourcing facilities
  - Inspections – frequency of FDA inspections, State desire to conduct inspections and for related training
  - Open discussion – achieving a functional outsourcing facility sector, issues not yet raised
- 3:15 PM – 3:30 PM      **Break**
- 3:30 PM – 4:30 PM      **Physician Compounding**
- Panelists:
- Emily Gebbia, Senior Advisor, Office of Compliance, CDER/FDA
  - Nadine Shehab, Senior Scientist, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
  - Claudette Dalton, Board Member, Federation of State Medical Boards (FSMB); Chair, FSMB Ethics and Professionalism Committee
  - Cameron McNamee, Director of Policy and Communications, Ohio Board of Pharmacy
  - Cheri Atwood, Director of Compliance, Mississippi Board of Pharmacy
- Panel Topics:
- Oversight mechanisms
  - Quality and safety
- 4:30 PM – 4:45 PM      **Closing Remarks**
- Julie Dohm, Senior Science Advisor for Compounding, CDER; Agency Lead for Compounding, FDA

**#A3 General Administration Report**

- Financial Report
- 2017 Legislative Implementation
- 2017 Proposed Legislation
- General Office Update
- New/Pending Rules
- Renewal/Licensing Update
- Joint Patient Safety Conference
- BNDD/BOP Drug Diversion Conference
- December Training/Holiday Lunch
- Employee Recognitions

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	Pharmacy - 0637																
2	FY 2017 Monthly Fund Balance Sheet																
3		FY 2017 Actual													FY 2017 Projections		
4		July	August	September	October	November	December	January	February	March	April	May	June	Lapsed July	YTD Total	Projected	Remaining (Projected - YTD Total)
5	Beginning Fund Balance	7,249,523.21	7,125,038.78	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	286,900.83	0.00	(286,900.83)
6	Revenue	53,060.00	233,840.83												0.00	0.00	0.00
7	Revenue Adjustment														0.00	0.00	0.00
8	<b>Total Revenue</b>	<b>7,302,583.21</b>	<b>7,358,879.61</b>	<b>7,189,789.76</b>	<b>0.00</b>	<b>286,900.83</b>	<b>0.00</b>	<b>(286,900.83)</b>									
9	Total Funds Available	7,302,583.21	7,358,879.61	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	7,189,789.76	286,900.83		
10																	
11	<b>Appropriation Costs:</b>																
12	Expense and Equipment	28,196.28	27,356.05												55,552.33	0.00	(55,552.33)
13	Personal Service and Per Diem	84,974.43	87,805.10												172,779.53	0.00	(172,779.53)
14	<b>Total Appropriation Costs</b>	<b>113,170.71</b>	<b>115,161.15</b>	<b>0.00</b>	<b>228,331.86</b>	<b>0.00</b>	<b>(228,331.86)</b>										
15																	
16	<b>PR Appropriated Transfers (HB 7.540):</b>																
17	Licensure System Cost														0.00	0.00	0.00
18	Rent														0.00	0.00	0.00
19	DIFP Department Cost Allocation														0.00	0.00	0.00
20	Licensee Refunds														0.00	0.00	0.00
21	Start-up Loan - Borrower's Expense														0.00	0.00	0.00
22	Division PR Transfer:																
23	Division-Wide Costs	16,646.20	12,913.33												29,559.53	0.00	(29,559.53)
24	Purchasing Staff	338.48	371.93												710.41	0.00	(710.41)
25	PR/IT Staff														0.00	0.00	0.00
26	Legal Team	16.76	44.79												61.55	0.00	(61.55)
27	CRR Staff	1,570.72	2,130.92												3,701.64	0.00	(3,701.64)
28	Board Specific:																
29	Expense/Equipment	2,483.07													2,483.07	0.00	(2,483.07)
30	Personal Services														0.00	0.00	0.00
31	Fringe Benefits														0.00	0.00	0.00
32	Technical Support Staff	1,367.40	923.15												2,290.55	0.00	(2,290.55)
33	Central Mail Processing	1,999.87	1,738.12												3,737.99	0.00	(3,737.99)
34	CIU Investigations	138.67	41.06												179.73	0.00	(179.73)
35	<b>Total Division PR Transfer</b>	<b>24,561.17</b>	<b>18,163.30</b>	<b>0.00</b>	<b>42,724.47</b>	<b>0.00</b>	<b>(42,724.47)</b>										
36	<b>Total PR Appropriated Transfers (HB 7.540)</b>	<b>24,561.17</b>	<b>18,163.30</b>	<b>0.00</b>	<b>42,724.47</b>	<b>0.00</b>	<b>(42,724.47)</b>										
37																	
38																	
39	<b>GR Transfer (HB 7.535):</b>																
40	Attorney General	2,352.55													2,352.55	0.00	(2,352.55)
41	Administrative Hearing Comm.	38.00													38.00	0.00	(38.00)
42	<b>Total GR Transfer</b>	<b>2,390.55</b>	<b>0.00</b>	<b>2,390.55</b>	<b>0.00</b>	<b>(2,390.55)</b>											
43																	
44	<b>Other Transfers:</b>																
45	Workers Compensation														0.00	0.00	0.00
46	Unemployment														0.00	0.00	0.00
47	Board Staff Fringe Benefits	34,576.00	35,765.40												70,341.40	0.00	(70,341.40)
48	Biennium Sweep														0.00	0.00	0.00
49	OA Cost Allocation Transfer	2,846.00													2,846.00	0.00	(2,846.00)
50																	
51	<b>FY 2015 Transfers Carried Over:</b>																
52	FY 2016 June PR Transfer														0.00	0.00	0.00
53	FY 2016 July Lapse PR Transfer														0.00	0.00	0.00
54	FY 2016 PR Transfer Adjustment														0.00	0.00	0.00
55	FY 2016 Final Rent Transfer Adj														0.00	0.00	0.00
56	FY15 & FY16 DIFP Transfer Adjustment														0.00	0.00	0.00
57	FY 2016 AG - May & June														0.00	0.00	0.00
58	FY 2016 AHC - June														0.00	0.00	0.00
59	<b>Total FY 2016 Transfers Carried Over</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>													
60	<b>Total Transfers</b>	<b>64,373.72</b>	<b>53,928.70</b>	<b>0.00</b>	<b>118,302.42</b>	<b>0.00</b>	<b>(118,302.42)</b>										
61	<b>Total Appropriation Costs and Transfers</b>	<b>177,544.43</b>	<b>169,089.85</b>	<b>0.00</b>	<b>346,634.28</b>	<b>0.00</b>	<b>(346,634.28)</b>										
62	<b>Ending Fund Balance</b>	<b>7,125,038.78</b>	<b>7,189,789.76</b>														
63																	
64																	
65	<i>*Please note that the Projected Total Appropriation Costs and Transfers does NOT include the Lapsed Appropriation Costs/Transfers Estimate included on your 5 Year Projections (line 48).</i>																
66	<b>Total PR Transfer - HB 7.540</b>	<b>24,561.17</b>	<b>18,163.30</b>	<b>0.00</b>	<b>42,724.47</b>	<b>0.00</b>	<b>(42,724.47)</b>										
67	<b>Total GR Transfer - HB 7.535</b>	<b>2,390.55</b>	<b>0.00</b>	<b>2,390.55</b>	<b>0.00</b>	<b>(2,390.55)</b>											
68	<b>Total</b>	<b>26,951.72</b>	<b>18,163.30</b>	<b>0.00</b>	<b>45,115.02</b>	<b>0.00</b>	<b>(45,115.02)</b>										
69	<b>Total Appropriation Costs</b>	<b>113,170.71</b>	<b>115,161.15</b>	<b>0.00</b>	<b>228,331.86</b>	<b>0.00</b>	<b>(228,331.86)</b>										
70	<b>Total Other Transfers</b>	<b>37,422.00</b>	<b>35,765.40</b>	<b>0.00</b>	<b>73,187.40</b>	<b>0.00</b>	<b>(73,187.40)</b>										
71	<b>Total</b>	<b>177,544.43</b>	<b>169,089.85</b>	<b>0.00</b>	<b>346,634.28</b>	<b>0.00</b>	<b>(346,634.28)</b>										

***FY 2017 YTD Expenses by Budget Class Code  
As of August 31, 2016  
Pharmacy (0637)  
Expense & Equipment: Approp 2262***

<b><i>Budget Object Class</i></b>	<b><i>Budget Object Class Name</i></b>	<b><i>YTD Expended</i></b>	<b><i>Appropriation</i></b>	<b><i>Remaining Appropriation</i></b>	<b><i>Percent Remaining</i></b>
140	TRAVEL, IN-STATE	1,161.10	25,000.00	23,838.90	95.36%
160	TRAVEL, OUT-OF-STATE	4,938.41	20,000.00	15,061.59	75.31%
180	FUEL & UTILITIES			0.00	
190	SUPPLIES	9,176.11	61,190.00	52,013.89	85.00%
320	PROFESSIONAL DEVELOPMENT	2,731.50	13,300.00	10,568.50	79.46%
340	COMMUNICATION SERV & SUPP	2,012.61	18,480.00	16,467.39	89.11%
400	PROFESSIONAL SERVICES	31,379.04	443,600.00	412,220.96	92.93%
420	HOUSEKEEP & JANITOR SERV			0.00	
430	M&R SERVICES	1,798.14	13,000.00	11,201.86	86.17%
480	COMPUTER EQUIPMENT			0.00	
560	MOTORIZED EQUIPMENT		50,462.00	50,462.00	100.00%
580	OFFICE EQUIPMENT		11,050.00	11,050.00	100.00%
590	OTHER EQUIPMENT		0.00	0.00	
640	PROPERTY & IMPROVEMENTS		5,000.00	5,000.00	100.00%
680	BUILDING LEASE PAYMENTS		3,000.00	3,000.00	100.00%
690	EQUIPMENT RENTAL & LEASES		500.00	500.00	100.00%
740	MISCELLANEOUS EXPENSES	2,327.09	10,348.00	8,020.91	77.51%
800	PROGRAM DISTRIBUTIONS	28.33	20,000.00	19,971.67	99.86%
	<b>TOTAL</b>	<b>55,552.33</b>	<b>694,930.00</b>	<b>639,377.67</b>	<b>92.01%</b>

# TECHNICIAN RENEWAL REPORT

(As of June 16, 2016)

FY2016				Total Approved		Paper Renewals		On-Line Renewals	
Date	Board	Expiration Date	Renewals Mailed (beginning of renewal period)	Total Approved	% Approved Compared to Total Renewals Mailed	Approved by CRR	% of Paper Approved Compared to Total Renewals Approved	Approved On-Line	% of Online Approved Compared to Total Renewals Approved
6/15/2016	Pharmacy Tech	5/31/2016	22584	17137	75.88%	3269	19.08%	13868	80.92%
<b>Grand Total</b>			<b>22,584</b>	<b>17,137</b>	<b>75.88%</b>	<b>3,269</b>	<b>19.08%</b>	<b>13,868</b>	<b>80.92%</b>

FY 14/15									
Date	Board	Expiration Date	Renewals Mailed (beginning of renewal period)	Total Approved	% Approved	Renewals Approved By CRR	Paper % Approved	Approved Online	Online % Approved
6/15/2015	Pharmacy Tech	5/31/2015	21954	16756	76.32%	3269	19.51%	13487	80.49%
<b>Grand Total</b>			<b>21,954</b>	<b>16,756</b>	<b>76.32%</b>	<b>3,269</b>	<b>19.51%</b>	<b>13,487</b>	<b>80.49%</b>

# PHARMACIST RENEWAL REPORT

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*(As of October 14, 2016)*

FY17				Total Approved		Paper Renewals		On-Line Renewals	
Date	Board	Expiration Date	Renewals Mailed (beginning of renewal period)	Total Approved	% Approved Compared to Total Renewals Mailed	Approved by CRR	% of Paper Approved Compared to Total Renewals Approved	Approved On-Line	% of Online Approved Compared to Total Renewals Approved
10/14/2016	Pharmacists	10/31/2016	10659	8813	82.68%	536	6.08%	8277	93.92%

**#A4 Approval of Minutes**

- April 5, 2016 Open Session
- May 11, 2016 Conference Call
- June 15, 2016 Conference Call
- July 19, 2016 Strategic Planning
- July 20, 2016 Open Session

**OPEN MINUTES**  
**Missouri Board of Pharmacy**

**April 5-6, 2016**  
**Holiday Garden Inn**  
**3300 Vandiver, Drive**  
**Columbia, MO**

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:02 a.m. on April 5, 2016, at Holiday Garden Inn, Columbia, Missouri. Each item in the minutes is listed in the order discussed.

**Board Members Present**

Christina Lindsay, R.Ph., President  
Christian Tadrus, R.Ph., Member  
Barbara Bilek, PharmD., Member  
Douglas R. Lang, R.Ph., Member  
Pamela Marshall, R.Ph., Member

**Board Members Absent**

Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, R.Ph., Chief Inspector  
Bennie Dean, R.Ph., Inspector  
Katie DeBold, R.Ph., Inspector  
Joe Dino, R.Ph., Inspector  
Jennifer Luebbert, Compliance Coordinator  
Andi Miller, PharmD, Inspector  
Tammy Siebert, Administrative Coordinator  
Lisa Thompson, R.Ph., Inspector  
Dan Vandersand, R.Ph., Inspector  
Elaina Wolzak, R.Ph., Inspector  
Barbara Wood, R.Ph., Inspector

**Others Present**

Curtis Thompson, Legal Counsel

**MOTION TO CLOSE 8:03 A.M.**

**At 8:03 a.m., Pamela Marshall made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section**

Missouri Board of Pharmacy  
Open Minutes  
April 5-6, 2016  
Page 1 of 9

610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes

Pamela Marshall – yes

Anita Parran – absent

Douglas Lang – yes

Christian Tadrus- yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 8:03 AM

### **RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 9:04 a.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 9:04 A.M

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 9:09 A.M.

### **#A1 Agenda Additions/Corrections**

Kimberly Grinston reported items # D4A, # D5A, # D6A, # D7A, # D8A, # D9A, # E4A, # E5A were added to the open session agenda.

### **#A2 Board Member Report**

**DISCUSSION:** Christian Tadrus commented Kimberly Grinston gave a presentation at the Missouri Pharmacy Association's Legislative Day which Mr. Tadrus reported approximately 450 people attended. Ron Fitzwater, CEO of the Missouri Pharmacy Association, indicated there were multiple timely presentations and thanked the Board for its support.

### **#A3 General Administration Report**

DISCUSSION: Kimberly Grinston provided the following updates:

- **Technician Renewals:** Technician renewal is currently underway; renewals must be submitted before May 31<sup>st</sup>.
- **Financial Report:** The Board's previously approved fee decreases for pharmacists and intern pharmacists will be effective in 2016. The technician renewal fee decrease will be effective in 2017. Due to delays in approval, the Board was unable to reduce technician fees for 2016.
- **NABP Meeting:** The NABP annual meeting will be held in May in San Diego; multiple board meetings will be attending.
- **TALKOM Meeting:** Ms. Grinston attended the meeting in Oklahoma and indicated a strong discussion between the states. Ms. Grinston reported Oklahoma's pharmacist inspector presented an interesting program on pharmacy ethics that may be beneficial for Missouri licensees. Ms. Grinston suggested the Board

contract with Oklahoma to present a similar webinar in Missouri. **A motion was made by Pamela Marshall, seconded by Barbara Bilek, to pursue and approve the ethics program for 1.5 continuing education (CE) hours. Motion passed 4:0:0:1 with roll call vote as follows:**

**Barbara Bilek – yes      Douglas Lang- yes      Pamela Marshall – yes  
Anita Parran – absent      Christian Tadrus – yes**

- **Pharmacy Diversion Conference:** Ms. Grinston reported BNDD reported an increase in controlled substance diversion during the MPA annual meeting. Ms. Grinston indicated she talked with BNDD and asked if the Board would be interested in funding/sponsoring a diversion awareness conference for pharmacy licensees. Discussion was held. Barbara Bilek suggested meeting after office hours to increase attendance. Pamela Marshall suggested a Saturday conference which she reported was effective for the DEA. Douglas Lang suggested adding diversion prevention/awareness to strategic planning and noted the NADDI conference had a “tough love” presentation that may be beneficial. Mr. Lang also asked the office to contact BNDD to determine if there are any statistics on where the most diversion is occurring. Board consensus to proceed with planning the diversion conference. Ms. Grinston reported they may be able to develop a presentation by June/July.
- **Suicide Prevention Week:** Ms. Grinston indicated suicide prevention week is recognized in the fall and noted pharmacist Patrick Tharp has previously presented to the Board on this issue. Ms. Grinston asked the Board about providing suicide prevention and awareness resources in the Board’s newsletter or on the Board’s website. Ms. Grinston also discussed a potential suicide prevention/awareness webinar. Board consensus to provide resources as suggested.
- **DHSS Training:** Ms. Grinston has held discussions with Dean Linneman about scheduling a training for DHSS surveyors on Missouri’s pharmacy requirements, including, long-term care and sterile compounding issues. Additional information will be provided at a later date.

#### **#D1 Inspection Violation Summary**

DISCUSSION: Ms. Grinston presented the inspection violation summary report and indicated the information is based on currently known data. Multiple Board members suggested including the report findings on the Board’s website and in future newsletters. Board members commented the report identifies areas where more education may be needed. Ms. Grinston indicated it may be time to consider other outreach tools such as social media and reported she has been in discussions with the Department.

#### **#D2 Best Practices for State Oversight of Drug Compounding**

DISCUSSION: Ms. Grinston reported the office continues to review its sterile compounding inspection/investigation procedures and noted multiple inspectors have received additional

sterile compounding training. Ms. Grinston reported inspector Katie DeBold is developing a sterile compounding checklist and working with other inspectors to assist with sterile compounding inspections. Ms. Grinston indicated the Board may need to consider how to handle/license non-resident sterile compounders in the future and suggested possibly requiring an inspection either by the Board, NABP or from their home state. Douglas Lang reported other states have increased and expanded their sterile compounding review and noted many states require a state inspection within the last 12-18 months. Mr. Lang reported the current cost for a NABP inspection is approximately \$ 5,000 for a sterile compounding inspection and \$ 3,000 for a non-sterile compounding inspection. Bert McClary, Hospital Advisory Committee Chairman, indicated hospitals are not being meaningfully inspected/surveyed for sterile compounding compliance currently and suggested the Board work with DHSS surveyors. Mr. McClary noted most DHSS surveyors are non-pharmacists. Board consensus to review non-resident sterile compounding issues along with the pending non-resident sterile compounding survey results.

### **#D3 Collection of Non-Controlled Medication**

DISCUSSION: Ms. Grinston reported she has received inquiries from various state entities regarding the proposed rule. Douglas Lang inquired about the mail back provisions in the draft rule and commented the rule should not require mailers to come back to the pharmacy. Mr. Lang noted returned mailers could be sent directly to a reverse distributor. Pamela Marshall asked if the rule clearly addressed how receptacles should be maintained when the pharmacy is closed. Christian Tadrus asked if the rule would allow collection receptacles to be maintained at a non-pharmacy location and also commented the “direct visual observation” requirement may be overreaching. Mr. Tadrus suggested receptacle security could be otherwise addressed (e.g., the receptacle could be permanently affixed within the pharmacy). Bert McClary suggested the Board keep the rule as simple as possible to avoid the unintended consequences of the MTS rule. Mr. McClary noted some licensees have opted out of MTS partially because the rule is too complicated/restrictive. Board consensus to revise the rule based on Board comments and review at a future meeting.

### **#D5A 2016-2017 Legislation**

DISCUSSION: Ms. Grinston provided general legislative updates and reported legislation is moving slowly. The PMP legislation has been assigned to committee for hearing. Ms. Grinston also reported the naloxone bill may pass this year and indicated the Board’s fund proposal has been introduced but has not been assigned to committee. Ron Fitzwater reported MPA will be attending a combined hearing in the health committee for several pharmacy related proposals.

### **#D6A Hospital Advisory Committee**

DISCUSSION: Bert McClary provided an update on the Committee’s progress and indicated the Committee has met twice since the January Board meeting. Mr. McClary reported the Committee is in the process of reviewing the administration by prescription order rule and is

working with Board/DHSS staff on a hospital related webinar. Mr. McClary reported the Committee will be looking at other hospital related issues, such as, expanded technician roles and pharmacy issues related to hospital owned/related care centers (e.g., infusion centers).

#### **#D8A Sterile Compounding Committee Update**

DISCUSSION: Christian Tadrus reported the Committee met on April 4<sup>th</sup> and will meet again on April 6<sup>th</sup>. Mr. Tadrus indicated the Committee is considering an emergency rule that will provide inspectors more enforcement ability and help close the regulatory gaps until USP Chapter 797 is revised. Mr. Tadrus noted the emergency rule will be presented to the Board for full discussion/approval once finalized.

#### **#D9A Pharmacy Permits**

DISCUSSION: Ms. Grinston reported the final order of rulemaking needs to be approved by the Board. Ms. Grinston indicated she has received comments suggesting that the rule retain the language that prohibits dispensing without a valid preexisting patient-practitioner relationship and also retain the language prohibiting dispensing based on an internet-based questionnaire. Christian Tadrus and Barbara Bilek suggested there was value in keeping the language as suggested; Barbara Bilek also suggested prohibiting dispensing based on a telephonic consultation. Additional discussion was held. Ms. Grinston commented the proposed telehealth bill currently pending may address the telehealth/telemedicine issues. **A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the order of rulemaking with the retention of the internet questionnaire prohibition and the prohibition on dispensing without a valid preexisting patient-practitioner relationship. Motion passed 4:0:0:1 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – absent</b>	<b>Christian Tadrus – yes</b>	

#### **#C1 Applications for Intern Training Pharmacy Special Site**

- GeriCo Pharma
- St. Joseph Regional Medical Center
- Student National Pharmaceutical Assoc.
- IU Health Physicians South
- Peking Union Medical College Hospital

DISCUSSION: Tom Glenski recommended approval of special sites/non-pharmacist preceptors. **A motion was made by Barbara Bilek, seconded by Pamela Marshall, to approve all Intern Training Special Site/Non-Pharmacist Applications for 500 hours. Motion passed 4:0:0:1 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – absent</b>	<b>Christian Tadrus – yes</b>	

**#C2A STLCOP and UMKC College of Pharmacy**

- UMKC Site List
- UMKC Preceptor List
- STLCOP Site List
- STLCOP Preceptor List

DISCUSSION: Tom Glenski recommended approval of the school lists as presented. **A motion was made by Barbara Bilek, seconded by Christian Tadrus, to approve the site/preceptor lists as recommended. Motion passed 4:0:0:1 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – absent</b>	<b>Christian Tadrus – yes</b>	

**#A3 General Administration Report (Cont'd)**

DISCUSSION: Kimberly Grinston reported Tammy Siebert has announced her retirement. The Board thanked Ms. Siebert for her service and presented her with a retirement gift.

**MOTION TO CLOSE 11:19 A.M.**

At 11:19 a.m., Pamela Marshall made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – absent</b>	<b>Christian Tadrus – yes</b>	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 11:20 A.M.

**RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:12 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT APPROXIMATELY 2:12 P.M.

**#B3 James Williams, #029907, #2014-003538**

**ITEMS ENCLOSED:**

- Notice of Disciplinary Hearing
- Complaint
- Administrative Hearing Commission Default Decision

- Consent Order

DISCUSSION: The Board convened a disciplinary hearing at 2:16 p.m. for James Williams. Mr. Williams was present without counsel; Joshua Hill appeared on behalf of the Board. Mr. Williams and Mr. Hill provided opening statements. Mr. Williams was sworn in and testified on his behalf. Mr. Hill presented no witnesses but admitted Exhibit 1 without objection. Mr. Williams offered Exhibit A which was objected to as hearsay. After further testimony by Mr. Williams, the objection to Exhibit A was withdrawn and Exhibit A was admitted. Board members questioned Mr. Williams. Mr. Williams indicated the Kansas Board of Pharmacy placed him on probation for five (5) years and stated he is a full-time floating pharmacist for Genoa in both Missouri and Kansas. Mr. Hill and Mr. Williams provided closing statements. The hearing adjourned at 2:57 p.m. A transcript of the hearing is available in the Board's records.

**#B4 Michael Jones, #045077, #2013-006818**

**ITEMS ENCLOSED:**

- Notice of Felony Disciplinary Hearing
- Felony Conviction Complaint

DISCUSSION: The Board convened a disciplinary hearing for Michael Jones at approximately 3:00 p.m. Mr. Jones was present without counsel; Cotton Walker appeared on behalf of the Board. Mr. Jones and Mr. Walker provided opening statements. Exhibits 1 and 2 were offered into evidence by Mr. Walker and admitted without objection. Mr. Jones was sworn in and testified on his behalf; Mr. Jones indicated he is currently on criminal probation for three (3) years. Exhibit A was offered into evidence by Mr. Jones and admitted. Mr. Walker cross-examined Mr. Jones. Questions were received from Board members. Mr. Walker requested to amend the complaint by interlineation. Mr. Walker and Mr. Jones provided closing statements. The hearing adjourned at 3:51 p.m. A transcript of the hearing is available in the Board's records.

**MOTION TO CLOSE 3:51 P.M.**

**At 3:51 p.m., Christian Tadrus made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – absent</b>	<b>Christian Tadrus – yes</b>	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 3:51 P.M.

**RECONVENE OPEN 11:55 A.M.**  
**WEDNESDAY, APRIL 6, 2016**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 11:55 a.m. on April 6, 2016.

**#D4A 2016-2017 Legal Contracts**

DISCUSSION: Ms. Grinston reported Curt's legal contract has been submitted for review/approval with a requested rate increase. Board members asked if the requested rate was comparable to rates paid for other Board legal services and commented the Board should ensure the rates are consistent. Ms. Grinston indicated she will provide other legal fee rates once new contracts are submitted. **A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve Curtis Thompson's legal contract and to review the applicable rate after other attorney contracts have been submitted. Motion passed 4:0:0:1 with roll call vote as follows:**

**Barbara Bilek – yes      Douglas Lang- yes      Pamela Marshall – yes  
Anita Parran – absent      Christian Tadrus – yes**

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

**#E1 Licensees Presently Under Discipline**

- Pharmacists
- Pharmacies
- Drug Distributors
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List

**#E2 Brehe V. MO Dept. of Elementary Secondary Education**

- MO Court of Appeals, Western District Decision

**#E3 Massachusetts Opioid Restrictions**

**#E4A APhA 2015 Annual Report**

**#E5A Board Licensee Statistics**

**MOTION TO ADJOURN 11:56 A.M.**

At approximately 11:56 a.m., a motion was made by Pamela Marshall, seconded by Barbara Bilek, to adjourn the April 5-6, 2016 meeting. Motion passed 4:0:0:1 with roll call vote as follows:

**Barbara Bilek – yes      Douglas Lang- yes      Pamela Marshall – yes  
Anita Parran – absent      Christian Tadrus – yes**

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED:

**OPEN MINUTES**  
**Missouri Board of Pharmacy**  
**Telephone Conference Call**  
**May 11, 2016**

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christina Lindsay at 3:08 p.m. on May 11, 2016. Each item in the minutes is listed in the order discussed.

**Board Members Present**

Christina Lindsay, President  
Christian Tadrus, PharmD, Vice-President  
Barbara Bilek, PharmD, Member  
Douglas Lang, R.Ph., Member  
Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector  
Jennifer Luebbert, Administrative Coordinator

**Other Attendees**

Curtis Thompson, Legal Counsel

**Staff/Board Members Absent**

Pamela Marshall, R.Ph.

*\* Board member Barbara Bilek joined the meeting at 3:18 p.m.*

**#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor**

- CVS Pharmacy District Office
- CVS Regional Business Office
- Jesse Brown VA Medical Center
- Sharp Rees-Stealy Pharmacy Benefits Administration
- Veterans Affairs Medical Center – Jefferson Barracks (VA-JB)
- Walgreens District Office
- Walmart Multisite Management

**DISCUSSION:** Tom Glenski recommended approval of all special sites/non-pharmacist preceptors. Christian Tadrus asked for additional information on the training that will be provided at the Walmart special site. **A motion was made by Christian Tadrus, seconded by Douglas Lang, to approve all Intern Training Special Site/Non-Pharmacist Applications for 500 hours with the exception of the Walmart Multisite**

**Management site. It was further moved that staff request additional information on the proposed Walmart training program. Motion passed 3:0:0:2 with roll call vote as follows:**

**Barbara Bilek – absent     Douglas Lang- yes     Pamela Marshall – absent  
Anita Parran – yes             Christian Tadrus – yes**

**#C2 STLCOP Site/Preceptor List**

- STLCOP Site Listing
- STLCOP Preceptor Listing

**DISCUSSION: Tom Glenski recommended approval of the school lists as presented. A motion was made by Christian Tadrus, seconded by Anita Parran, to approve the site/preceptor lists as recommended. Motion passed 3:0:0:2 with roll call vote as follows:**

**Barbara Bilek – absent     Douglas Lang- yes     Pamela Marshall – absent  
Anita Parran – yes             Christian Tadrus – yes**

**#D1 New FDA Guidance on 503A and 503B**

- Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act (draft)
- Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act (draft)
- Facility Definition Under Section 503B of the Federal, Drug, and Cosmetic Act (draft)

**DISCUSSION: Kimberly Grinston reported the agenda materials were provided for informational purposes. Christian Tadrus expressed concerns that the FDA has not provided clear direction and asked how the guidance documents would affect pharmacists operating under protocol. Board consensus to add this topic to the July strategic planning meeting.**

**#D2 2016 Legislative Update**

- SB 875(Truly agreed and finally passed): <http://www.senate.mo.gov/16info/pdf-bill/perf/SB875.pdf>
- HB 2007 (budget bill)-no documents
- SB 579: <http://www.senate.mo.gov/16info/pdf-bill/perf/SB579.pdf>

**DISCUSSION: Kimberly Grinston reported SB 875 has passed along with the Board's proposed language requiring reporting of out-of-state discipline. Other pharmacy related proposals are still pending, including, consolidation of refills, MAC pricing and telehealth/telemedicine. Ms. Grinston reported the PMP bill has stalled in the Senate and indicated she does not believe it will pass this year. Christina Lindsay asked if the PMP bill would allow practitioners/pharmacies access to the data; Kimberly Grinston reported one of the proposals would only grant BNDD data access.**

BARBARA BILEK JOINED THE CONFERENCE CALL AT 3:18 P.M.

**#D3 Sterile Compounding Emergency/Amended rule**

**#D5A Revised Sterile Compounding Rule**

- Email from Grinston
- SC Emergency Rule (draft)
- SC Amended Rule (draft)

DISCUSSION: *(These agenda items were discussed together)*. Kimberly Grinston reported the subcommittee met several times and also met with various industry stakeholders to develop the draft rule. Ms. Grinston indicated USP Chapter 797 revisions may not be complete until 2017/2018 although an exact date is unknown. Board discussion was held. Christian Tadrus inquired about the fiscal note and asked if costs were estimated over the life of the rule. Mr. Tadrus noted the higher fiscal note is likely to garner additional review/comments. Douglas Lang suggested sterile gloves should be required for all risk levels and noted that 75% of responders to the Board's previous sterile compounding survey indicated using sterile gloves already. Christina Lindsay asked inspector Katie DeBold about what she is seeing in the field; Katie DeBold replied approximately 50% of licensees are using sterile gloves. Christian Tadrus suggested revisiting the sterile gloves requirement after USP Chapter 797 is revised. Additional Board discussion was held on requiring sterile alcohol. Douglas Lang and Barbara Bilek indicated the rule should allow for sterile alcohol or use of an equivalent or superior agent. Board consensus to revise the emergency/amended rule as reflected in Attachment A. **A motion was made by Christian Tadrus, seconded by Barbara Bilek, to approve the proposed changes as reflected in Attachment A and to bring the draft rules back to the Board for final approval before filing. Motion passed 4:0:0:1 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – absent</b>
<b>Anita Parran – yes</b>	<b>Christian Tadrus – yes</b>	

**#D6A NABP Annual Meeting**

DISCUSSION: Kimberly Grinston reported she asked legal counsel for advice related to Missouri's Sunshine Law that should be discussed in closed.

**#D4 Update on Board of Healing Arts discussion on telehealth/telemedicine**

DISCUSSION: Kimberly Grinston reported she will provide additional updates in June.

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

**#E1 Approval of Hospital Advisory Committee Group Minutes**

- November 6, 2015 Hospital Advisory Committee Minutes
- December 14, 2015 Hospital Advisory Committee Minutes

**MOTION TO CLOSE 4:40 P.M.**

At 4:40 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 620.021(1), (5), (7), and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek– yes	Douglas Lang- yes	Pamela Marshall – absent
Anita Parran – yes	Christian Tadrus – yes	

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 5:58 p.m.

**MOTION TO ADJOURN**

At approximately 5:59 p.m., upon motion made by Barbara Bilek, seconded by Christian Tadrus, the May 11, 2016, open session conference call meeting was adjourned. Motion passed 3:0:0:2 with roll call vote as follows:

Barbara Bilek– yes	Douglas Lang- yes	Pamela Marshall – absent
Anita Parran – absent	Christian Tadrus – yes	

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved:

# ATTACHMENT A

1 Title 20—DEPARTMENT OF  
2 INSURANCE, FINANCIAL  
3 INSTITUTIONS AND  
4 PROFESSIONAL REGISTRATION  
5 Division 2220—State Board of Pharmacy  
6 Chapter 2—General Rules  
7

8  
9 PROPOSED AMENDMENT

10 20 CSR 2220-2.200 Sterile Pharmaceuticals. The Board is amending all sections of this rule.  
11 Additionally, the Board is deleting sections (5), (6), (8), (15) and (16) of the current rule and  
12 adding new sections (5), (6), (7), (8), (10), (17), (20) and (21).  
13

14  
15 *PURPOSE: This Board is amending all sections of this rule to update, clarify and*  
16 *delineate requirements for sterile compounding pharmacies.*  
17

18 20 CSR 2220-2.200 Sterile ~~Pharmaceuticals~~ Compounding

19 *PURPOSE: This rule establishes standards for the ~~preparation~~, labeling, ~~and~~ distribution and*  
20 *dispensing of sterile pharmaceuticals compounded sterile preparations by licensed pharmacies,*  
21 *pursuant to a physician's order or prescription.*

22 (1) Definitions.

23 (A) Aseptic processing: The technique involving procedures designed to preclude  
24 contamination of drugs, packaging, equipment, or supplies by microorganisms during  
25 processing.

26 (B) Batch: Compounding of multiple sterile ~~product~~ preparation units in a single discrete  
27 process, by the same individuals, carried out during one (1) limited time period.

28 (C) Beyond-Use date: A date after which a compounded preparation should not be used and is  
29 determined from the date the preparation is compounded. Because compounded preparations are  
30 intended for administration immediately or following short-term storage, their beyond-use dates  
31 must be assigned based on criteria different from those applied to assigning expiration dates to  
32 manufactured drug products.

33 (D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate  
34 risk agents where there is a need for protection of the ~~product~~ preparation, personnel and  
35 environment, according to National Sanitation Foundation (NSF) International standards.

36 ~~.(E) Class 100 environment: An atmospheric environment which contains less than one~~  
37 ~~hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal~~  
38 ~~standards.~~

39 ~~(F) Class 10,000 environment: An atmospheric environment which contains less than ten~~  
40 ~~thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal~~  
41 ~~standards.~~

42 ~~.(G) Clean room: A room —~~

- 43 ~~1. In which the concentration of airborne particles is controlled;~~
- 44 ~~2. That is constructed and used in a manner to minimize the introduction, generation, and~~  
45 ~~retention of particles inside the room; and~~
- 46 ~~3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled~~  
47 ~~as necessary.~~

48 ~~(H) Clean zone: Dedicated space —~~

- 49 ~~1. In which the concentration of airborne particles is controlled;~~
- 50 ~~2. That is constructed and used in a manner that minimizes the introduction, generation, and~~  
51 ~~retention of particles inside the zone; and~~
- 52 ~~3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled~~  
53 ~~as necessary.~~

54 ~~This zone may be open or enclosed and may or may not be located within a clean room.~~

55 (E) Buffer Area: An ISO Class 7 or better area where the primary engineering control is  
56 physically located that is constructed and used in a manner to minimize the introduction,  
57 generation, and retention of particles inside the room and in which other relevant variables (e.g.,  
58 temperature, humidity, and pressure) are controlled as necessary.

59 ~~(F) Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR~~  
60 ~~2220-2.400(1). Compounded sterile medications may include, but are not limited to, ~~injectables,~~~~  
61 ~~parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and~~  
62 ~~ophthalmic preparations.:~~

- 63 1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that  
64 must or are required to be sterile when they are administered to patients, including, but not  
65 limited to the following dosage forms: bronchial and inhaled nasal preparations intended for  
66 deposition in the lung, baths and soaks for live organs and tissues, epidural and intrathecal

67 solutions, bladder/wound solutions, injectables, implantable devices and dosage forms,  
68 inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations,  
69 parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations  
70 intended for deposit in the nasal passages may be prepared as nonsterile compounds;

71 2. An FDA approved manufactured sterile product that is either prepared according to  
72 the manufacturers' approved labeling/recommendations or prepared differently than published in  
73 such labeling; and

74 3. Assembling point-of-care assembled systems.

75 (G) Compounding Aseptic Containment Isolator (CACI): A RABS that is designed for  
76 compounding sterile hazardous drugs and designed to provide worker protection from exposure  
77 to undesirable levels of airborne drugs throughout the compounding and material transfer  
78 processes and to provide an aseptic environment for CSPs.

79 (H) Compounding Aseptic Isolator (CAI): A RABS specifically designed for compounding  
80 sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic  
81 compounding environment within the isolator throughout the compounding and material transfer  
82 processes.

83 ~~(I)~~(I) Controlled area: For purposes of these regulations, a controlled area is ~~the area a~~  
84 separate room designated for preparing sterile ~~products~~preparations or an area designated for  
85 preparing sterile preparations that is separated from other activities/operations by a line of  
86 demarcation that clearly separates the area from other operations. ~~This is referred to as the buffer~~  
87 ~~zone (i.e., the clean room in which the laminar airflow workbench is located) by the United~~  
88 ~~States Pharmacopoeia (USP).~~

89 ~~(K)~~(J) Critical area: Any area in the controlled area where ~~products~~ preparations or containers  
90 are exposed to the environment.

91 ~~(L)~~(K) Critical site: ~~An opening providing a direct pathway between a sterile product and the~~  
92 ~~environment or any surface coming into contact with the product or environment.~~ Any surface,  
93 pathway or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct  
94 pathway between a compounded sterile preparation or other ingredient used to compound a  
95 sterile preparation and the air, environment or moisture or that poses a risk of touch  
96 contamination.

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97 ~~(M) Critical surface: Any surface that comes into contact with previously sterilized products or~~  
98 ~~containers.~~

99 (L) CSP: Compounded sterile preparation.

100 ~~(N)(M)~~ Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action  
101 on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the  
102 immune system and the alteration of a host's inflammatory response system.

103 ~~(O)(N)~~ Emergency dispensing: Is a situation where a Risk Level 3 ~~product~~preparation is  
104 necessary for immediate administration of the ~~product~~preparation -and no alternative product is  
105 available and the prescriber is informed that the ~~product~~preparation is being dispensed prior to  
106 appropriate testing. Documentation of the dispensing of the ~~product~~preparation, the prescriber's  
107 approval for dispensing prior to the receipt of test results and the need for the emergency must  
108 appear within the prescription record. A separate authorization from the prescriber is required  
109 for each emergency dispensing.

110 ~~(P)(O)~~ High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter  
111 medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air  
112 forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point  
113 ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA  
114 filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an  
115 environment can be created consistent with standards for ~~a Class 100 clean room~~an ISO 5  
116 environment.

117 (P) In-Use Time/Date: The time/date before which a conventionally manufactured product or  
118 a CSP must be used after it has been opened or needle-punctured.

119 (Q) ISO Class 5: An area with less than 3,520 particles (0.5 µm and larger in size) per cubic  
120 meter.

121 (R) ISO Class 7: An area with less than 352,000 particles (0.5 µm and larger in size) per cubic  
122 meter.

123 ~~(Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-~~  
124 ~~handling system, and transfer and interaction devices. The walls are constructed so as to provide~~  
125 ~~surfaces that are cleanable with coving between wall junctures. The air handling system provides~~  
126 ~~HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings,~~

127 ~~or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take~~  
128 ~~place through either glove ports or half suits.~~

129 (S) Multiple-Dose Container: A multiple unit container for articles or compounded sterile  
130 preparations that contains more than one dose of medication and usually contains an  
131 antimicrobial preservative.

132 ~~(R)(T)~~ Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of  
133 skin.

134 (U) Primary Engineering Control (PEC): A system that provides an ISO 5 environment for  
135 the exposure of critical sites when compounding sterile preparations. PECs include, but may not  
136 be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, RABS such as  
137 compounding aseptic isolators (CAIs) or compounding aseptic containment isolators (CACIs).

138 (V) Point of Care Assembled System: A closed system device that creates a physical barrier  
139 between diluents, fluids or other drug components and is designed to be activated by the end user  
140 by allowing the components to mix prior to administration.

141 ~~(S)(W)~~ Process validation or simulation: Microbiological simulation of an aseptic process with  
142 growth medium processed in a manner similar to the processing of the ~~product~~preparation and  
143 with the same container or closure system.

144 ~~(P)(X)~~ Quality assurance: For purposes of these regulations, quality assurance is the set of  
145 activities used to ensure that the processes used in the preparation of sterile drug  
146 ~~products~~preparations lead to ~~products~~preparations that meet predetermined standards of quality.

147 ~~(U)(Y)~~ Quality control: For the purposes of these regulations, quality control is the set of  
148 testing activities used to determine —that the ingredients, components and final sterile  
149 ~~products~~preparations prepared meet predetermined requirements with respect to identity, purity,  
150 nonpyrogenicity and sterility.

151 (Z) RABS: Restricted access barrier system (RABS): A primary engineering control that is  
152 comprised of a closed system made up of four (4) solid walls, an air-handling system, and  
153 transfer and interaction devices. The walls are constructed so as to provide surfaces that are  
154 cleanable with coving between wall junctures. The air-handling system provides HEPA filtration  
155 of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports.  
156 Transfers are designed to minimize the entry of contamination. Manipulations can take place

157 through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a  
158 CAI or CACI.

159 ~~(V)~~(AA) Repackaging: The subdivision or transfer of a compounded ~~product~~preparation from  
160 one container or device to a different container or device.

161 (BB) Single-Dose/Single-Unit Container/Vial: A container/vial of medication intended for  
162 administration that is meant for use in a single patient for a single case, procedure or injection.

163 ~~(W) Sterile pharmaceutical: A dosage form free from living microorganisms.~~

164 ~~(X)~~(CC) Sterilization: A validated process used to render a ~~product~~preparation free of viable  
165 organisms.

166 ~~(Y)~~(DD) Temperatures:

167 1. Frozen means temperatures between twenty-five degrees below zero and ten degrees  
168 below zero Celsius ~~(-20 and -10°C) (four below zero and fourteen degrees Fahrenheit (-4 and~~  
169 ~~14°F))~~. (-25° and -10°C) (thirteen degrees below zero and fourteen degrees Fahrenheit (-13° and  
170 14°F)).

171 2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C)  
172 (thirty-six and forty-six degrees Fahrenheit (36 and 46°F)).

173 3. Controlled Rroom temperatures ~~means room temperatures between fifteen and thirty~~  
174 ~~degrees Celsius (15 and 30°C) (fifty nine and eighty six degrees Fahrenheit (59 and 86°F))~~. a  
175 temperature maintained thermostatically that encompasses the usual and customary working  
176 environment of 20° to 25° Celsius (68° to 78° F). Excursions between 15° and 30° Celsius  
177 (59° to 86° F) as commonly experienced in pharmacies and other facilities shall be deemed  
178 compliant. Transient spikes up to 40° Celsius are permitted as long as they do not exceed 24  
179 hours. Spikes above 40° Celsius are permitted if allowed by the manufacturer.

180 (EE) USP: The United States Pharmacopeia and the National Formulary (USP-NF) as  
181 adopted and published by the United States Pharmacopeial Convention, effective May 2013.  
182 Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway,  
183 Rockville, MD 20852-1790 or online at <http://www.usp.org/>. The USP-NF is incorporated  
184 herein by reference. This rule does not include any later amendments or additions to the USP-  
185 NF.

186 ~~(Z)~~(FF) Validation: Documented evidence providing a high degree of assurance that specific  
187 processes will consistently produce a productpreparation meeting predetermined specifications  
188 and quality attributes.

189 ~~(AA)~~(GG) Definitions of sterile compounded productpreparations by risk level:

190 1. Risk Level 1: Applies to compounded sterile productpreparations that exhibit  
191 characteristics A., B., ~~and~~or C., stated below. All Risk Level 1 productpreparations shall be  
192 prepared with sterile equipment; ~~and~~ sterile ingredients and solutions ~~and sterile contact surfaces~~  
193 ~~for the final product in an ISO Class 5 environment~~. Risk Level 1 includes the following:

194 A. ProductPreparations:

195 (I) Stored at controlled room temperature and ~~completely administered within~~ assigned a  
196 beyond-use date of forty-eight (48) hours ~~after preparation or less~~; or

197 (II) Stored under refrigeration ~~for~~ and assigned a beyond-use date of seven (7) days or  
198 less ~~before complete administration to a patient over a period not to exceed forty eight (48)~~  
199 ~~hours~~; or

200 (III) ~~Stored Frozen for~~ and assigned a beyond-use date of thirty (30) days or less ~~before~~  
201 ~~complete administration to a patient over a period not to exceed forty eight (48) hours~~.

202 B. Unpreserved sterile productpreparations prepared for administration to one (1) patient or  
203 batch-prepared productpreparations containing suitable preservatives prepared for administration  
204 to more than one (1) patient with an assigned beyond-use date that does not exceed the beyond-  
205 use date allowed for under section (1)(GG)1.A. of this rule.

206 C. ProductPreparations prepared by closed-system aseptic transfer of sterile, nonpyrogenic,  
207 finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into  
208 sterile final containers obtained from licensed manufacturers with an assigned beyond-use date  
209 that does not exceed the beyond-use date allowed under section (1)(GG)1.A. of this rule.

210 2. Risk Level 2: Sterile productpreparations exhibit characteristic A., B., or C., stated below.  
211 All Risk Level 2 productpreparations shall be prepared with sterile equipment; ~~and~~ sterile  
212 ingredients and solutions ~~and sterile contact surfaces for the final product in an ISO Class 5~~  
213 environment and with closed-system transfer methods. Risk Level 2 includes the following:

214 A. ~~Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30)~~  
215 ~~days frozen or administered beyond forty eight (48) hours after preparation and storage at room~~  
216 ~~temperature~~. Preparations stored under refrigeration and assigned a beyond-use date greater than

217 seven (7) days or preparations stored frozen and assigned a beyond-use date greater than thirty  
218 (30) days or preparations stored at controlled room temperature and assigned a beyond-use date  
219 greater than forty-eight hours.

220 B. Batch-prepared ~~product~~preparations without preservatives that are intended for use by  
221 more than one (1) patient.

222 C. ~~Product~~Preparations compounded by complex or numerous manipulations of sterile  
223 ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from  
224 a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder).

225 3. Risk Level 3: Sterile ~~products~~preparations exhibit either characteristic A. or B.:

226 A. ~~Products~~Preparations compounded from nonsterile ingredients or compounded with  
227 nonsterile components, containers or equipment before terminal sterilization.

228 B. ~~Products~~Preparations prepared by combining multiple ingredients (sterile or nonsterile)  
229 by using an open-system transfer or open reservoir before terminal sterilization.

230 (2) Policy and Procedure Manual/Reference Manuals.

231 (A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2  
232 and 3 ~~products~~ compounding, shall be available for inspection at the pharmacy. The manual shall  
233 be reviewed on an annual basis. The pharmacy shall have current reference materials related to  
234 sterile ~~products~~ preparations.

235 (3) Personnel Education, Training and Evaluation.

236 (A) Risk Level 1: All pharmacy personnel preparing sterile ~~products~~preparations must receive  
237 suitable didactic and experiential training in aseptic technique and procedures and shall be  
238 skilled and trained to accurately and competently perform the duties assigned. Additional  
239 training must be provided if the risk level of sterile activity conducted by the individual changes  
240 or if there is a change in compounding methods performed. To ensure competency, individuals  
241 preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that  
242 complies with section (10) of this rule. The pharmacy shall establish policies and procedures for  
243 staff training and assessment.

244 (B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training must includes  
245 assessment of competency in all Risk Level 2 procedures via process simulation.

246 (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific  
247 education, training and experience to prepare Risk Level 3 ~~products~~ preparations. The pharmacist  
248 knows principles of good compounding practice for risk level ~~products~~preparations, including—

- 249 1. Aseptic processing;
- 250 2. Quality assurance of environmental, component, and end-~~product~~preparation testing;
- 251 3. Sterilization; and
- 252 4. Selection and use of containers, equipment, and closures.

253 (4) Storage and Handling in the Pharmacy.

254 (A) Risk Level 1 and 2: Solutions, drugs, supplies and compounding equipment must be stored  
255 ~~according to manufacturer or USP requirements~~ and maintained in a manner that will maintain  
256 the chemical and microbiological stability of CSPs. Refrigeration ~~and~~, freezer and, if applicable,  
257 incubator temperatures shall be documented daily. Other storage areas shall be inspected  
258 regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be  
259 shelved above the floor. Removal of ~~products~~drugs and supplies from boxes shall be done  
260 outside controlled areas. Removal of used supplies from the controlled area shall be done at least  
261 daily. ProductPreparation recall procedures must comply with section (21) of this rule and must  
262 permit retrieving affected ~~product~~preparations from specific involved patients.

263 (B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, the pharmacy must establish  
264 procedures ~~include for~~ procurement, identification, storage, handling, testing, and recall of  
265 components and finished ~~products~~ preparations. Finished ~~but untested~~ Risk Level 3 ~~products~~  
266 preparations awaiting test results must be quarantined under minimal risk for contamination in a  
267 manner that will maintain chemical and microbiological stability.

268 ~~(5) Facilities and Equipment.~~

269 ~~(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled~~  
270 ~~area must be clean and well lit. A sink with hot and cold water must be near, but not in, the~~  
271 ~~controlled area. The controlled area and inside equipment must be cleaned and disinfected~~  
272 ~~regularly. Sterile products must be prepared in at least a Class 100 environment (the critical~~  
273 ~~area). Computer entry, order processing, label generation, and record keeping shall be performed~~  
274 ~~outside the critical area. The critical area must be disinfected prior to use. A workbench shall be~~  
275 ~~recertified every six (6) months and when it is moved; prefilters must be visually inspected on a~~

276 ~~regularly scheduled basis and replaced according to manufacturer's specifications. Pumps~~  
277 ~~utilized in the compounding process shall be recalibrated and documented according to~~  
278 ~~manufacturer procedures.~~

279 ~~(B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet~~  
280 ~~Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room~~  
281 ~~standards; critical area work surface must be cleaned between batches; floors should be~~  
282 ~~disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental~~  
283 ~~monitoring of air and surfaces. Automated compounding devices must be calibrated and verified~~  
284 ~~as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis~~  
285 ~~must be cleaned prior to use as stated above.~~

286 ~~(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in~~  
287 ~~a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a~~  
288 ~~positive pressure barrier isolator. Access to the clean room must be limited to those preparing the~~  
289 ~~products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized,~~  
290 ~~calibrated, and documented according to manufacturer's standards. Walls and ceilings must be~~  
291 ~~disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final~~  
292 ~~product must be sterilized before introduction in the clean room. Appropriate cleaning and~~  
293 ~~disinfection of the environment and equipment are required.~~

294 (5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to  
295 ensure environmental quality, prevent environmental contamination and maintain air quality in  
296 all ISO classified areas.

297 (A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled  
298 area that meets the requirements of this rule. A sink with hot and cold water must be near, but  
299 not in, the controlled area. The controlled area and inside equipment must be cleaned and  
300 disinfected as provided in section (17) of this rule. Activities within the critical area shall be  
301 kept to a minimum to maintain the ISO classified environment. Primary engineering controls  
302 shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a  
303 regularly scheduled basis and replaced according to manufacturer's specifications. Pumps  
304 utilized in the compounding process shall be recalibrated and documented according to  
305 manufacturer procedures.

306 (B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must  
307 be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled  
308 area. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the  
309 preparation.

310 (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations  
311 must be prepared in a PEC located in a buffer area or prepared in a RABS located within a  
312 controlled area. All non-sterile equipment that is to come in contact with the sterilized final  
313 preparation must be sterilized before introduction in the buffer area or into the RABS. Once  
314 compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of  
315 the preparation.

316 (D) Automated compounding devices shall be tested for content, volume and weight accuracy  
317 prior to both initial and daily use according to manufacturer procedures. Test results shall be  
318 reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and  
319 the review date shall be documented in the pharmacy's records.

320 (E) All PECs and ISO classified areas shall be certified to ensure compliance with  
321 requirements of this rule prior to beginning sterile compounding activities and every six (6)  
322 months thereafter. Certification shall be conducted by competent staff/vendors using recognized  
323 and appropriate certification and testing equipment. Certification results shall be reviewed by a  
324 pharmacist once received. Deficiencies or failures shall be investigated and corrected prior to  
325 further compounding which may include recertification of the PEC/ISO classified area.

326 1. The PEC and ISO classified areas must be recertified when: (1) any changes or major  
327 service occurs that may affect airflow or environmental conditions or (2) the PEC or room is  
328 relocated or the physical structure of the ISO classified area has been altered.

329 2. Corrections may include, but are not limited to, changes in the use of the affected PEC  
330 or ISO classified area or initiating a recall. The identity of the pharmacist conducting the  
331 required review and the review date shall be documented in the pharmacy's records.

332 (F) Pressure Differential: If the controlled area is equipped with a device to monitor pressure  
333 differential, pressure differential results must be recorded and documented each day that the  
334 pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may  
335 be used to record pressure differential results if the system maintains ongoing documentation of  
336 pressure recordings or maintains pressure alerts that are reviewed daily.

337  
338 (6) Primary Engineering Controls (PECs):  
339 (A) PECs must be properly used, operated and maintained and must be located out of traffic  
340 patterns and away from conditions that could adversely affect their operation or disrupt intended  
341 airflow patterns (e.g., ventilation systems or cross-drafts).  
342 (B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions  
343 and while compounding sterile preparations, including, when transferring ingredients into and  
344 out of the PEC and during exposure of critical sites;  
345 (C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to  
346 prevent airborne particles from contacting critical sites.  
347 (D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the  
348 pharmacy's policies and procedures. Procedures must be developed to ensure adequate recovery  
349 time is allowed before or during compounding operations and after material transfer.  
350  
351 (7) Controlled Areas. The controlled area shall be designed, maintained and controlled to allow  
352 effective cleaning and disinfection and to minimize the risk of contamination and the  
353 introduction, generation and retention of particles inside the PEC.  
354 (A) Controlled areas must be clean and well-lit and shall be free of infestation by insects,  
355 rodents and other vermin. Trash shall be disposed of in a timely and sanitary manner and at least  
356 daily. Tacky mats or similar articles shall be prohibited in the controlled area or any ISO  
357 classified environment.  
358 (B) Traffic flow in or around the controlled area shall be minimized and controlled. Food  
359 items, chewing gum, eating, drinking and smoking are prohibited in the area;  
360 (C) Nonessential objects that shed particles shall not be brought into the controlled area,  
361 including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g.,  
362 gauze pads). Furniture, carts, supplies and equipment shall be removed from shipping  
363 cartons/containers and properly cleaned and disinfected with sterile alcohol before entering any  
364 ISO classified area. No shipping or other external cartons may be taken into the controlled area  
365 or an ISO classified area.  
366 (D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or  
367 other non-essential equipment shall not be stored in or on the PEC.

368 ~~(6) Apparel.~~

369 ~~(A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers.~~  
370 ~~Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile~~  
371 ~~preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is~~  
372 ~~compromised.~~

373 ~~(B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn~~  
374 ~~inside the controlled area at all times during the preparation of Risk Level 3 sterile products~~  
375 ~~except when positive pressure barrier isolation is utilized. Attire shall consist of a low shedding~~  
376 ~~coverall, head cover, face mask, and shoe covers.~~

377 (8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be  
378 trained and demonstrate competence in proper personal garbing, gloving and hand hygiene.  
379 Competence must be documented and assessed through direct visual observation as part of the  
380 aseptic technique skill assessment required by this rule.

381 (A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks  
382 and beard covers must be worn during compounding and cleaning. All head and facial hair must  
383 be covered. During sterile preparation, gloves shall be disinfected before use and frequently  
384 thereafter with a suitable agent and changed when integrity is compromised. All personnel in the  
385 controlled area must be appropriately garbed as required by this section.

386 (B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and  
387 sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All  
388 personnel in the controlled or buffer area must garb as required by this section.

390 ~~(7)~~(9) Aseptic Technique and Product Preparation. Appropriate quality control methods shall  
391 be maintained over compounding methods at all times to ensure proper aseptic technique.

392 (A) Risk Level 1: Sterile ~~products~~preparations must be prepared in ~~a Class 100~~ an ISO Class 5  
393 environment. Personnel shall scrub their hands and forearms for~~an appropriate period at the~~  
394 ~~beginning of each aseptic compounding process~~ a minimum of thirty (30) seconds and remove  
395 debris from underneath fingernails under warm running water before donning the required  
396 gloves. Eating, drinking and smoking are prohibited in the controlled area. Talking shall be  
397 minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible,

398 | and appropriate for the ~~productpreparation~~ to be prepared, according to manufacturer, USP, or  
399 | scientific references. Ingredients and containers shall be inspected for defects, expiration and  
400 | integrity before use. Only materials essential for aseptic compounding shall be placed in the  
401 | ~~workbenchPEC. Surfaces of ampules and vials shall be disinfected before placement in the~~  
402 | ~~workbench.~~ Supplies, equipment and the surfaces of ampules and vials shall be disinfected  
403 | before entering the PEC by wiping the outer surface with sterile alcohol or an equivalently  
404 | effective non-residue generating disinfectant. Sterile components shall be arranged in the  
405 | ~~workbenchPEC~~ to allow clear, uninterrupted laminar airflow path of HEPA-filtered air over  
406 | critical ~~surfaces of needles, vials, ampules, etc.~~ sites. Automated devices and equipment shall be  
407 | cleaned, disinfected and placed in the ~~workbenchPEC~~ to enable laminar airflow. Aseptic  
408 | technique shall be used to avoid touch contamination of critical sites of containers and  
409 | ingredients. Particles shall be filtered from solutions if applicable. Needle cores shall be avoided.  
410 | The pharmacist shall check before, during, and after preparation to verify the identity and  
411 | amount of ingredients before release.

412 | (B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing the formula,  
413 | components, procedures, sample label, and final evaluation shall be made for each  
414 | ~~productpreparation batch~~. A separate work sheet and lot number for each batch shall be  
415 | completed. When combining multiple sterile ~~products~~ preparations, a second verification of  
416 | calculations shall take place. The pharmacist shall verify data entered into any automatic  
417 | compounder before processing and check the end ~~productpreparation~~ for accuracy.

418 | (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must  
419 | meet compendial standards ~~if available, as or must be~~ verified by a pharmacist and a certificate  
420 | of analysis. Batch preparation files shall also include comparisons of actual with anticipated  
421 | yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used  
422 | when feasible. Final containers must be sterile and capable of maintaining ~~productpreparation~~  
423 | integrity throughout the shelf life. Sterilization methods must be based on properties of the  
424 | ~~productpreparation and must be conducted in a method recognized for the preparation by USP.~~

425 | (D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or  
426 | cleaner air may be used in compounding until the assigned in-use time which shall not exceed six  
427 | (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened

428 single-dose ampules shall not be stored for any time period. The in-use time must be placed on  
429 the vial/container.

430 (E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an  
431 antimicrobial preservative may be used in compounding until the assigned in-use date which  
432 shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g.,  
433 needle-puncture). The in-use date must be placed on the vial/container.

434 ~~(8) Process Validation.~~

435 ~~(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process~~  
436 ~~validation of aseptic technique before compounding sterile products. Pharmacy personnel~~  
437 ~~competency must be reevaluated by process validation at least annually, whenever the quality~~  
438 ~~assurance program yields an unacceptable result, or whenever unacceptable techniques are~~  
439 ~~observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective~~  
440 ~~action taken, and the process simulation test performed again.~~

441 ~~(B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall~~  
442 ~~cover all types of manipulations, products and batch sizes.~~

443 ~~(C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be~~  
444 ~~maintained to validate all processes, procedures, components, equipment and techniques.~~

445  
446 (10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must  
447 take and successfully pass an aseptic technique skill assessment to verify aseptic competency.  
448 The assessment must include a direct visual observation of the individual's aseptic competency  
449 during a process simulation that represents the most challenging or stressful conditions  
450 encountered or performed by the person being evaluated. The assessment must include media  
451 fill testing for all risk levels.

452 (A) The required visual observation shall assess:

453 1. Proper aseptic technique, manipulations and work practices, including, but not  
454 limited to, avoiding touch contamination, proper use of first air and if  
455 applicable, sterilizing high risk CSPs;

456 2. Cleaning and disinfection;

457 3. Hand hygiene, gloving and garbing;

458 4. Identifying, weighing, and measuring of ingredients;

459 5. Maintaining sterility in ISO Class 5 areas;  
460 6. Labeling and inspecting CSPs for quality.  
461 (B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for  
462 media-fill testing. Media-fill testing shall comply with USP Chapter 797's recommended  
463 procedures and methods and must be conducted using the most challenging or stressful  
464 conditions/compounding actually encountered or performed by the person being evaluated using  
465 the same container or closure. A minimum of three media-fill tests must be completed during  
466 initial media-fill testing and one media-fill test completed for ongoing testing.  
467 (C) Frequency: The required Aseptic Technique Skill Assessment must be conducted  
468 prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2  
469 compounding and every (6) months thereafter for Risk Level 3 compounding. Additionally, an  
470 Aseptic Technique Skill Assessment must be conducted whenever the quality assurance program  
471 yields an unacceptable result, whenever unacceptable techniques are observed, if the risk level of  
472 sterile activity conducted by the individual changes or if there is a change in compounding  
473 methods performed.  
474 (E) Individuals who fail written tests; visual observation of hand hygiene, garbing, and  
475 aseptic technique; or media-fill tests must undergo immediate requalification through additional  
476 training by competent compounding personnel. Individuals who fail visual observation of hand  
477 hygiene, garbing, and aseptic technique; or media-fill tests must pass three successive  
478 reevaluations in the deficient area before they can resume compounding of sterile preparations.  
479 ~~(9)~~(11) Record Keeping.  
480 (A) Risk Level 1: The following must be documented:  
481 1. Training and competency evaluation of pharmacy personnel involved in sterile ~~product~~  
482 ~~preparation~~compounding, including, the dates and results of the required aseptic technique  
483 training, aseptic technique skill assessment and media-fill testing;  
484 2. Refrigerator, ~~and~~ freezer and, if applicable, incubator temperature logs;  
485 3. Certification ~~of workbenches~~ dates and results for any PEC or ISO classified area;  
486 4. ~~Copies of any m~~Manufacturer ~~standards~~manuals that are relied upon to maintain  
487 compliance with this rule; ~~and~~  
488 5. Other facility quality control logs as appropriate including all maintenance, cleaning, and  
489 calibration records; and

490 6. If applicable, pressure recordings including documentation of the review of continuous  
491 monitoring system results as required by section (5)(F).

492 (B) Risk Level 2: In addition to Risk Level 1 requirements, records of any end-  
493 ~~product~~preparation testing and batch preparation records must be maintained.

494 (C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk  
495 Level 3 ~~products~~ preparations must include:

- 496 1. Preparation work sheet;
- 497 2. Sterilization records;
- 498 3. Quarantine records, if applicable;
- 499 4. End-~~product~~preparation evaluation and testing records as required in section ~~(12)~~(14); and
- 500 5. Ingredient validation records as required in section ~~(12)~~(14).

501 (D) All records and reports shall be maintained either electronically or physically for two (2)  
502 years and shall be readily retrievable; and subject to inspections by the board of pharmacy or its  
503 agents. At a minimum, records shall be physically or electronically produced immediately or  
504 within two (2) hours of a request from the Board or the Board's authorized designee.

505 ~~(10)~~(12) Labeling.

506 ~~(A)~~ Risk Level 1: Sterile ~~products dispensed to patients~~ preparations shall be labeled in  
507 accordance with section 338.059, RSMo and with the following supplemental information  
508 ~~affixed to a permanent label:~~

- 509 1. Beyond-use date;
- 510 2. Storage requirements if stored at other than controlled room temperature;
- 511 3. Any device specific instructions; ~~and~~
- 512 4. Auxiliary labels, when applicable; and

513 5. If applicable, a designation indicating the preparation is hazardous.

514 ~~(B) Risk Level 2: All requirements for Risk Level 1 must be met.~~

515 ~~(C) Risk Level 3: All requirements for Risk Level 1 must be met.~~

516 ~~(11)~~(13) Beyond-Use Dating.

517 (A) Risk Level 1 and Risk Level 2: All sterile ~~products~~preparations must bear a beyond-use  
518 date. Beyond-use dates ~~are~~must be assigned based on current drug and microbiological stability  
519 information and sterility considerations.

520 (B) ~~Risk Level 2: All requirements for Risk Level 1 must be met.~~  
521 ~~(C)~~ Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method  
522 for establishing all ~~expiration~~beyond-use dates, including laboratory testing of product stability,  
523 pyrogenicity, particulate contamination and potency. ~~Expiration dating not specifically~~  
524 ~~referenced in the product's approved labeling or not established by product specific instrumental~~  
525 ~~analysis, shall be limited to thirty (30) days.~~ Beyond-use dating not specifically referenced in the  
526 products approved labeling or not established by product specific instrumental analysis shall be  
527 limited to thirty (30) days. There must be a reliable method for establishing all beyond-use  
528 dating. ~~Products maintaining beyond-use dating~~Preparations assigned a beyond-use date of  
529 greater than thirty (30) days shall have lab testing of ~~product~~preparation stability and potency.

530 ~~(12)~~(14) End-~~Product~~Preparation Evaluation.

531 (A) Risk Level 1: The final ~~product~~preparation must be inspected for clarity, container leaks,  
532 integrity, and appropriate solution cloudiness or phase separation, ~~particulates in solution,~~  
533 ~~appropriate~~ solution color, and solution volume. The pharmacist must verify that the  
534 ~~product~~preparation was compounded accurately as to the ingredients, quantities, containers, and  
535 reservoirs. Background light or other means for the visual inspection of ~~products~~preparations for  
536 any particulate and/or foreign matter must be used as part of the inspection process, provided an  
537 alternate means of inspection shall be used if a visual inspection or exposure to the preparation  
538 may pose a health hazard.

539 (B) Risk Level 2: All Risk Level 1 requirements must be met.

540 (C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure  
541 shall be supplemented with a program of end-~~product~~preparation sterility testing according to a  
542 formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A  
543 method for recalling batch ~~products~~preparations shall be established if end-~~product~~preparation  
544 testing results are unacceptable. ~~All~~A sample from each sterile ~~products~~preparation/batch must  
545 be tested for sterility. ~~All~~A sample of each parenteral sterile ~~products~~preparation/batch must also  
546 be tested for pyrogenicity. ~~Sterile products compounded from nonsterile components~~Risk Level  
547 3 preparations must be quarantined and stored to maintain chemical and microbiological stability  
548 pending results of end-~~product~~preparation testing.

549 1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of  
550 preparation. The sterility test, including the sampling scheme, shall be conducted according to  
551 ~~one (1) of the~~ a recognized USP methods for the preparation.

552 2. Pyrogen/Endotoxin testing: ~~Each~~ Sterile parenteral ~~product~~preparations prepared from  
553 non-sterile drug components shall be tested for pyrogen or endotoxin according to recommended  
554 USP methods.

555 3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of  
556 the active ingredients in the compounded sterile ~~product~~preparation prepared from non-sterile  
557 bulk active ingredients. The procedure shall include at least the following verifications by a  
558 pharmacist:

559 A. The lot of the active ingredients used for compounding have the necessary labeling,  
560 potency, purity, certificate of analysis and other relevant qualities;

561 B. All weighings, volumetric measurements, and additions of ingredients were carried out  
562 properly;

563 C. The compounding or control records include documentation that the fill volumes of all  
564 units available for release were checked and were correct; and

565 D. The final potency is confirmed by instrumental analysis for sterile ~~product~~preparations  
566 that have been assigned a beyond-use date of more than thirty (30) days.

567 (D) Emergency Dispensing of a Risk Level 3 Sterile ~~Product~~Preparation: When a compounded  
568 Risk Level 3 ~~product~~preparation must be released prior to the completion of -testing, the sterile  
569 ~~product~~preparation may be dispensed pending test results. Emergency dispensing shall be  
570 defined as, and comply with, section (1)(N) of this rule.

571 ~~(13) Handling Sterile Products Outside the Pharmacy.~~ (15) Storage, Handling and Transport.

572 ~~(A) Risk Level 1: Sterile preparations shall be packaged, stored, dispensed and distributed in a~~  
573 manner that will maintain the preparation's chemical and microbiological stability until the  
574 assigned beyond-use date or until delivery to the patient or intended recipient. The pharmacist-  
575 in-charge shall assure the environmental control of all sterile compounded ~~product~~preparations  
576 shipped. Sterile ~~product~~preparations shall be transported so as to be protected from excesses of  
577 temperatures and light within appropriate packaging or delivery containers that maintain  
578 necessary storage conditions to preserve the quality and integrity of sterile ~~product~~preparations.  
579 The pharmacy shall follow written procedures that specify packing techniques, configuration,

580 and materials for groups of ~~product~~preparations with common storage characteristics and for  
581 specific ~~product~~preparations where unique storage conditions are required to retain adequate  
582 stability and ~~product~~preparation quality.

583 ~~(B) Risk Level 2: All requirements for Risk Level 1 must be met.~~

584 ~~(C) Risk Level 3: All requirements for Risk Level 1 must be met.~~

585  
586 (16) Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be  
587 considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a  
588 beyond-use date which may exceed the beyond-use-date authorized for Risk Level 1 preparations  
589 provided the date is assigned in accordance with the manufacturer's recommendations or  
590 labeling.

591 (A) When dispensed, an assembled non-activated system shall be labeled with beyond-  
592 use dates for both activated and non-activated states. The compounding record must document  
593 both dates. The beyond-use date of an assembled non-activated system shall be limited to a  
594 maximum of fifteen (15) days unless the pharmacy has documentation from the system's  
595 manufacturer that a longer date is acceptable.

596 (B) Point of care assembled systems shall be assembled and stored in accordance with  
597 the manufacturer's labeling and recommendations.

598  
599 (17) General Cleaning and Disinfection Requirements. Except as otherwise provided herein,  
600 cleaning and disinfection of controlled and buffer areas, supplies and equipment shall be  
601 performed and conducted in accordance with USP Chapter 797 timeframes and procedures.  
602 Controlled areas that do not meet ISO air classifications shall be cleaned and disinfected as  
603 required by USP Chapter 797 for segregated compounding areas. If compounding is done less  
604 frequently than the cleaning and disinfection timeframes specified in USP Chapter 797, cleaning  
605 and disinfection must occur before each compounding session begins.

606 (A) The pharmacy shall establish and follow written policies and procedures governing all  
607 aspects of cleaning and disinfection, including, approved cleaning/disinfecting agents  
608 and materials, schedules of use and methods of application.

609 (B) Individuals shall be trained in proper cleaning and disinfection procedures prior to  
610 performing such activities. Training shall include direct visual observation of the  
611 individual's cleaning and disinfecting process by qualified staff. The individual shall be  
612 annually reassessed for competency through direct visual observation. Documentation  
613 of the required training and training dates shall be maintained in the pharmacy's records.  
614 Individuals who fail to demonstrate competency shall be reinstructed and successfully  
615 reevaluated prior to any further cleaning or disinfection.

616 (C) Cleaning and disinfection activities shall be performed using approved  
617 cleaning/disinfection agents and procedures described in the pharmacy's written policies  
618 and procedures. Manufacturers' directions for minimum contact time shall be followed.

619 (D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated  
620 for use in the controlled area and buffer area.

621 (E) Primary engineering controls shall be cleaned with a germicidal agent followed by  
622 sterile alcohol. Sterile water for irrigation shall be used to dilute germicidal agents used  
623 inside the PEC that require dilution.

624 (F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding,  
625 between batches and whenever contamination is suspected using sterile alcohol which is  
626 allowed to dry immediately prior to compounding.

627 ~~(14)~~

628 (18) Environmental Sampling/Testing. The pharmacy shall establish and follow proper controls  
629 to ensure environmental quality, prevent environmental contamination and maintain air quality in  
630 all ISO classified areas. Applicable environmental monitoring of air and surfaces must be  
631 conducted. Air monitoring must be conducted prior to initial compounding and every six (6)  
632 months thereafter. Surface sampling/monitoring must be conducted every six (6) months for  
633 Risk Level 2 and every thirty (30) days for Risk Level 3 compounding.

634 (19) Cytotoxic Drugs.

635 (A) The following additional requirements are necessary for those licensed pharmacies that  
636 prepare cytotoxic drugs to insure the protection of the personnel involved:

637 1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet  
638 or ~~an isolator~~ a CACI. If used for other ~~product~~ preparations, the cabinet must be thoroughly  
639 cleaned;

640 2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall  
641 include disposable masks, gloves and gowns with tight cuffs;

642 3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be  
643 used in conjunction with the aseptic techniques required for preparing sterile  
644 ~~product~~preparations. Chemotherapy preparations should be compounded using a closed system  
645 drug transfer device;

646 4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic  
647 waste from the preparation of chemotherapy agents and infectious waste from patients' homes.  
648 Disposal of cytotoxic waste shall comply with all applicable local, state and federal  
649 requirements;

650 5. Written procedures for handling major and minor spills and generated waste of cytotoxic  
651 agents must be developed and must be included in the policy and procedure manual;

652 6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and  
653 outside, and shipped in a manner to minimize the risk of accidental rupture of the primary  
654 container.

655 ~~(15) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be~~  
656 ~~exempt from this rule when compounding is restricted to utilizing compounds or products that~~  
657 ~~are contained only in a closed or sealed system and can be transferred or compounded within this~~  
658 ~~self-contained system or topical products that require further transfer or combination in order to~~  
659 ~~achieve a finished product without further modification of the product.~~

660 ~~(16) In addition to the requirements outlined in this rule, all standards and requirements as~~  
661 ~~outlined in 20-CSR-2220-2.400 must be maintained. Pharmacies that are registered with the Food~~  
662 ~~and Drug Administration (FDA) are exempt from the distribution restrictions in 20-CSR-2220-~~  
663 ~~2.400(12) for compounded sterile pharmaceuticals distributed with FDA's knowledge and~~  
664 ~~enforcement discretion. This exemption applies only to a twenty four (24) hour course of~~  
665 ~~therapy which is needed:~~

666 ~~(A) To treat an emergency situation; or~~

667 ~~(B) For an unanticipated procedure for which a time delay would negatively affect a patient~~  
668 ~~outcome. In order to continue beyond twenty four (24) hours, the pharmacy must obtain a~~  
669 ~~prescription and comply with all record and labeling requirements as defined by law or~~  
670 ~~regulation.~~

671 (20) Remedial Investigations: A remedial investigation shall be required if: (1) any sampling or  
672 testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP  
673 Chapter 797 recommended action levels for the type of sampling/testing or (2) if a highly  
674 pathogenic microorganism is detected in any preparation or ISO classified area (e.g., Gram-  
675 negative rods, coagulase positive staphylococcus, molds, fungus or yeasts).

676 (A) CSPs and any ingredients used within the compounding process that are part of the  
677 remedial investigation shall be quarantined until the results of the investigation are known. All  
678 affected areas shall be resampled to ensure a suitable state of microbial control prior to further  
679 compounding. The pharmacy shall ensure that no misbranded, contaminated or adulterated CSP  
680 is administered or dispensed for patient use.

681 (B) The pharmacy shall notify the Board in writing within seven (7) days if any  
682 preparation or environmental monitoring/testing detects a highly pathogenic microorganism,  
683 regardless of CFU count.

684  
685 (21) Recalls. A recall must be initiated when a CSP is deemed to be misbranded, adulterated or  
686 non-sterile or if end-preparation testing results are out of specification. The pharmacy shall  
687 notify the prescriber of the nature of the recall, the problem(s) identified and any recommended  
688 actions to ensure public health and safety. In cases where the CSP has the potential to harm the  
689 patient, the same notification shall be provided to all patients that received the recalled CSP(s).  
690 Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3)  
691 business days. The pharmacy shall document their activities related to the recall.

692 *AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and section 338.010, RSMo*  
693 *Supp. 2007.\* This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992,*  
694 *effective Feb. 26, 1993. Amended: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded and*  
695 *readopted: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 220-2.200, effective*  
696 *Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

697 \*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo  
698 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended  
699 1971, 1981.

700  
701 *PUBLIC COST: This proposed amendment will not cost state agencies or political more*  
702 *than five hundred dollars (\$ 500) in the aggregate.*

703  
704 *PRIVATE COST: This proposed amendment will cost private entities approximately*  
705 *\$\_\_\_\_\_ over the life of the rule.*

706

**FISCAL NOTE  
PRIVATE COST**

- I. Department Title: Department of Insurance, Financial Institutions and Professional Registration**  
**Division Title: State Board of Pharmacy**  
**Chapter Title: General Rules**

<b>Rule Number and Title:</b>	<b>20 CSR 2220-2.200 (Sterile Pharmaceuticals)</b>
<b>Type of Rulemaking:</b>	<b>Proposed Amendment</b>

**II. SUMMARY OF FISCAL IMPACT**

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
97-123	Missouri Sterile Compounding Pharmacies	\$ 99,245 <i>(Y1 Implementation)</i>
97-123	Missouri Sterile Compounding Pharmacies	\$ 2,289,007.48 <i>recurring annually over the life of the rule</i>
125	Non-Resident Sterile Compounding Pharmacies	\$ 572,251.87 <i>recurring annually over the life of the rule</i>

**\*\* Total annual \$ 2,960,504.35**

**III. ASSUMPTIONS/WORKSHEETS**

The following general estimations were used to calculate private fiscal costs:

1. The Board conducted a survey in 2014 of all Missouri resident and non-resident sterile compounding pharmacies. Private fiscal costs were estimated based on survey results which reflects the most recent Board data on the scope of sterile compounding activities performed by Missouri licensed pharmacies.
2. Approximately 123 pharmacies were licensed by the Board to perform sterile compounding as of May 1, 2016. Based on survey results and Board licensing data, the Board estimates:
  - o Twenty-eight (28) pharmacies are/will be engaged in only Risk level 1 compounding (approx. 23% of sterile compounding pharmacies)
  - o Sixty-eight (68) pharmacies are/will be engaged in Risk Level 2 or lower compounding (55% of sterile compounding pharmacies)

- Twenty-seven (27) pharmacies are/will be engaged in Risk level 3 compounding or lower compounding (22% of sterile compounding pharmacies)
3. The proposed amendment substantively incorporates current United States Pharmacopeia (USP) Chapter 797 requirements. After consultation with Missouri hospital pharmacy directors, the Missouri Hospital Advisory Commission and representatives from the Missouri Hospital Association, the Board understands the majority of Class-B hospital pharmacies licensed with the Board are currently required to comply with USP Chapter 797 by the Centers for Medicare and Medicaid Services (CMS) and/or the Joint Commission which governs hospital accreditation.
  4. Approximately 24% of Missouri sterile compounding pharmacies are licensed Class-B hospital pharmacies and are estimated to be engaged in Risk Level 2 and 3 compounding. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies impacted by proposed requirements that mirror USP Chapter 797 has been reduced by 20% to:
    - Twenty-eight (28) Risk Level 1 pharmacies
    - Fifty-Four (54) Risk Level 2 pharmacies, and
    - Twenty-two (22) Risk level 3 pharmacies
  5. The 20% reduction represents Class-B hospital pharmacies that are currently required to comply with Chapter 797 and would not incur any additional fiscal costs. The reduction has been adjusted to account for license duplication and other allied entities under common ownership or control of the hospital that may also be licensed as a Class-B hospital pharmacy.
  6. An hourly pharmacist salary of \$ 59.24 and an hourly pharmacy technician salary of \$ 18.47 was utilized which represents an average of the mean hourly wage for pharmacists/technicians practicing in a General Medical and Surgical Hospital setting (\$57.43) and pharmacists/technicians practicing in an Outpatient Care Center setting (\$61.05) as reflected in the United States Bureau of Labor Statistics Occupational Employment and Wages data for May 2015. An average of the identified hourly rates was selected due to the variant practice settings of Board licensees/registrants.
  7. Where applicable, costs were projected using the estimated hourly pharmacy technician salary for activities not required to be performed by a pharmacist.
  8. Compounding staff per pharmacy can fluctuate widely depending on the scope and level of compounding services performed. The Board estimates the average pharmacy will hire/train two (2) new sterile compounding technicians per year and further estimates a total of 3 sterile compounding employees per pharmacy.
  9. The Board estimates 261 business days per year based on the United States Office of Personal Management's 28-year work-calendar study.
  10. Except as otherwise provided herein, fiscal costs were estimated based on Board licensing data as of May 1, 2016. The number of sterile compounding pharmacies and

scope of sterile compounding activities is estimated to remain consistent over the life of the rule.

11. Fiscal costs were also based on estimates from selected sterile compounding pharmacies, current market prices and current vendor/certification fees and have been adjusted to reflect compliance costs required by the current rule.
12. Based on current licensing data and 2014 survey results, the Board estimates non-resident sterile compounding pharmacies will incur 25% of total fiscal costs estimated for Missouri resident pharmacies.
13. The Board anticipates the total estimated costs may vary with inflation and increase at the rate projected by the Legislative Oversight Committee.

Facilities/Equipment Costs:

14. The proposed certification/recertification requirements for ISO classified areas will primarily be applicable to Risk Level 2 and 3 pharmacies and are similar to current USP Chapter 797 requirements. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been adjusted to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
15. Due to the potential longevity of properly functioning primary engineering controls, the Board estimates 25-new primary engineering controls will be purchased annually by sterile compounding pharmacies. Additionally, the Board estimates 25 pharmacies will be required to recertify primary engineering controls (PECs) because of deficiencies, relocation or other PEC changes.
16. The Board estimates seven (7) new Missouri sterile compounding pharmacies will require initial certification of ISO classified areas per year.
17. An estimated 50 pharmacies will be required to place or install a line of demarcation.

Description of Cost	Calculation	Total
Line of Demarcation	• Tape/Marker Costs: \$ 3.00 per tape roll/marketing equipment x 50 pharmacies	<b>\$ 150</b> (Y1 implementation)
PEC Initial Certification (all risk levels)	• Certification Costs: 25 pharmacies X \$ 200 certification fee	<b>\$5,000</b> annually
PEC Recertification (all risk levels)	• Certification Costs: 25 pharmacies X \$ 200 certification fee	<b>\$5,000</b> annually
ISO Classified Areas Certification (New)	• Certification Costs: \$ 2,750 x 7 new pharmacies	<b>\$19,250</b> annually
ISO Classified Areas Certification (Ongoing)	• Certification Costs: \$ 2,750 x 76 Risk Level 2 & 3 pharmacies x 2 times per year	<b>\$418,000</b> annually
	<b>TOTAL</b>	<b>\$ 150 (Y1 implementation)</b> <b>\$ 447,250 (annually)</b>

Garbing/Hand Hygiene Costs:

18. The proposed garbing/hand hygiene requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
19. The Board estimates the average pharmacy will employ approximately 3 staff people to perform sterile compounding daily and further estimates 2 garbing changes per person/per day.
20. The Board estimates a total cost of \$ 4.80 for Risk Level 1 garbing and \$ 5.65 for Risk Level 2 and 3 garbing based on the following estimated costs: beard covers (\$.08), face mask ( \$.32), gown ( \$ 3.50), gloves (\$.55), hair cover (\$.35), sterile gloves (\$1.20) and shoe Covers (\$.20)

Description of Cost	Calculation	Total
Garbing (Risk Level 1: Beard cover, face mask, gloves, gown, hair cover)	• Garbing (\$ 4.80) x 28 pharmacies x 3 staff people x 2 changes per day x 261 business days.	<b>\$ 210,470.40</b> annually
Garbing (Risk Level 2 & 3: Beard cover, face mask, sterile gloves, gown, hair cover, shoe covers)	• Garbing (\$ 5.65) x 76 pharmacies x 3 staff people x 2 changes per day x 261 business days.	<b>\$ 672,440.40</b> annually
<b>TOTAL</b>		<b>\$ 882,910.80</b> annually

Environmental Monitoring/Sampling Costs:

21. The proposed amendment delineates specific time intervals for the air monitoring and surface sampling currently required for Risk Level 2 and Risk Level 3 pharmacies.
22. The proposed air monitoring requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
23. An average of two (2) surface samples is estimated per pharmacy during each required sampling using settling plates. Costs to incubate samples have been later reflected in the aseptic technique skill assessment section which includes costs for purchasing an incubator which could also be used for settling plates.
24. The Board estimates 15-minutes of technician time will be separately required to perform/document the required air monitoring and the required surface sampling.

Description of Cost	Calculation	Total
Air Monitoring (every six (6) months)	<ul style="list-style-type: none"> <li>Technician Salary Costs: \$4.62 (1/4 of 18.47 hourly wage) x 76 Risk Level 2 &amp; 3 pharmacies x 2 air monitoring collections per year.</li> </ul>	<b>\$ 702.24</b> annually
Surface Sampling (Risk Level 2)	<ul style="list-style-type: none"> <li>Sample Costs: \$2.00 per settling plate x 2 samples per year x 68 Risk Level 2 pharmacies = \$ 272 annually</li> <li style="text-align: center;">+</li> <li>Technician Salary Costs: \$4.62 (1/4 of 18.47 hourly wage) x 68 Risk Level 2 pharmacies x 2 samples per years = \$ 628.32 annually</li> </ul>	<b>\$ 900.32</b> annually
Surface Sampling (Risk Level 3)	<ul style="list-style-type: none"> <li>Sample Costs: \$2.00 per settling plate x 2 samples x 12 samples per year x 27 Risk Level 3 pharmacies = \$ 1,296 annually</li> <li style="text-align: center;">+</li> <li>Technician Salary Costs: \$4.62 (1/4 of 18.47 hourly wage) x 12 samples per year x 27 Risk Level 3 pharmacies = \$ 1,496.88 annually</li> </ul>	<b>\$ 2,792.88</b> annually
	<b>TOTAL</b>	<b>\$ 4,395.44</b> annually

Aseptic Technique Skill Assessment Costs:

25. Sterile compounding pharmacies are currently required to perform both initial and ongoing process validation which has been renamed media-fill testing in the proposed amendment. Accordingly, media-fill testing costs have been estimated only to the extent the proposed amendment exceeds the current process validation requirements.
26. The Board estimates approximately two (2) new personnel will be hired and require an annual aseptic technique skill assessment per pharmacy. The Board estimates the average aseptic technique skill assessment will require one (1) hour of both pharmacist and technician time.
27. The current rule requires Risk Level 2 and 3 pharmacies to perform a competency assessment via process simulation. Accordingly, initial assessment costs have not been estimated for Risk Level 2 and 3 pharmacies.
28. Absent specific data, the Board estimates approximately one (1) pharmacy technician per year will require an aseptic technique reevaluation assessment under section (10)(C).
29. While media-fill testing can be outsourced, in-house media fill testing through the use of media-fill kits and an incubator is currently the most cost-efficient method for testing. The Board estimates 70% of pharmacies already have equipment for media fill testing and has consequently estimated only 30% of affected pharmacies may opt to purchase an incubator.

30. The proposed aseptic technique skill assessment requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.

Description of Cost	Calculation	Total
Initial aseptic skill assessment evaluation (Risk level 1)	<ul style="list-style-type: none"> <li>Pharmacist Observation Costs: \$59.24 per hour x 2 employees per year x 28 pharmacies = \$ 3,317.44</li> <li>+</li> <li>Technician Salary Costs (\$1,034.32): \$ 18.47 per hour x 2 employees x 28 pharmacies</li> </ul>	<b>\$ 4,351.76</b> annually
Annual aseptic skill assessment evaluation (all risk levels)	<ul style="list-style-type: none"> <li>Pharmacist Observation Costs (\$ 18,482.88): \$59.24 per hour x 3 employees per year x 104 pharmacies</li> <li>+</li> <li>Technician Salary Costs (\$ 5,762.64): \$ 18.47 per hour x 3 employees x 104 pharmacies</li> </ul>	<b>\$ 24,245.52</b> annually
Additional 6-month aseptic skill assessment (Risk Level 3)	<ul style="list-style-type: none"> <li>Pharmacist Observation Costs: \$59.24 per hour x 3 employees per year x 22 pharmacies = \$ 3,909.84</li> <li>+</li> <li>Technician Salary Costs: \$ 18.47 per hour x 3 employees x 22 pharmacies = \$1,219.02</li> </ul>	<b>\$ 5,128.86</b> annually
Reevaluation of aseptic technique	<ul style="list-style-type: none"> <li>Pharmacist Observation Costs (\$ 6,160.96): \$59.24 per hour x 1 employee per year x 104 pharmacies</li> <li>+</li> <li>Technician Salary Costs (\$ 1,920.88): \$ 18.47 per hour x 1 employee x 104 pharmacies</li> </ul>	<b>\$ 8,081.84</b> annually
Media-Fill Equipment	<ul style="list-style-type: none"> <li>Incubator: \$345 per incubator x 31 pharmacies (30% of 104 pharmacies w/ reduction in Risk Level 2 and 3 pharmacies)</li> </ul>	<b>\$ 10,695</b> (Y1 implementation)
Additional 6-Month Media-fill Test (Risk Level 3)	<ul style="list-style-type: none"> <li>Media-Fill Test Kits: \$ 65 per kit x 22 pharmacies x 1 additional test x 3 employees</li> </ul>	<b>\$4,290</b> annually
Reevaluation of aseptic technique media-fill	<ul style="list-style-type: none"> <li>Media-Fill Test Kits: \$ 65 per kit x 1 employee x 104 pharmacies</li> </ul>	<b>\$ 6,760</b> annually
	<b>TOTAL</b>	<b>\$ 10,695</b> (Y1 implementation) <b>\$ 52,857.98</b> annually

Cleaning and Disinfection Costs:

31. The proposed amendment incorporates current USP Chapter 797 cleaning and disinfection requirements. Accordingly, the number of Risk Level 2 pharmacies has been adjusted as described above. The proposed cleaning/disinfection intervals for Risk Level 3 pharmacies will remain consistent. Accordingly, no additional costs have been calculated.
32. The Board estimates the average pharmacy will hire/train two (2) new sterile compounding technicians per year to perform the required cleaning and further estimates annual cleaning/disinfection training will be required for three (3) sterile compounding employees per pharmacy.
33. The Board estimates the current training/observation requirements will require a total of one (1) hour staff time for both the trainee and the observing training pharmacist.
34. The Board estimates cleaning times will be increased by 1-hour daily and 2-hours monthly for Risk Level 1 pharmacies. For Risk Level 2, the Board estimates cleaning times will be increased by 30-minutes daily and 1-hour monthly.
35. Approximately 88% of sterile compounding pharmacies reported using sterile alcohol for disinfection in the Board's 2013 sterile compounding survey. The total number of sterile compounding pharmacies required to buy sterile alcohol has been correspondingly decreased by 88% to 15 pharmacies. The Board estimate an average of 3 gallons of sterile alcohol will be required per pharmacy per month.
36. The Board estimates pharmacies will be required to expend an additional \$ 5 per month in cleaning supplies not already required or used by the pharmacy to meet current rule requirements.

Description of Cost	Calculation	Total
Daily Cleaning (Risk Level 1)	<ul style="list-style-type: none"> <li>• Technician Salary Costs: \$ 18.47 per hour x 28 pharmacies x 1-hour x 261 business days.</li> </ul>	<b>\$ 134,978.76</b> annually
Monthly Cleaning (Risk Level 1)	<ul style="list-style-type: none"> <li>• Technician Salary Costs: \$ 18.47 per hour x 2-hours x 28 pharmacies x 261 business days.</li> </ul>	<b>\$ 269,957.52</b> annually
Daily Cleaning (Risk Level 2)	<ul style="list-style-type: none"> <li>• Technician Salary Costs: \$ 9.24 (½ of \$18.47 per hour) x 54 pharmacies x 261 business days.</li> </ul>	<b>\$ 130,228.56</b> annually
Monthly Cleaning (Risk Level 2)	<ul style="list-style-type: none"> <li>• Technician Salary Costs: \$ 18.47 per hour x 54 pharmacies x 1-hour x 261 business days.</li> </ul>	<b>\$ 260,316.18</b> annually
Initial Cleaning training and direct visual observation (All risk levels)	<ul style="list-style-type: none"> <li>• Pharmacist Observation Costs (\$ 12,321.92): \$59.24 per hour x 2 employees per year x 104 pharmacies</li> <li style="text-align: center;">+</li> <li>• Technician Salary Costs (43,841.76): \$ 18.47 per hour x 2 employees x</li> </ul>	<b>\$ 16,163.68</b> annually

	104 pharmacies	
Annual Cleaning training and direct visual observation (All risk levels)	<ul style="list-style-type: none"> <li>Pharmacist Observation Costs (\$ 18,482.88): \$59.24 per hour x 3 employees per year x 104 pharmacies</li> <li>+</li> <li>Technician Salary Costs (\$5,762.64): \$ 18.47 per hour x 3 employees x 104 pharmacies</li> </ul>	<b>\$ 24,245.52</b> annually
Sterile alcohol	<ul style="list-style-type: none"> <li>Purchase costs: \$ 55 per gallon x 3 gallons per month x 15 pharmacies x 12 months</li> </ul>	<b>\$ 29,700</b> annually
Other cleaning supplies (germicidal agents, low-lint supplies)	<ul style="list-style-type: none"> <li>\$5 per month x 104 pharmacies</li> </ul>	<b>\$ 520</b> annually
	<b>TOTAL</b>	<b>\$ 866,110.22</b> annually

Miscellaneous Costs:

37. The rule requires compliance with selected provisions of USP Chapter 797. Accordingly, costs have been estimated for purchasing a current copy of the United States Pharmacopeia and the National Formulary (USP-NF). The Board estimates the total number of pharmacies required to purchase the USP-NF will include 28 Risk Level 1 pharmacies, 54 Risk Level 2 pharmacies and 22 Risk Level 3 pharmacies (104 pharmacies). The number of affected pharmacies has been reduced to reflect Class-B hospital pharmacies that are currently required to comply with USP Chapter 797 and presumably already have access to the current USP-NF.
38. The proposed aseptic technique, cleaning and training requirements are intended to reduce incidences of environmental and microbial contamination and the need for the proposed remedial investigation. In the absence of more specific data, the Board estimates the average pharmacy will spend two (2) hours of pharmacist staff time to conduct remedial investigations per year.
39. The Board estimates an additional one (1) hour of pharmacist time would be required to comply with the additional documentation and policy and procedure requirements of the rule.
40. The Board estimates an additional thirty (30) minutes of pharmacy technician time would be required to comply with the additional documentation, verification and recording requirements per month.

Description of Cost	Calculation	Total
USP-NF	<ul style="list-style-type: none"> <li>Purchase Costs: \$ 850 x 104 pharmacies</li> </ul>	<b>\$ 88,400</b> Y1 implementation
Remedial Investigations	<ul style="list-style-type: none"> <li>Pharmacist Costs: \$59.24 per hour x 2-hours per year x 123 pharmacies</li> </ul>	<b>\$ 14,573.04</b> annually
Pharmacist Misc. activities	<ul style="list-style-type: none"> <li>Pharmacist Costs: \$59.24 per hour x 1-hour per year x 123 pharmacies</li> </ul>	<b>\$ 7,286.52</b>
Technician Misc. Activities	<ul style="list-style-type: none"> <li>Technician Salary Costs: \$ 9.24 (½ of \$18.47 per hour) x 123 pharmacies x 12-months.</li> </ul>	<b>\$ 13,623.48</b> annually
	<b>TOTAL</b>	<b>\$ 88,400</b> (Y1 implementation) <b>\$ 35,483.04</b> (annually)

**OPEN MINUTES**  
**Missouri Board of Pharmacy**  
**Telephone Conference Call**  
**June 15, 2016**

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christina Lindsay at 3:03 p.m. on June 15, 2016. Each item in the minutes is listed in the order discussed.

**Board Members Present**

Christina Lindsay, President  
Christian Tadrus, PharmD, Vice-President  
Barbara Bilek, PharmD, Member  
Douglas Lang, R.Ph., Member  
Pamela Marshall, R.Ph.  
Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Jennifer Luebbert, Administrative Coordinator

**Other Attendees**

Curtis Thompson, Legal Counsel  
Michael Burgard, Pharmacist/Public Participant

President Christina Lindsay called the meeting to order at approximately 3:03 p.m. in open session.

**#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor**

- Jay Weaver, Pharmaceutical Consulting
- Walmart Multi-site Management

DISCUSSION: Tom Glenski recommended approval of all special sites/non-pharmacist preceptors. Douglas Lang asked if preceptor J. Weaver should be licensed in Missouri. Tom Glenski noted a Missouri license may not be required depending on the preceptor's activities. Douglas Lang asked if the Walmart interns will be training at the pharmacy. Tom Glenski indicated it appears interns will be traveling with the manager and not at a single location. Pamela Marshall noted Walgreens has a similar program. Mr. Glenski noted the Board has previously allowed a district office to be identified as a special site even though interns will be traveling among multiple locations. **A motion was made and duly seconded to approve all Intern Training Special Site/Non-**

**Pharmacist Applications for 500 hours. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek-yes                      Douglas Lang- yes                      Pamela Marshall – yes**  
**Anita Parran – yes                      Christian Tadrus – yes**

**#C2 STLCOP and UMKC College of Pharmacy Site/Preceptor Additions**

- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

DISCUSSION: Tom Glenski recommended approval of the school lists as presented. **A motion was made by Barbara Bilek, seconded by Pamela Marshall, to approve the site/preceptor lists as recommended. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek-yes                      Douglas Lang- yes                      Pamela Marshall – yes**  
**Anita Parran – yes                      Christian Tadrus – yes**

**#D1 2016 Diversion Conference**

DISCUSSION: Kimberly Grinston reported the St. Louis conference is scheduled for July 16<sup>th</sup>; registration is now open. Approximately 100 people are currently registered. The Kansas City conference will likely be held on October 15, 2016; dates cannot be confirmed until after July 1<sup>st</sup> because of UMKC's scheduling system. Ms. Grinston reported Dr. Tara Shelley who spoke at the May NABP annual meeting has agreed to attend. Ms. Grinston further reported staff is researching to determine if the conference can be telecasted in Springfield.

**#D2 Upcoming Strategic Planning Meeting**

DISCUSSION: Kimberly Grinston reported Allison Collinger will be facilitating the meeting on July 19<sup>th</sup> and estimated strategic planning would likely end around 3:00 p.m. Ms. Grinston noted the Board will discuss other targeted Board items on July 20<sup>th</sup>.

**#D3 2016 Legislative Update**

DISCUSSION: Kimberly Grinston reported HB2029 has been signed regarding step therapy and indicated the telehealth/telemedicine legislation has also passed. Ms. Grinston reported the Board will discuss implementation of the 2016 legislation at the July meeting.

**#E1 Hospital Advisory Committee Meeting Minutes**

- 2/24/2016 Hospital Advisory Committee Meeting Minutes
- 3/2/2016 Hospital Advisory Committee Conference Call Minutes

DISCUSSION: Douglas Lang inquired about the Committee's scope of review and asked if the Committee has articulated any priority goals. Barbara Bilek and Kimberly Grinston noted the Committee is in the process of reviewing and ranking Committee goals. Mr. Lang asked to include future Committee agendas with Committee minutes.

**MOTION TO CLOSE 3:26 P.M.**

At 3:26 p.m., Barbara Bilek made a motion, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 620.021(1), (5), (7), and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:

Barbara Bilek-yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – yes	Christian Tadrus – yes	

PUBLIC ATTENDEES LEFT THE MEETING AT APPROXIMATELY 3:26 P.M.

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 5:08 p.m.

**MOTION TO ADJOURN**

At approximately 5:09 p.m., upon motion made by Douglas Lang, seconded by Anita Parran, the June 15, 2016, open session conference call meeting was adjourned. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek-yes	Douglas Lang- yes	Pamela Marshall – absent
Anita Parran – yes	Christian Tadrus – yes	

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved:

**OPEN MINUTES**  
**Missouri Board of Pharmacy**

**July 19, 2016**  
**STRATEGIC PLANNING**  
**Holiday Garden Inn**  
**3300 Vandiver, Drive**  
**Columbia, MO**

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:32 a.m. on July 19, 2016, at Holiday Garden Inn, Columbia, Missouri. Each item in the minutes is listed in the order discussed.

**Board Members Present**

Christina Lindsay, R.Ph., President  
Christian Tadrus, R.Ph., Member  
Barbara Bilek, PharmD., Member  
Douglas R. Lang, R.Ph., Member  
Pamela Marshall, R.Ph., Member  
Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, R.Ph., Chief Inspector  
Jennifer Luebbert, Compliance Coordinator

**Others Present**

Allison Collinger (AHC Consulting)  
Meritte McCarthy (AHC Consulting)  
Samuel Leveritt (Cardinal Health)  
Jennifer Kemna (Omnicare)  
David Wolfrath (MSHP)

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:32 A.M.

Opening Discussion: Kimberly Grinston introduced Allison Collinger with AHC Consulting LLC, to facilitate the strategic planning session. Ms. Collinger and Board members introduced themselves. Ms. Collinger provided an overview of the process and noted she has worked with other local/state governmental bodies as well as private sector groups.

Strategic Planning: Allison Collinger lead the Board in a SWOT analysis (strength, weaknesses, opportunities and threats). Public comments were received. A summary of the Board's discussion is included in Attachment A.

**MOTION TO CLOSE 3:01 P.M.**

**At 3:01 p.m., Barbara Bilek, seconded by Douglas Lang, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo.**

**Motion passed 5:0:0:0 with roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – yes</b>	<b>Christian Tadrus – yes</b>	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 3:01 P.M.

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 4:34 p.m. on July 19, 2016. The Board subsequently recessed the meeting at 4:34 p.m. until July 20, 2016, as posted.

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED:

# **ATTACHMENT A**

# Missouri Board of Pharmacy

**STRATEGIC PLAN - FINAL**

**October 11, 2016**



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## **Executive Summary**

This document outlines the Missouri Board of Pharmacy's strategic plan. It presents the mission/vision of the Board and reviews the organization's strengths, weaknesses, threats and opportunities. In addition, it outlines the Board's agreed upon goals and action strategies. Impact and outcomes of the initiatives are continually assessed by the Board, staff, public registrants and licensees.

## **Organizational Description**

The Missouri Board of Pharmacy was statutorily created in 1909 and has been proudly serving the citizens of Missouri for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration, and consists of seven members, including, six licensed pharmacists actively engaged in the practice of pharmacy and one public member. By statute, at least one board member must be a person who provides pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis.

Board members are appointed by the Governor and must be approved by the Missouri Senate. All members hold office for five years from the date of their appointment and until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one year terms.

## **Mission/Vision**

- It is the mission of the Division of Professional Registration to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:
  - Protects the public from incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty;
  - Licenses only "qualified" professionals by examination and evaluation of minimum competency;
  - Enforces standards by implementing legislation and administrative rules

## **SWOT ANALYSIS**

At a planning session on July 19, 2016, the Board addressed the following questions. Key staff completed a similar exercise in June 2016.

- What is the organization doing well?
- How can it improve?
- How can we best focus our efforts?
- What are some trends that you see?
- What opportunities are there?
- What threatens the organization?
- How can the organization distinguish itself and evolve in the future?
- How will this protect the public?

## **STRENGTHS:**

*Focused on protecting the health and safety of the public*

- Proactive on the education front with webinars and resource guides
- Transparent, open culture
- Excellent, dedicated inspectors and board staff
- Thoughtful leader among state pharmacy organizations
- Fiscally responsible

## **WEAKNESSES:**

- Inability to affect rulemaking
- Tend to be reactive vs. getting ahead of issues and trends
- Slow administrative process affected by legislation and other entity clarifications
- High volumes of Board paperwork
- Ineffective communications
- Practice of pharmacy is evolving with technology, resulting in a changing business model and operations not addressed by regulations
- Board vacancies
- Role of technicians is expanding; new challenges arise as education is potentially increased

## **OPPORTUNITIES:**

- Increase public engagement
- Develop strategic alliances (Pharmacy Schools, Healing Arts, etc.)
- Determine new opportunities in role of Board re: Drug Diversion and Drug Abuse, Well-Being program
- Work with other state divisions, boards

## **THREATS:**

- No succession plan
- Financial (budget, lower than market salaries, fund sweep)
- NAPB "taking over our turf"
- External forces pushing forecasted plans off track, decreasing autonomy  
Lack of Board appointments
- Legislative transitions -- especially this year

# Goals and Strategies

## ACTION PLAN

### Goal #1

- Provide clear rules/regulations

### Goal #2

- Increase stakeholder engagement

### Goal #3

- Expand impact through strategic alliances

### Strategy #1

- Develop template for clear communication for each (like legislative briefings in book)
  - Have PR person edit
- Review and process to reconcile difference in language, including input from stakeholders
  - Provide regular information on trends to watch, take action on (local, Federal, other state) Big picture – Fed; small picture -inspectors
  - Communicate externally any changes
- Determine legislative priorities and action items/action plan
- Assess and monitor technology as it relates to stakeholders
- Review and standardize inspector policies

## **Strategy #2**

- Conduct communications review – with focus on use of technology
- Identify stakeholders and analyze their behavior against actions we desire
- Identify specific events and tactics to engage (webinars, conferences, etc.)
- Determine a plan for each stakeholder group (eg; Technician Education)
- Obtain stakeholder input (town hall meeting, technology survey, etc.)
- Formalize input process, for staff to provide timely input to board
- Determine if staff has tools
- Expand impact through strategic alliances – be catalyst

## **Strategy #3**

- Identify key topic as focal point
- Identify two alliances
  - School of Pharmacy
  - TBD – Well-Being, MDH, Immunization, Drug Diversion, Healing Arts, Board of Nursing, dentists
- Do white paper/education campaign

**OPEN MINUTES**  
**Missouri Board of Pharmacy**

**July 20 - 21, 2016**  
**Holiday Garden Inn**  
**3300 Vandiver, Drive**  
**Columbia, MO**

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:02 a.m. on July 20, 2016, at Holiday Garden Inn, Columbia, Missouri. Each item in the minutes is listed in the order discussed.

**Board Members Present**

Christina Lindsay, R.Ph., President  
Christian Tadrus, R.Ph., Member  
Barbara Bilek, PharmD., Member  
Douglas R. Lang, R.Ph., Member  
Pamela Marshall, R.Ph., Member  
Anita Parran, Public Member

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, R.Ph., Chief Inspector  
Bennie Dean, R.Ph., Inspector  
Katie DeBold, R.Ph., Inspector  
Joe Dino, R.Ph., Inspector  
Jennifer Luebbert, Compliance Coordinator  
Andi Miller, PharmD, Inspector  
Tammy Siebert, Administrative Coordinator  
Lisa Thompson, R.Ph., Inspector  
Dan Vandersand, R.Ph., Inspector  
Elaina Wolzak, R.Ph., Inspector  
Barbara Wood, R.Ph., Inspector

**Others Present**

Curtis Thompson, Legal Counsel

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:02 A.M.

**#A1 Agenda Additions/Corrections**

No agenda additions/corrections reported.

## **#A2 Board Member Report**

**DISCUSSION:** Board members reported on the following:

- Pamela Marshall, Douglas Lang and Christian Tadrus reported on the Board's recent drug diversion conference in St. Louis and noted attendance was very good (approximately 125 attendees). Board members commented program content was strong and suggested modifying the program in the future to allow more open discussion/question time. Kimberly Grinston reported the next diversion conference is scheduled for Kansas City.
- Christina Lindsay reported on the NABP annual meeting that was held in May in San Diego, California; President Lindsay attended with Pamela Marshall and Douglas Lang. Meeting content was informative and focused on drug diversion, compounding, USP 797 and technician practice. President Lindsay noted many of the issues on the July agenda were discussed at the NABP meeting.
- Douglas Lang reported he attended and Tom Glenski presented at the April MSHP meeting. Mr. Lang commented Mr. Glenski's presentation focused on the recent rule changes and was very informative.

## **#A3 General Administration Report**

**DISCUSSION:** Kimberly Grinston provided the following updates:

- Financial Report: FY16 ended on June 30<sup>th</sup>. Ms. Grinston reported revenue continues to trend upward. The Board was able to expend funds this year that slightly reduced the fund balance, however, Ms. Grinston recommended the Board consider permanent fee decreases in the future.
- Pharmacist Renewals: Pharmacist renewals will be mailed in August; renewal fees have been decreased to \$ 50. Ms. Grinston asked Board members to notify the office if candidates are experiencing delays in exam scheduling.
- NABP Meeting: The District 6, 7 and 8 meeting will be held in Portland, Oregon in September; Ms. Grinston and Board members Marshall and Lang will be attending.
- MPJE Review: Ms. Grinston asked for volunteers to assist in the MPJE review. Christina Lindsay and Christian Tadrus volunteered to assist.
- Electronic Inspections: The Board piloted a program that would allow the office to e-mail inspection reports using Wal-Mart pharmacy. Ms. Grinston reported the program can be implemented statewide. Christina Lindsay asked about compliance notices; Ms. Grinston indicated these could be e-mailed but a copy of the written notice will still be left at the pharmacy. Ms. Grinston indicated the office will begin to contact pharmacies to attempt to gather e-mail addresses. Tom Glenski reported the inspectors are also issuing electronic quality assurance reports and reported the process has gone well.
- Inspector Folders: Ms. Grinston presented a new inspection folder that would be used to provide additional Board/compliance information to licensees. As a result

of the December meeting, Ms. Grinston also reported the office has drafted new inventory reconciliation materials that may assist licensees. Board members expressed the folders would be helpful; general Board consensus to proceed with the informational folders.

- Opioid Abuse/Multi-Disciplinary Collaboration: Ms. Grinston reported she has been talking with the Board of Nursing and the Board of Healing Arts to discuss ways to address the rising opioid misuse/abuse issues. Ms. Grinston reported the Missouri Department of Mental Health has launched a patient education website: [endRxmisuse.org](http://endRxmisuse.org). Ms. Grinston indicated the licensing Boards will continue to discuss forming a multi-disciplinary task force; Ms. Grinston will reach out to Board members who may be interested in joining the planning/steering committee. Ms. Grinston noted the task force would like to focus on available options to deter opioid misuse/abuse even though Missouri does not have a PMP. Douglas Lang commented there are also resources at [AwareRx.com](http://AwareRx.com) that may be helpful.
- Staff Introductions: Ms. Grinston introduced Alicia Edmonson as the new Compliance Coordinator.
- NABP Survey of Pharmacy Law: Ms. Grinston reported the latest NABP survey is available in the Board's handouts.

#### **#A4 Approval of Minutes**

- March 23, 2016 conference call

**DISCUSSION: A motion was made by Christian Tadrus, seconded by Pamela Marshall, to approve the March 2016 minutes as printed. Motion passed 5:0:0:0 by roll call vote as follows:**

<b>Barbara Bilek – yes</b>	<b>Douglas Lang- yes</b>	<b>Pamela Marshall – yes</b>
<b>Anita Parran – yes</b>	<b>Christian Tadrus – yes</b>	

#### **STRATEGIC PLANNING ITEM # 7 (Review of Inspection Survey Results)**

**DISCUSSION:** Kimberly Grinston reported previous survey methods were unsuccessful; the office is now using a postage prepaid survey card that has a higher response rate. Ms. Grinston reported survey responses are overwhelmingly positive. President Lindsay asked for inspector input. Inspector Dan Vandersand said handing out the survey card at the end of an inspection may place the inspector in a compromising position. Mr. Vandersand suggested doing an annual survey or having the office mail the survey card separately. A public attendee suggested it may be better to provide the survey card at the end of the inspection because the information is fresh in the licensee's mind. Board members Pamela Marshall and Anita Parran indicated the current process may provide more accurate responses. Board discussion was held. A suggestion was made that the office try mailing the survey card in a designated territory. Board consensus to try a pilot office mailing program and to review results/response rates at a future meeting.

#### **STRATEGIC PLANNING ITEM # 8 (Implementation of 2016 Legislation)**

DISCUSSION: Kimberly Grinston reported the agenda includes new legislation that will be effective on 8/28/2016 along with a suggested Board implementation guide. Ms. Grinston noted the office will be hosting a webinar on 8/25/16 to discuss legislative changes. Kimberly Grinston noted it appears all of the legislation is self-executing and suggested that Board rules are permitted but not mandatory. The following Board discussion occurred:

- HB 579 (Naloxone): Christian Tadrus noted the language appears to grant more allowances for the public than for pharmacists and questioned if the 5% drug distributor threshold would be applicable. Kimberly Grinston suggested discussing the 5% limit with counsel in closed session.
- SB 1568 (Telehealth): Kimberly Grinston reported there are still some unanswered questions such as what is within the standard of care and how does the new language apply to out-of-state prescribers. Christian Tadrus and Douglas Lang noted the language may raise more questions than answers. Christian Tadrus expressed concerns with placing the burden on pharmacy to verify a valid patient-practitioner relationship which may be particularly difficult with telehealth/telemedicine prescriptions and noted the language may be problematic absent further direction from the Board of Healing Arts. Douglas Lang suggested doing a separate telehealth/telemedicine brochure; Christian Tadrus agreed and suggested the Board provide as much education as possible. Barbara Bilek noted the positive thing is that the Board of Healing Arts has recognized that a physical examination is not required in all cases.
- SB 875 (Biosimilars): Christian Tadrus asked if the legislation would require prescriber notification even if no substitution is made. Kimberly Grinston suggested discussing the legal interpretation with counsel in closed session.

### **STRATEGIC PLANNING ITEM # 9 (Board Rule Review)**

DISCUSSION: Kimberly Grinston reported on the updated review schedule and noted the Board is not required to revise/amend the rules. Instead, the Board is required to review the rules for designated factors identified in the legislation. Board members Tadrus and Bilek asked if there were particular Board rules that were more problematic for the inspectors. Kimberly Grinston noted the schedule was organized based on rules the office identified as more pressing. The following additional discussion occurred:

- Christian Tadrus and Pamela Marshall suggested reviewing the rule governing the transfer of prescriptions for the purpose of refills earlier. Tom Glenski suggested considering the Class J-Shared Services earlier; Board consensus to move the Class-J rule to October 2016 and the MTS rule to April 2016. Board consensus to also move the long-term care rule and the electronic transmission of prescription data rule to April, 2016. Board members asked staff to notify licensees about the review schedule and asked to include the schedule on the Board's website and in e-alerts. Christian Tadrus also suggested creating an online comment form.

- Kimberly Grinston noted the Governor has approved the emergency/amended sterile compounding rules; the emergency rule will be effective August 1<sup>st</sup> 2016 if there are no delays in rule filing. Ms. Grinston reported the office has planned a series of webinars to discuss the new rule and has also drafted a rule implementation guide that will be mailed to all sterile compounding pharmacies. Douglas Lang noted several thousand comments were submitted on USP Chapter 797 and suggested the final revision may not be completed for some time.
- Return Rule: Board discussion was held. Kimberly Grinston asked if the Board wanted notification of the pharmacies engaged in a return program; Board consensus that notification is not required but the Board could ask at renewal if desired. Board members discussed the length of time a liner may be stored at the pharmacy before disposal. The public commented some states require monthly disposal. **A motion was made by Pamela Marshall, seconded by Douglas Lang, to modify section (3)(B) to require removal within thirty (30) days. Motion passed 5:0:0:0 by roll call vote as follows: Barbara Bilek – yes Douglas Lang- yes Pamela Marshall – yes Anita Parran – yes Christian Tadrus – yes**
- Temporary Absence from a Pharmacy: Board discussion was held regarding requirements from other states. Pamela Marshall noted she would be open to discussing allowing technicians to receive and fill prescriptions when the pharmacist is absent but would have concerns about technicians selling prescription in the pharmacist's absence because of counseling requirements. Christian Tadrus noted mail order is not required to offer immediate counseling and suggested the Board may be able to draft language that would similarly allow a retail pharmacy to make counseling available in a timely fashion. Christina Lindsay asked if the Board wanted to create a rule; Board consensus to pursue a draft rule on this topic. Barbara Bilek noted the ultimate concern is diversion while a pharmacist is absent. The public commented patients may have to wait for the pharmacist to return.
- USP Chapter 800: Kimberly Grinston reported the revised chapter will be effective in 2018. President Lindsay asked if the Board wanted to adopt USP Chapter 800 or wait until after the nuclear rules are revised and the sterile compounding rule is effective and fully implemented. Board consensus to review the topic again after the sterile compounding rule is implemented.

### **STRATEGIC PLANNING ITEM # 10 (Combatting Pharmacy Diversion)**

DISCUSSION: Kimberly Grinston reported on the upcoming Kansas City diversion conference on 10/15 and asked if the Board had any additional suggestions for addressing pharmacy diversion. President Lindsay asked the public if there were any suggestions on how the Board may assist with diversion prevention; public members commented additional patient resources would be helpful. Public attendees also suggested disseminating some best practices guidance. It was also suggested the Board provide

additional education/training on identifying drug seeking behaviors. Board consensus to continue reviewing this issue and researching available resources.

### **STRATEGIC PLANNING ITEM # 12 (Pharmacy Technician Working Group)**

DISCUSSION: Kimberly Grinston provided the names of current Working Group members but noted Tim Koch should be listed as a member. Ms. Grinston reported the Working Group would be meeting in November and asked for official direction on what the Board would like the Working Group to review. Board discussion was held. Board consensus to ask the Working Group to review: (1) Missouri's technician definition/scope of practice, (2) the adequacy of current Missouri regulation and (3) potential education/training requirements. Board members commented pharmacists would be better able to serve patients and perform clinical functions if technicians were allowed/trained to perform additional non-discretionary functions. Pamela Marshall suggested including additional technicians from chain retail pharmacy and hospital pharmacy on the Working Group; Board consensus to include the additions suggested. Kimberly Grinston asked for Board member suggestions/nominations for additional technicians by the end of the week.

### **STRATEGIC PLANNING ITEM # 13 (Potential 2017 Legislation/New Decision Items)**

DISCUSSION: Kimberly Grinston reported state agencies were cautioned about the number of proposals submitted for 2017 and asked to limit proposals to ten (10) items. Ms. Grinston noted the approval process is unclear given that a new governor will be in office. The following discussion was held:

- **New Decision Items:** Ms. Grinston asked the Board to approve a NDI to increase inspector salaries. Christian Tadrus asked how this would impact the fund; Ms. Grinston reported the fund is healthy and can easily sustain the increase. Board consensus to proceed.
- **Fining Authority:** Ms. Grinston reported this has been a political issue in the past. Curtis Thompson provided information on fining authority by other Missouri licensing boards. Board members asked if the fine would be reportable discipline; Ms. Grinston indicated it would depend on how the legislation was drafted. Douglas Lang asked if fines would go to the Board; Curtis Thompson indicated fines would go to the applicable school district under Missouri law. Board discussion was held. Board consensus to have staff draft language for future Board review.

### **STRATEGIC PLANNING ITEM # 11 (PTCB Changes/Updates)**

DISCUSSION: President Lindsay introduced Miriam Mobley-Smith, Director of Strategic Alliances for PTCB. Ms. Smith provided information on PTCB's program and indicated PTCB would require applicants to complete an ASHP or ACPE accredited program to register for the examination beginning in 2020. Board discussion was held. Douglas Lang

asked if the Board collects data on the number of certified Missouri technicians; Kimberly Grinston reported not currently. Mr. Lang suggested collecting this data at renewal.

**STRATEGIC PLANNING ITEM # 13 (Potential 2017 Legislation/New Decision Items-Cont'd)**

DISCUSSION: The following additional discussion was held:

- 3PL Legislation: Ms. Grinston reported the Governor's office asked how Missouri will be impacted without a 3PL classification. Board discussion was held. Board consensus to proceed with a legislative proposal for 3PLs.
- Charitable Pharmacy: Kimberly Grinston reported the proposal has been simplified from previous years to remove the detailed regulatory requirements formerly included. Board consensus to review draft language at the next meeting, however, Board members suggested prioritizing legislative proposals once legislative drafts are complete. Board members suggested this proposal could be postponed if more pressing items need to be addressed.
- 2-Line Prescription Requirements: Kimberly Grinston noted information from other states is available in NABP's Survey of Pharmacy Law. Douglas Lang said the current requirement is antiquated and creates difficulty for pharmacies handling non-Missouri prescriptions. Christian Tadrus asked if the Board is citing pharmacies for something that may not be directly pertinent to patient safety. Douglas Lang added telehealth/telemedicine adds to the difficulty here. Mr. Lang further suggested Missouri's law should allow substitution unless specifically prohibited by the prescriber. Further Board discussion was held. Board consensus to draft language for Board review removing the two-line format and allowing substitution unless prohibited by the prescriber.
- Consolidation of Refills: Kimberly Grinston reported legislative language was passed on this issue that will be effective on 8/28/16.
- Expansion of Immunization Authority: Board members proposed meeting with the Board of Healing Arts to discuss expanded authority and decreasing restrictions/paperwork. Board discussion was held. Christian Tadrus strongly supported expanding immunization authority to increase patient access. Board consensus to arrange a meeting with the Board of Healing Arts in lieu of a legislative proposal at this time. Christian Tadrus asked if there was something that could be done in the interim to decrease the notification requirements and to address the mandatory CDC compliance requirement which has become legislatively problematic. Kimberly Grinston noted the Board has not been successful in addressing the CDC issue and noted this issue could always be raised by the pharmacy association groups. Christian Tadrus asked if VaxServe could be used as the notification system. Board consensus to hold for this year and to discuss immunization issues with the Board of Healing Arts.
- Board Fund Proposal: Board discussion was held; Board consensus to proceed with a proposal.

- Mandatory Disciplinary Reporting: Kimberly Grinston reported the language passed in the 2016 session and will be effective on 8/28/16.
- Non-Resident Renewals: Kimberly Grinston reported the language passed in the 2016 session and will be effective on 8/28/16.
- Continuing Education (CE) Clarification: Kimberly Grinston reported this was raised in the most recent Board audit; Board consensus to proceed with proposal. Board members also asked staff to review how the Board could synchronize the annual immunization CE requirements with the biennial renewal period.
- Board consensus to review draft proposals at a later conference call for final approval.

**MOTION TO CLOSE 3:34 P.M.**

At 3:34 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1) and (14), RSMo, and under Section 324.001.8, RSMo. Motion passed 5:0:0:0 by roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – yes	Christian Tadrus – yes	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 3:34 P.M.

**RETURN TO OPEN**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 4:11 p.m.

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT APPROXIMATELY 4:11 P.M.

**STRATEGIC PLANNING ITEM # 16 (Hospital Advisory Committee Update)**

DISCUSSION: Chairman Bert McClary provided a general update and indicated the Committee will begin to look at strategic goals. Douglas Lang agreed with establishing and prioritizing goals.

**STRATEGIC PLANNING ITEM # 17 (Class-B Hospital Pharmacy Guidance)**

DISCUSSION: Kimberly Grinston reported the office has postponed the hospital webinar; the office would like to clarify topics and issue a Class-B guidance document simultaneously with the webinar. The following additional discussion was held on the draft guidance document:

- Ms. Grinston asked if the Board agreed with allowing Class-B pharmacies to share pharmacy space/inventory with DHSS regulated pharmacies. Tom Glenski noted we

currently allow commingling. Tom Glenski also commented inspectors would only inspect for compliance with the Board's regulation and further noted that a drug audit may require auditing of the entire hospital if inventory is not separated. Board consensus to allow the practice in the Class-B Guidance document.

- Kimberly Grinston asked if the Board would allow a waiver from section 338.059's labeling requirements for medication that will be administered onsite by a healthcare practitioner and not actually given to the patient. James Gray, Hospital Advisory Committee Member, noted this issue is most common with infusion centers where the patient may never actually see or handle the medication. Mr. Gray noted the medication is labeled just not with a full patient label. Pamela Marshall suggested labeling should be the same regardless of how it is dispensed. Board discussion was held; Board consensus to discuss the interpretation of section 338.059 with legal counsel.
- Kimberly Grinston asked if the required immunization notifications could be made in a common electronic medical record that is accessible to the protocol physician. Tom Glenski indicated this is already allowed for MTS. Board consensus that an EMR notification would be sufficient.
- Kimberly Grinston asked if the Board would allow nurses to access the pharmacy as part of their non-pharmacy job duties without registering as technicians. Board discussion was held. James Gray and Bert McClary commented nurse access is common in hospitals. Bert McClary noted the Joint Commission and CMS both require the pharmacy to be responsible for medication and further asked if the pharmacy can maintain stock outside of the pharmacy for nursing access (e.g., a Pyxis machine) and still have the medication considered part of the pharmacy's inventory. Board discussion on how you would define the practitioners authorized to access the pharmacy (e.g., all healthcare professionals, nurses only or anyone authorized to administer). Kimberly Grinston suggested discussing this issue with the Committee further and returning the topic at a later Board meeting.

#### **STRATEGIC PLANNING ITEM # 9 (Non-Resident Sterile Compounding Survey)**

DISCUSSION: Board discussion held; this topic was also discussed in open session the previous day. Board consensus to include the violations report in the inspection folders and newsletter and to consider including on a webinar. Board members asked if the report could be compiled more frequently. Kimberly Grinston reported a regular inspection summary report could be provided.

#### **STRATEGIC PLANNING ITEM # 14 (Pharmacist Collaborative Practice in Missouri)**

DISCUSSION: Christian Tadrus commented this is an emerging issue and noted there are several national examples of expanded pharmacist scope of practice. Mr. Tadrus indicated expanding pharmacist clinical services would increase patient access to healthcare and asked if this should be addressed in Missouri law. Douglas Lang asked how this topic has been previously received by the legislature. Kimberly Grinston reported there has been general

resistance to pharmacists being granted prescriptive authority and that questions have also been raised as to whether an expanded scope would constitute the practice of medicine. Douglas Lang asked about pharmacist ability to order and interpret lab testing. Barbara Bilek indicated pharmacists in hospital settings are reviewing test results now but are just not able to prescribe. Christian Tadrus asked if any data exists on how many pharmacists may already be engaged in advanced clinical services; staff replied this information is not currently collected. Christian Tadrus suggested conducting a survey to gather additional data; Board consensus to consider a survey. Christian Tadrus and Douglas Lang agreed to assist in drafting potential survey questions.

### **STRATEGIC PLANNING ITEM # 15 (DQSA Implementation)**

DISCUSSION: Kimberly Grinston reported the Board has received multiple inquiries regarding the Board's regulation of 503(B) outsourcers and presented a draft guidance letter. Barbara Bilek suggested clarifying the language that entities operating as both a 503(b) and a pharmacy are required to have two Missouri licenses. Douglas Lang suggested striking the sentence that provides: "Drug outsourcers who also dispense patient-specific medication must be dually licensed as both a Missouri drug distributor and a Missouri licensed pharmacy." Mr. Lang further suggested adding: "non-patient specific preparations must be labeled with 503(b) outsourcer requirements." Douglas Lang noted members of the industry have questioned FDA's authority to promulgate some of the guidance documents. Members of the public discussed concerns with the DQSA track and trace requirements; a public attendee commented manufacturers are not producing the required certificate of analysis in a timely manner. Samuel Leveritt expressed it would be difficult to track every container and product that goes into the drug in his nuclear. Board consensus to continue monitoring this issue.

### **STRATEGIC PLANNING ITEM # 9 (Board Rule Review- Cont'd.)**

DISCUSSION: Board members asked questions regarding how the rule review would be structured; President Lindsay suggested forming a rule review sub-committee to make recommendations to the full Board. Board discussion was held. Board consensus was to have the full Board initially try to review the designated rules during open session, however, Board members suggested limited public comments to a designated time period. Board consensus to review the sub-committee suggestion after the first meeting.

### **AGENDA ITEM # 20 (Review of Board Disciplinary Terms)**

DISCUSSION: Board consensus to review during October meeting.

### **AGENDA ITEM # 21 (2017 Meeting Dates)**

DISCUSSION: Kimberly Grinston asked if Board members would like to plan a strategic planning meeting for 2017; Board consensus to host a strategic planning meeting in April 2017. Board members also asked to schedule the April 2017 meeting for three (3) days to

discuss legislative proposals along with strategic planning. Board members generally consented to proposed 2017 dates with the exception of changing the February date to February 22<sup>nd</sup> and hosting the April meeting during the week of April 18<sup>th</sup>. Kimberly Grinston reported St. Louis College of Pharmacy has asked to host a meeting for the Board and to provide the Board with a tour of its new facility. Board consensus to schedule a meeting at both Missouri pharmacies schools; Board members asked staff to talk with the schools to ensure students are present or able to participate. Board consensus to host the UMKC meeting in January and the St. Louis College of Pharmacy meeting in October.

### **AGENDA ITEM # 22 (Election of Officers)**

DISCUSSION: President Lindsay opened the floor for officer nominations. Pamela Marshall nominated Christian Tadrus; Barbara Bilek nominated Christina Lindsay; Anita Parran and Douglas Lang concurred. Christian Tadrus indicated he is comfortable with serving as either President or Vice-President. **A motion was made by Douglas Lang, seconded by Barbara Bilek, to elect Christina Lindsay as president and Christian Tadrus as Vice-President. Motion passed by unanimous acclimation.**

#### **#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor**

- GeneriCo Pharma
- Target/CVS Pharmacy
- Webster Internal Medicine
- Walgreens District Office- Springfield, IL
- Walgreens District Office – Earth City, MO
- Webster Internal Medicine

DISCUSSION: Tom Glenski reported GeneriCo was approved in April 2016 but noted the non-pharmacist preceptor needs to be approved. Mr. Glenski also noted Target/CVS is a pharmacy and would not need special site approval. **A motion was made by Pamela Marshall, seconded by Barbara Bilek, to approve all Intern Training Special Site/Non-Pharmacist Applications for 500 hours with the exception of Target/CVS. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek – yes      Douglas Lang- yes      Pamela Marshall – yes**  
**Anita Parran – yes      Christian Tadrus – yes**

#### **#C2 STLCOP and UMKC College of Pharmacy**

- STLCOP Site Listing

DISCUSSION: Tom Glenski recommended approval of the school list as presented. **A motion was made by Douglas Lang, seconded by Christian Tadrus, to approve the site/preceptor list as recommended. Motion passed 5:0:0:0 with roll call vote as follows:**

**Barbara Bilek – yes      Douglas Lang- yes      Pamela Marshall – yes**  
**Anita Parran – yes      Christian Tadrus – yes**

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

**#E1 Licensees Presently Under Discipline**

- Pharmacists
- Pharmacy Interns
- Pharmacies
- Drug Distributors
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List

**#E2 Board Licensee Statistics**

**#E3 The Federation of Associations of Regulatory Boards Publishes Model for Identifying and Addressing Antitrust Issues**

**#E4 Hospital Advisory Committee Meeting Minutes**

- January 11, 2016
- February 24, 2016
- March 2, 2016

**MOTION TO CLOSE**

At 7:15 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:

Barbara Bilek – yes	Douglas Lang- yes	Pamela Marshall – yes
Anita Parran – absent	Christian Tadrus – yes	

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 7:15 P.M.

**RECONVENE OPEN 2:28 P.M.**

**WEDNESDAY, JULY 21, 2016**

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 2:28 p.m. on July 21, 2016.

DISCUSSION: Board consensus to schedule a conference call at 11:30 a.m. on July 29, 2016, to review proposed 2017 legislation.

**MOTION TO ADJOURN 2:32 P.M.**

At approximately 2:32 p.m., a motion was made by Barbara Bilek, seconded by Anita Parran, to adjourn the July 2016 meeting. Motion passed 5:0:0:0 with roll call vote as follows:

Barbara Bilek – yes  
Anita Parran – yes

Douglas Lang- yes  
Christian Tadrus – yes

Pamela Marshall – yes

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

DATE APPROVED:

**#A5 Inspection/Investigation Update (Tom Glenski, Chief Inspector)**

- General inspection/investigation update
- Current inspection/investigation statistics
- Compliance issues and trends
- Sterile compounding rule implementation
- Upcoming LWTC Webinars/Training
- DHSS Training opportunity

**SECTION B – OPEN  
HEARINGS**

**Wednesday October 26, 2016**  
**10:00 A.M. – 1<sup>st</sup> case**

**#B1 Susan Baker, #042267, #2013-006080**

**ITEMS ENCLOSED:**

- Notice of Hearing on Violation of Disciplinary Order
- Complaint
- Stipulation For Cause to Discipline
- Consent Order



**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing Notice of Disciplinary Hearing was mailed this 23rd day of September, 2016, by UPS express delivery, return receipt requested, to:

Susan H. Baker, R.Ph.  
8650 Girl Scout Road  
Pevely, MO 63070

9314 8699 0430 0026 8858 38

Johnny Richardson, Attorney  
Brydon, Swearngen & England  
312 E. Capitol Avenue  
PO Box 456  
Jefferson City, MO 65102

9314 8699 0430 0026 8860 40

I further certify that a true and correct copy of this Notice of Disciplinary Hearing was mailed by first-class mail to Alicia Embley Turner, Newman, & Comley Ruth, 601 Monroe Street, Suite 301, Jefferson City, MO 65101.

  
KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR  
MISSOURI BOARD OF PHARMACY

Date Produced: 10/03/2016

WALZ GROUP:

The following is the delivery information for Certified Mail™/RRE item number 9314 8699 0430 0026 8858 38. Our records indicate that this item was delivered on 09/27/2016 at 03:41 p.m. in PEVELY, MO 63070. The scanned image of the recipient information is provided below.

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Address of Recipient :

8650 Girl Scout  
Pevely, MO 63070

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Sincerely,  
United States Postal Service

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Information in this section provided by Walz Group, LLC.

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Susan H. Baker, R.Ph.  
8650 Girl Scout Road  
Pevely, MO 63070

**Reference Number:** 2013-006080-Baker

Date Produced: 10/03/2016

WALZ GROUP:

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C. Hoeme

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**Recipient Information:**  
Johnny Richardson, Attorney  
Brydon, Swearengen & England  
312 E. Capitol Avenue  
PO Box 456  
Jefferson City, MO 65102

**Reference Number:** 2013-006080-Baker

**BEFORE THE  
ADMINISTRATIVE HEARING COMMISSION  
STATE OF MISSOURI**

**FILED**

OCT 09 2015

ADMINISTRATIVE HEARING  
COMMISSION

MISSOURI BOARD OF PHARMACY )  
3605 Missouri Boulevard )  
P.O. Box 625 )  
Jefferson City, Missouri 65102, )  
 )  
Petitioner, )  
 )  
v. )  
 )  
SUSAN H. BAKER )  
License Number 042267 )  
Serve: 8650 Girl Scout Road )  
Pevely, Missouri 63070, )  
 )  
Respondent. )

Case No. \_\_\_\_\_

**COMPLAINT**

COMES NOW Petitioner, Missouri Board of Pharmacy ("Board"), by and through its attorneys, and for its cause of action states:

1. Jurisdiction and venue are proper under §338.055, RSMo.
2. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo<sup>1</sup>, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
3. Susan H. Baker ("Respondent") is licensed by the Board as a pharmacist, License No. 042267. Respondent's license is, and was at all times relevant herein, current and active.
4. Respondent also is licensed by the Colorado State Board of Pharmacy, License No PHA.0012734. Respondent's Colorado license is, and was at all times relevant herein, current and active, but is subject to discipline in the form of a letter of admonition issued by the

<sup>1</sup> All statutory references are to the 2000 Revised Statutes of Missouri, (Cum. Supp. 2013), unless otherwise stated.

Colorado State Board of Pharmacy dated August 3, 2015.

5. Respondent's license is subject to discipline in Colorado because Respondent tested positive for marijuana on a pre-employment drug screen on or about October 4, 2013, and therefore violated §12-42.5-123(1)(c)(III), C.R.S.

6. Section 12-42.5-123(1)(c)(III), C.R.S., allows for discipline of a license issued in Colorado upon proof that a licensee has violated "[a]ny state or federal law pertaining to drugs."

7. On or about October 15, 2013, AMN Healthcare filed a complaint with the Board and with the Colorado State Board of Pharmacy indicating that Respondent had tested positive for marijuana in a pre-employment drug screen on or about October 11, 2013.

8. On or around December 2, 2013, Respondent admitted to Board Inspector Barbara Wood over the telephone that she had acquired marijuana in 2006 or 2007 to relieve her migraine symptoms.

9. Respondent also informed Inspector Wood during this December 2, 2013, telephone call that she had acquired the marijuana in New Mexico and had smoked it three or four times since she acquired it.

10. During this December 2, 2013, telephone call, Respondent also informed Inspector Wood that she was dismissed from her employment with St. John's Mercy Hospital Pharmacy, St. Louis, Missouri, ("Mercy") on or about January 31, 2012.

11. Respondent worked at Mercy from November 3, 2003 through January 31, 2012.

12. During an administrative review meeting with the Board's Executive Director on September 26, 2013, Respondent admitted to acquiring and possessing marijuana and to smoking marijuana five times since 2008.

13. Marijuana is a Schedule I controlled substance pursuant to §195.017.2(4)(w),

RSMo.

14. By testing positive for marijuana, Respondent was in unlawful possessions of a Schedule I controlled substance pursuant to § 324.041, RSMo, which states:

For the purpose of determining whether cause for discipline or denial exists under the statutes of any board, commission, or committee within the division of professional registration, any licensee, registrant, permittee, or applicant that tests<sup>1</sup> positive for a controlled substance, as defined in chapter 195, is presumed to have unlawfully possessed the controlled substance in violation of the drug laws or rules and regulations of this state, any other state, or the federal government unless he or she has a valid prescription for the controlled substance. The burden of proof that the controlled substance was not unlawfully possessed in violation of the drug laws or rules and regulations of this state, any other state, or the federal government is upon the licensee, registrant, permittee, or applicant.

15. Respondent's possession of marijuana was in violation of §195.202, RSMo, which states:

Except as authorized by sections 195.005 to 195.425, it is unlawful for any person to possess or have under her control a controlled substance.

16. By possessing marijuana, Respondent further violated 21 U.S.C. § 844(a)<sup>2</sup>.

(a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter . . .

17. At the time of the events alleged herein, Respondent had formed a relationship of professional trust and confidence with her employer which relied upon her professional expertise to ensure that all applicable state and federal laws and regulations regarding the practice of

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<sup>2</sup> All statutory references are to the United States Code (2012), as supplemented, unless otherwise indicated.

pharmacy were followed.

18. Cause exists to discipline Respondent's license to practice pharmacy for violation of §338.055.2(5), (8), (13), (15) and (17), RSMo:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

\* \* \*

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

\* \* \*

(13) Violation of any professional trust or confidence;

\* \* \*

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

\* \* \*

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

19. Respondent's enumerated and, in some cases, repeated violations of the laws and regulations governing the practice of pharmacy constitutes incompetency, misconduct, dishonesty, fraud and/or misrepresentation in the performance of the functions or duties of a licensed pharmacist in violation of section 338.055.2(5), RSMo.

20. Respondent's conduct as alleged herein constitutes a violation of professional trust or confidence in violation of §338.055.2(13), RSMo.

21. Respondent's conduct as alleged herein constitutes a violation of the drug laws or rules and regulations of this state and the federal government in violation of §338.055.2(15), RSMo.

22. Under § 338.055.2(8), RSMo, cause exists to discipline Respondent's license in Missouri because the Colorado State Board of Pharmacy disciplined her license in that state for violating drugs laws under §12-42.5-123(1)(c)(III) C.R.S, which is also grounds for discipline in Missouri under § 338.055.2(15), RSMo.

23. Respondent's conduct as alleged herein constitutes the personal use or consumption of a controlled substance in violation of section 338.055.2(17), RSMo.

WHEREFORE, Petitioner prays this Commission to conduct a hearing in accordance with Chapter 621, RSMo, and pursuant to Section 338.055.3, RSMo, and thereafter issue its findings of fact and conclusions of law that Petitioner may take disciplinary action against Respondent's pharmacist license for violations of Section 338.055, RSMo.

NEWMAN, COMLEY & RUTH P.C.

By:



Alicia Embley Turner #48675

601 Monroe Street, Ste. 301

P.O. Box 537

Jefferson City, MO 65102

573-634-2266

573-636-3306 (fax)

turnera@ncrpc.com

Attorneys for Petitioner  
Missouri Board of Pharmacy

BEFORE THE  
ADMINISTRATIVE HEARING COMMISSION  
STATE OF MISSOURI

MISSOURI BOARD OF PHARMACY, )  
)  
Petitioner, )  
)  
v. )  
)  
SUSAN H. BAKER, R.Ph. )  
License No. 042267 )  
)  
Respondent. )

**FILED**

AUG 04 2016

ADMINISTRATIVE HEARING  
COMMISSION

Case No. 15-1540 PH

**STIPULATION FOR CAUSE TO DISCIPLINE**

Comes Now Petitioner, Missouri Board of Pharmacy, and Respondent, Susan H. Baker, through counsel and stipulate as follows:

1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Susan H. Baker ("Respondent") is licensed by the Board as a pharmacist, License No. 042267. Respondent's license is, and was at all times relevant herein, current and active.

3. Respondent also is licensed by the Colorado State Board of Pharmacy, License No PHA.0012734. Respondent's Colorado license is, and was at all times relevant herein, current and active, but is subject to discipline in the form of a letter of admonition issued by the Colorado State Board of Pharmacy dated August 3, 2015, based upon the 2013 pre-employment drug screen referenced below in paragraph 4 that was positive for marijuana.

4. On or about October 25, 2013, AMN Healthcare filed a complaint with the Board and with the Colorado State Board of Pharmacy indicating that Respondent had tested positive for marijuana in a pre-employment drug screen on or about October 11, 2013.

5. Respondent's license could have been subject to further discipline in Colorado, pursuant to Section 12-42.5-123(1)(c)(III), C.R.S., which allows for discipline of a license issued in Colorado upon proof that a licensee has violated "[a]ny state or federal law pertaining to drugs" because Respondent tested positive for marijuana on a pre-employment drug screen on or about October 4, 2013, and therefore violated §12-42.5-123(1)(c)(III), C.R.S.

6. Two assessments were performed by Peer Assistance Service, Inc. for the Pharmacy Peer Health Assistance Diversion Program, Colorado State Board of Pharmacy. The later of the two evaluations, dated April 23, 2015, concluded that Respondent "is not recommended to participate in the PAS Pharmacy Peer Health Program at this time."

7. Earlier this year, Respondent was evaluated by Dr. Ralph Orlovick, who concluded that Respondent "does not meet the criteria for a substance use disorder." Thereafter, Mr. Jim Wieberg, M.Ed., LPC, Director of the Missouri Association of Osteopathic Physicians and Surgeons (MAOPS), Physician Health Program (PHP), recommended that the Board allow Respondent to participate in the MAOPS PHP monitoring program for two years, pursuant to an in lieu of discipline agreement with the Board.

8. During an administrative review meeting with the Board's Executive Director on May 28, 2014, Respondent admitted to acquiring and possessing marijuana and to smoking marijuana five times since 2008.

9. Marijuana is a Schedule I controlled substance pursuant to §195.017.2(4)(w), RSMo.

10. By testing positive for marijuana, Respondent was in unlawful possessions of a Schedule I controlled substance pursuant to § 324.041, RSMo, which states:

For the purpose of determining whether cause for discipline or denial exists under the statutes of any board, commission, or committee within the division of professional registration, any licensee, registrant, permittee, or applicant that tests<sup>1</sup> positive for a controlled substance, as defined in chapter 195, is presumed to have unlawfully possessed the controlled substance in violation of the drug laws or rules and regulations of this state, any other state, or the federal government unless he or she has a valid prescription for the controlled substance. The burden of proof that the controlled substance was not unlawfully possessed in violation of the drug laws or rules and regulations of this state, any other state, or the federal government is upon the licensee, registrant, permittee, or applicant.

- 11. Respondent's possession of marijuana was in violation of §195.202, RSMo,

which states:

Except as authorized by sections 195.005 to 195.425, it is unlawful for any person to possess or have under her control a controlled substance.

- 12. By possessing marijuana, Respondent further violated 21 U.S.C. § 844(a) which

states:

(a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter . . .

- 13. Cause exists to discipline Respondent's license to practice pharmacy for violation of §338.055.2 (8), and (15), RSMo:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(8) . . . disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

\* \* \*

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

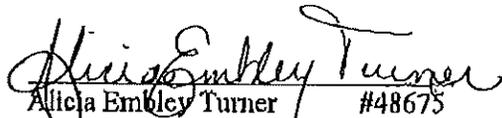
14. Respondent's conduct as alleged herein constitutes a violation of the drug laws or rules and regulations of this state and the federal government in violation of §338.055.2(15), RSMo.

15. Under § 338.055.2(8), RSMo, cause exists to discipline Respondent's license in Missouri because the Colorado State Board of Pharmacy disciplined her license in that state for violating drugs laws under §12-42.5-123(1)(c)(III) C.R.S, which is also grounds for discipline in Missouri under § 338.055.2(15), RSMo.

16. Based upon the facts contained herein, Respondent agrees that there is cause to discipline her license to practice pharmacy, numbered 042267, under sections 338.055.2(8) and (15), RSMo.

17. Cause exists to discipline Respondent's license to practice pharmacy for violations of Section 338.055.2(8) and (15), RSMo.

NEWMAN, COMLEY & RUTH P.C.



Alicia Embley Turner #48675

601 Monroe Street, Suite 301  
P.O. Box 537  
Jefferson City, Missouri 65102  
Telephone: (573) 634-2266  
Facsimile: (573) 636-3306  
Email: [turnera@ncrpe.com](mailto:turnera@ncrpe.com)

ATTORNEYS FOR MISSOURI BOARD  
OF PHARMACY

BRYDON, SWEARENGEN &  
ENGLAND P.C.



Johnny K. Richardson #28744

312 East Capitol Ave.  
P.O. Box 456  
Jefferson City, MO 65102-0456  
Telephone: (573) 635-7166  
Facsimile: (573) 635-3847  
E-mail: [johnnyr@brydonlaw.com](mailto:johnnyr@brydonlaw.com)

Jill A. Silverstein  
ST. LOUIS LAWYERS GROUP  
231 S. Bemiston Avenue, Suite 910  
St. Louis, MO 63105  
Telephone: (314) 862-7999  
Facsimile: (314) 863-4340  
[jas@stl-law.com](mailto:jas@stl-law.com)

ATTORNEYS FOR RESPONDENT

Before the  
Administrative Hearing Commission  
State of Missouri



MISSOURI BOARD OF PHARMACY, )

Petitioner, )

v. )

SUSAN H. BAKER, )

Respondent. )

No. 15-1540 PH

**CONSENT ORDER**

The licensing authority filed a complaint. Section 621.045<sup>1</sup> gives us jurisdiction.

On August 4, 2016, the parties filed a Joint Request for Consent Order and a Stipulation for Cause to Discipline. Our review of the document shows that the parties have stipulated to certain facts and waived their right to a hearing before us. Because the parties have agreed to these facts, we incorporate them into this order and adopt them as stipulated. *Buckner v. Buckner*, 912 S.W. 2d 65, 70 (Mo. App., W.D. 1995). We conclude that the licensee is subject to discipline under § 338.055.2(8) and (15). We incorporate the parties' proposed findings of fact and conclusions of law into this Consent Order. We will certify the record to the licensing agency under § 621.110.

The only issue before this Commission is whether the stipulated conduct constitutes cause to discipline the license. The appropriate disciplinary action is not within our power to decide; that is subject to the licensing authority's decision or the parties' agreement. Section 621.110.

SO ORDERED on August 5, 2016.

  
SREENIVASA RAO DANDAMUDI  
Commissioner

---

<sup>1</sup>Statutory references are to RSMo Cum. Supp. 2013 unless otherwise noted.

**Thursday October 27, 2016**  
**10:00 A.M. – 1<sup>st</sup> case**

**#B2 Shannon Krieg, #200500313, #2016-001469**

**ITEMS ENCLOSED:**

- Notice of Hearing on Violation of Disciplinary Order
- Violation Complaint

BEFORE THE BOARD OF PHARMACY  
STATE OF MISSOURI

MISSOURI BOARD OF PHARMACY,     )  
  )  
          Petitioner,                    )  
  )  
          v.                                )     Case No. 2016-001469-V2  
  )  
SHANNON KRIEG, R.PH.                )  
  )  
          Respondent.                    )

**NOTICE OF HEARING ON VIOLATION OF DISCIPLINARY ORDER**

PLEASE TAKE NOTICE that the Missouri Board of Pharmacy shall hold a hearing for the purpose of determining the truth of the allegations set forth in the Violation Complaint, copy attached, and if the allegations are true, whether or not further disciplinary action shall be taken. The complaint was filed on September 13, 2016. No answer or responsive pleading is required to the complaint. No Board rules exist regarding discovery in this matter.

The violation of discipline hearing has been scheduled for Thursday, October 27, 2016, at 10:00 am, first case on the docket, at the Hilton Garden Inn, 3300 Vandiver Drive, Columbia, Missouri. Please be advised your failure to appear at the hearing at the above-noted time and place will result in the hearing being held in your absence. Respondent and/or attorney should check in with the appropriate Board staff at that time. All parties should prepare a minimum of ten (10) copies of all exhibits to be presented during the hearing.

All parties have the right to be represented by legal counsel and to a full, fair and open hearing conducted in accordance with the provisions of Chapter 536, RSMo.

ENTERED THIS 14 day of September, 2016.

  
KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR  
MISSOURI BOARD OF PHARMACY

**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing document was mailed by first class, postage prepaid, certified mail return receipt requested this 14 day of September, 2016, to:

Shannon M. Krieg, R.Ph.  
17 Wistar Way  
O'Fallon, MO 63366

9314 8699 0430 0026 5599 37

Johnny Richardson, Attorney  
Brydon, Swearingen & England  
312 E. Capitol Avenue  
PO Box 456  
Jefferson City, MO 65102

9314 8699 0430 0026 5600 70

I further certify that a copy of the foregoing document was mailed by first-class, postage prepaid mail to Stephan Cotton Walker, Cotton Walker & Associates, 1739 East Elm Street, Suite 101, Jefferson City, MO 65101, and that a copy was mailed by first-class, postage prepaid mail to Midwest Litigation Services, 3432 West Truman Blvd, Suite 207, Jefferson City, MO 65109.

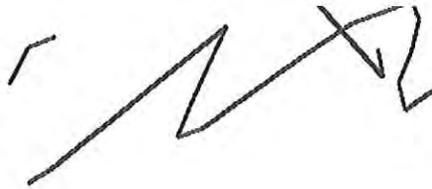
  
\_\_\_\_\_  
KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR  
MISSOURI BOARD OF PHARMACY

Date Produced: 09/19/2016

WALZ GROUP:

The following is the delivery information for Certified Mail™/RRE item number 9314 8699 0430 0026 5599 37. Our records indicate that this item was delivered on 09/16/2016 at 01:06 p.m. in O FALLON, MO 63366. The scanned image of the recipient information is provided below.

Signature of Recipient :



Address of Recipient :



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Sincerely,  
United States Postal Service

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Information in this section provided by Walz Group, LLC.

**Recipient Information:**  
Shannon M. Krieg, R.Ph.  
17 Wistar Way  
O'Fallon, MO 63366

**Reference Number:** 2016-001469

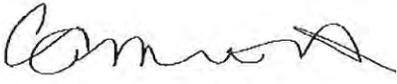


Date Produced: 09/19/2016

WALZ GROUP:

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C. Hoeme

Address of Recipient :

4 5 6

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Sincerely,  
United States Postal Service

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Information in this section provided by Walz Group, LLC.

**Recipient Information:**  
Johnny Richardson, Attorney  
Brydon, Swearengen & England  
312 E. Capitol Avenue  
PO Box 456  
Jefferson City, MO 65102

**Reference Number:** Krieg 2016-001469

**BEFORE THE  
STATE BOARD OF PHARMACY  
STATE OF MISSOURI**

MISSOURI BOARD OF PHARMACY )  
3605 Missouri Boulevard )  
P.O. Box 625 )  
Jefferson City, Missouri 65102 )

Petitioner, )

v. )

Case No. 2016-001469-V2

SHANNON M. KRIEG )  
License No. 2005000313 )  
17 Wistar Way )  
O'Fallon, MO 63366 )

Respondent. )

**VIOLATION COMPLAINT**

COMES NOW Petitioner, Missouri Board of Pharmacy ("Board), by and through its attorneys, and for its cause of action against Respondent states as follows:

1. The Board is an agency of the State of Missouri created and established pursuant to §338.110, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
2. Shannon Krieg ("Respondent") is licensed as a pharmacist in the state of Missouri, license number 2005000313. At all times relevant herein his license was current and active.
3. Respondent's license to practice pharmacy is currently on probation until March 22, 2018.

### Prior Disciplinary Actions

4. On or about September 23, 2010, Respondent and the Board entered into a Settlement Agreement (the "Agreement") which contained a Joint Stipulation of Facts and Conclusions of Law, and a Joint Agreed Disciplinary Order.

5. The Agreement was executed by Respondent on August 1, 2010, and executed by the Board on September 8, 2010. Pursuant to the terms of the Agreement, it went into full force and effect on September 23, 2010.

6. Pursuant to the Agreement, Respondent's license was suspended for a period of six (6) months and immediately thereafter placed on probation for five (5) years because Respondent:

- a. Misappropriated narcotics for his personal consumption and falsely documented narcotic inventory;
- b. Obtained a controlled substance by fraud or subterfuge, an offense involving moral turpitude and reasonably related to the functions and duties of a licensed pharmacist such offense is also an offense an essential element of which is fraud and/or dishonesty; and
- c. Was indicted for obtaining a controlled substance by fraud or subterfuge in violation of Title 21, United States Code, Section 843(a)(3).

7. On November 23, 2015, the Missouri Board of Pharmacy entered Findings of Fact, Conclusions of Law, and Order of Discipline pursuant to a probation violation complaint.

8. Pursuant to the Findings of Fact, Conclusions of Law, and Order of Discipline, Respondent's license was placed on probation through March 22, 2018, because Respondent:

- a. Tested positive for marijuana during his period of probation; and

- b. Failed to comply with conditions of discipline by missing required testing for drugs.

9. The Order of Discipline imposed certain terms during the five (5) years of Respondent's Probation, including:

3. Respondent shall keep the Board apprised of his current home, electronic mail (e-mail) and work addresses and telephone numbers. Respondent shall notify the Board of any change in Respondent's employer or Respondent's home or work address within ten (10) days of such change in a manner approved by the Board. For employer/work changes, Respondent's notification shall include the reasons for the change. If at any time Respondent is employed by a temporary employment agency or maintains employment that requires frequent daily or weekly changes of work locations he must provide the Board a list of locations worked if requested by the Board or Board's representative.
5. Respondent shall cooperate with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of the Disciplinary Order. Respondent shall make himself available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings shall be at the Board's discretion and may occur periodically during the disciplinary period.
8. Respondent shall submit to any drug, alcohol or urinalysis testing requested by the Board, at Respondent's cost. Testing may be conducted on any human sample, including but not necessarily limited to urine, blood, breath, hair, nails, skin, or saliva. The timing, manner and scheduling for testing is within the Board's sole discretion.
27. Respondent shall ensure that he is not in the same physical location as individuals who are using illicit drugs/substances, even if Respondent is not personally ingesting the drug/substance.
34. Licensee shall enroll in FirstLab's Professional Health Monitoring Program, on or before the effective date of this Disciplinary Order. Respondent shall comply with all requirements imposed by FirstLab of the Professional Health Monitoring Program, including, but not limited to, any drug test/urinalysis requirements, any scheduling requirements, any reporting or telephone contact requirements and any requirements for payment of fees, purchasing/maintaining chain of custody (COC) forms or other required program documents/materials.

10. In addition to the terms of discipline, the Order provides that should Respondent "violate any term or condition of [the] Order or any provision of Chapter 338, RSMo, the Board

may vacate the order of discipline imposed...and order such further or additional discipline as the Board deems appropriate, including, but not limited to, revocation, suspension and/or probation...” Respondent” and “may elect to pursue any lawful remedies or procedures afforded it . . .”

**Respondent’s Breach of the Settlement Agreement**

11. On or about February 9, 2016, the licensee informed the Board he had moved on approximately February 2, 2016.

12. Respondent was reminded by Board Inspector Vandersand that he had 10 days to notify the Board of any such address changes.

13. Respondent said he would update his address with the Board but he never did.

14. By failing to update his address with the Board within 10 days, Respondent violated Paragraph 3 of the Order of Discipline.

15. Respondent failed to show up for a personal interview scheduled for May 17, 2016 at the Board office. A certified letter was sent to the address listed in Board records informing Respondent of the meeting (17 Wistar Way, O’Fallon, Missouri 63366).

16. Respondent failed to show up for a personal interview scheduled for June 20, 2016 at the Board office. A certified letter was sent to the address listed in Board records informing Respondent of the meeting (17 Wistar Way, O’Fallon, Missouri 63366). The letter was also hand-delivered to the Respondent on June 13, 2016

17. Respondent failed to show for either scheduled meeting and did not contact the Board office in violation of Paragraph 5 of the Order of Discipline.

18. On January 4, 2016, Board Inspector Vandersand informed Respondent he needed to provide a sample for drug testing. The Respondent informed Inspector Vandersand he was unable to test because he had to make a catering delivery for his employer.

19. Respondent's failure to submit to the requested drug testing was a violation of Paragraph 8 of the Order of Discipline.

20. A hair sample was collected from the Respondent on February 9, 2016.

21. The hair sample tested positive for cocaine, benzoylecgonine and cocaethylene.

22. Although the hair sample results do not necessarily indicate the Respondent ingested cocaine, the results indicate he was in the same physical location as individuals who used cocaine.

23. Additionally, the Respondent told the Medical Review Officer at First Lab that he worked at a bar where cocaine and other drugs were being used.

24. Respondent violated Paragraph 27 of the Discipline Order by failing to ensure that he was not in the same physical location as individuals using illicit drugs.

25. The Respondent failed to call in for drug testing since June 13, 2016, and has missed at least three (3) scheduled drug tests.

26. Respondent's failure to comply with the drug testing and requirements of FirstLab's Professional Health Monitoring Program constitutes a violation of Paragraph 34 of the Discipline Order.

#### **Additional Discipline Authorized**

27. Respondent's actions violate the terms of the Order of Discipline as set forth herein.

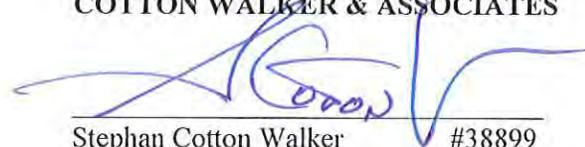
28. Since Respondent violated the disciplinary terms contained in the Order of Discipline, the Board is authorized to impose further discipline on Respondent's license in accordance with Section 338.055.3, RSMo, which provides, in pertinent part:

...the board may impose additional discipline on a licensee, registrant or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. §338.055.3, RSMo.

**WHEREFORE**, Petitioner prays that the Missouri Board of Pharmacy conduct an evidentiary hearing to determine whether or not Respondent has violated the terms of the Agreement and, if such violations have occurred, to impose such additional discipline as the Board deems appropriate.

Respectfully submitted,

**COTTON WALKER & ASSOCIATES**



Stephan Cotton Walker #38899  
Elm Court Plaza  
1739 East Elm Street, Suite 101  
Jefferson City, MO 65101  
(573) 635-9200 FAX (573) 635- 6584  
[Cotton.Walker@cottonwalkerlaw.com](mailto:Cotton.Walker@cottonwalkerlaw.com)

**Attorneys for Petitioner  
Missouri Board of Pharmacy**

## **SECTION C – OPEN**

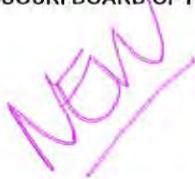
**#C1 Applications for Intern Training Special Site/Non-Pharmacist Preceptor**

- Medication Management Resolution
- SSM Health



### Special Site or Non-Pharmacist Preceptor Application

## SPECIAL SITE OR NON-PHARMACIST PRECEPTOR APPLICATION

STATE OF MISSOURI DIVISION OF PROFESSIONAL REGISTRATION MISSOURI BOARD OF PHARMACY    - KEEP COPY OF COMPLETED APPLICATION FOR YOUR RECORDS - QUESTIONS: E-MAIL: <a href="mailto:intern@pr.mo.gov">intern@pr.mo.gov</a> or call (573) 751-0092	MAILING ADDRESS: MISSOURI BOARD OF PHARMACY PO BOX 625 JEFFERSON CITY, MO 65102	APPROVAL DATE _____ NO. HOURS _____
	OVERNIGHT ADDRESS: 3605 MISSOURI BLVD. JEFFERSON CITY, MO 65109	DISAPPROVAL DATE _____
	RECEIVED DATE <div style="text-align: center; color: red; font-weight: bold; font-size: 1.2em;">RECEIVED</div> <div style="text-align: center; color: red; font-weight: bold; font-size: 1.2em;">SEP 22 2016</div>	

<b>INSTRUCTIONS</b>	MISSOURI BOARD OF PHARMACY
<ul style="list-style-type: none"> <li>✓ Use this form to request approval of:           <ul style="list-style-type: none"> <li>a. A preceptor that does <u>not</u> hold a pharmacist license issued by a U.S. state or territory, or;</li> <li>b. An intern training state that is <u>not</u> licensed as a pharmacy in the U.S. or a U.S. territory.</li> </ul> </li> <li>✓ After the special site/non-pharmacist preceptor has been approved by the Board, <b>interns must also file a Special Site/Non-Pharmacist Preceptor Notice of Employment Approval Application</b> before beginning their internship hours.</li> <li>✓ <b>Missouri Pharmacy School Students:</b> If you are a student of a Missouri located pharmacy school/college, your school will submit an approval request for special sites/preceptors that will be used to earn intern hours as part of your school/college curriculum. This form and the Intern Special Site/Non-Pharmacist Preceptor Notice of Employment form are only required if you will be independently earning hours <u>outside</u> of your school curriculum at a special site or with a non-pharmacist preceptor. <i>This allowance only applies to students attending a Missouri located pharmacy school/college.</i></li> </ul>	

<b>REQUEST TYPE</b>
I AM REQUESTING APPROVAL OF:
<input type="checkbox"/> Special Site and Non-Pharmacist Preceptor <input checked="" type="checkbox"/> Special Site <input type="checkbox"/> Non-Pharmacist Preceptor

<b>SITE APPROVAL</b>
NAME OF SPECIAL SITE Medication Management Resolution
SITE ADDRESS (STREET) (CITY) (STATE) (ZIP) 10309 Granada Lane Overland Park KS 66207
IS THE ENTITY AFFILIATED WITH A COLLEGE TRAINING AND/OR RESIDENCY PROGRAM? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
IF YES, NAME OF SCHOOL/COLLEGE: <u>St. Louis College of Pharmacy</u>
DESCRIPTION OF BUSINESS ACTIVITIES (Attach additional sheets if necessary)  See attached



## Special Site or Non-Pharmacist Preceptor Application

PROVIDE A DETAILED DESCRIPTION OF THE PROPOSED INTERN JOB DUTIES/RESPONSIBILITIES *(Attach additional sheets if necessary)*

See attached

LIST THE LEARNING OBJECTIVE(S) FOR THE INTERN *(Attach additional sheets if necessary)*

See attached

### PRECEPTOR APPROVAL

**A Preceptor Affidavit Form (see attached) must be completed by each preceptor listed below.  
Attach additional sheets if necessary.**

PRECEPTOR NAME Rebecca T. Pischke, Pharm.D. (KS License 1-13375, Expires 6/30/17)	TITLE Pharmacist
PRECEPTOR MAILING ADDRESS (STREET) (CITY) (STATE) (ZIP) 10309 Granada Lane Overland Park KS 66207	
PRECEPTOR NAME	TITLE
PRECEPTOR MAILING ADDRESS (STREET) (CITY) (STATE) (ZIP)	
PRECEPTOR NAME	TITLE
PRECEPTOR MAILING ADDRESS (STREET) (CITY) (STATE) (ZIP)	
PRECEPTOR NAME	TITLE
PRECEPTOR MAILING ADDRESS (STREET) (CITY) (STATE) (ZIP)	

**PRECEPTOR QUALIFICATIONS:** To complete this application, a resume or curriculum vitae must be attached to this application that shows/lists:

- All degrees obtained by the preceptor(s) listed above beyond high school/a general equivalency diploma; AND
- Preceptor employment history. Employment history must demonstrate the preceptor's experience/ability to train the intern in the proposed duties/responsibilities and should include the employer's name, employment dates and a description of job duties. Information must be submitted for each preceptor.

### INTERN INFORMATION *(List the names of interns that will be earning hours at the special site if known. Not required for Missouri located pharmacy schools/colleges. Attach additional sheets if necessary.)*

INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST) (FIRST) (MIDDLE)	INTERN LICENSE NUMBER



### Special Site or Non-Pharmacist Preceptor Application

CONTACT NAME		POSITION/TITLE	
Rebecca Pischke, Pharm.D.		Pharmacist	
CONTACT MAILING ADDRESS (STREET)	(CITY)	(STATE)	(ZIP)
10309 Granada Lane	Overland Park	KS	66207
E-MAIL ADDRESS	TELEPHONE NUMBER	FAX NUMBER	
rtpischke@hotmail.com	913-638-1701		

I hereby request approval of the site and/or preceptor identified herein. All the information and answers contained in this application and any attachments are true and correct to my best knowledge and belief. I am making this affidavit knowing that any false statements or material omission subjects me to criminal penalties for making a false affidavit under Section 575.050, RSMo.

I understand that I must comply with federal and state laws as well as the regulations of the Missouri Board of Pharmacy. I further understand that any intern hours earned at or credited by the proposed special site shall comply with 20 CSR 2220-7.030(1)(A). I hereby certify under penalty of perjury that the above statements, as well as all information provided herein, are true and accurate to the best of my knowledge and belief.

SIGNATURE OF APPLICANT	PRINT NAME
	Rebecca Pischke, Pharm.D.
TITLE	DATE
Pharmacist	9/18/16



### Special Site or Non-Pharmacist Preceptor Application

#### PRECEPTOR'S AFFIDAVIT

A PRECEPTOR'S AFFIDAVIT MUST BE SUBMITTED BY ALL PRECEPTORS DESIGNATED IN THE SPECIAL SITE/NON-PHARMACIST PRECEPTOR APPLICATION.

I hereby attest that I have reviewed 20 CSR 2220-7.025 and agree to serve as a preceptor at the site listed below. I understand that intern practice experience must comply with 20 CSR 2220-7.030(1)(A)3. I certify that all preceptor information contained in this application is true and correct to my best knowledge and belief. I am making this affidavit knowing that any false statements or material omission subjects me to criminal penalties for making a false affidavit under Section 575.050, RSMO.

I understand that I must comply with federal and state laws as well as the regulations of the Missouri Board of Pharmacy. I agree to report intern hours to the Board as required by 20 CSR 2220-7.025. I hereby certify under the penalty of perjury that the above statements, as well as all information provided by me, are true and accurate.

NAME OF SPECIAL SITE

Medication Management Resolution

SITE ADDRESS

(STREET)

(CITY)

(STATE)

(ZIP)

10309 Granada Lane

Overland Park

KS

66207

SIGNATURE OF PRECEPTOR

DATE

9/19/16

PRINT NAME

Rebecca Pischke, Pharm.D.

TITLE

Pharmacist

Kansas Board of Pharmacy  
License Portal



Facility/Provider Information

Search Again

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The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

General

Name or Business:	REBECCA PISCHKE	Original Date:	8/10/2001
DBA:	PISCHKE, HAMID		
Classification:	Pharmacist	On Probation:	No
L/P/R No:	1-13375	Discipline on File:	No
Status:	Active		

Licenses

L/P/R #	Description	Effective	Expires	Issued	Status
1-13375	Pharmacist License (Pharmacist)	6/29/2015	6/30/2017	8/10/2001	Active

Notes

N/A

## **Medication Management Resolution Special Site Permit Application (Attachment)**

### **Description of Business Activities:**

Med Management Resolution reaches out to communities, companies and individuals to provide education about the importance of a pharmacist liaison to work with any individual receiving medication for a medical problem or chronic disease. We help patients gain the best possible benefits from their medications by providing an active medication list, provide education on safety and best practices and follow up with all providers with any changes. This is usually done during a meeting between the pharmacist and the patient or a caregiver. A main goal of MTM is to identify, prevent, and resolve medication-related problems.

### **Provide a detailed description of the job duties/responsibilities of the intern:**

Students will assist in making new presentations depending upon what communities we are serving while they are on rotation.

Students will also be visiting patients in their homes to provide a comprehensive medication review using the SOAP note format. Recommendations will be provided to physicians and families. Students will also conduct follow-up visits with existing patients to see if there have been any changes in medical history or medications.

### **List the Learning Objective(s) for the Intern:**

- Effectively present the importance of medication therapy management and the benefits/outcomes provided by this service.
- Effectively demonstrate the proper process of gathering a Comprehensive Medication Review (CMR)
- Effectively present patient education and monitoring of all medication, supplements, vitamins and minerals
- Effectively recognize and deliver a patient compliance consultation when necessary
- Demonstrate knowledge in multi-disease state management
- Effectively provide medication safety education and monitoring
- Effectively communicate with the complete healthcare team; patient, family, and physicians with the follow up Medication Action Plan (MAP) and recommendations.

REBECCA PISCHKE  
10309 Granada Ln OP, KS 66207 [rtpischke@hotmail.com](mailto:rtpischke@hotmail.com)  
913-638-1701

## PROFESSIONAL EXPERIENCE

### MED MANAGEMENT RESOLUTION, OVERLAND PARK, KS

*Consultant Pharmacist, Owner June 2016-present*

- Provide in home Medication Therapy Management, which includes but not limited to a complete medication review with the most up to date active medication list for all providers, patient medication education and monitoring, medication safety monitoring, disease state management and patient compliance consultations.

### ARJ INFUSION SERVICES LENEXA, KANSAS

*Staff Compounding Pharmacist June 2015-March 2016*

- Clinically managed patient's with autoimmune diseases in conjunction with a nursing team. Provided counseling, filled/compounded prescriptions for daily deliveries.

### PERRY DRUG, OVERLAND PARK, KANSAS

*Staff Compounding Pharmacist May 2013-June 2015*

- Oversee all compounding- verification of all calculations, measurements, clean room processes.
- Control inventory of compounding chemicals, devices, equipment, training & support.
- Ensure IV room 797 regulations are completed.

### PHARMERICA LENEXA, KANSAS

*Pharmacy Director February 2009 - May 2012*

- Controlled pharmacy cost to meet or exceed budgeted cost per script.
- Provided leadership and direction to build an effective team and continually develop associates to improve performance.
- Managed staffing and scheduling to optimize production and contain labor costs.
- Ensured pharmacy compliance with all regulatory requirements; including but not limited to controlled substance inventory/logs, and IV room 797 regulations.
- Increased business by 42% (location serviced 23 nursing homes in 2009; 55 nursing homes in 2012)

- Review prescriptions to assure accuracy, to ascertain the needed ingredients, and to evaluate their suitability.

WALGREEN'S HOME INFUSION LENEXA, KANSAS

*Staff Pharmacist May 2007 - February 2009*

- Compound and dispense IV medications as prescribed by doctors, by calculating, weighing, measuring, and mixing ingredients, and oversee these activities.
- Followed patients closely in collaboration with the medical team to evaluate therapy, ensure lab work was current and adjust medications as needed with results.
- Hemophilia Champion

WALGREEN'S SHAWNEE KANSAS

*Pharmacy Manager January 2002 - May 2007*

*Staff Pharmacist May 2001 - January 2002*

- Review prescriptions to assure accuracy, to ascertain the needed ingredients, and to evaluate their suitability.
- Provide information and advice regarding drug interactions, side effects, dosage, and proper medication storage.
- Teach pharmacy students serving as interns in preparation for their graduation or licensure.
- Manage pharmacy operations, hiring or supervising staff, performing administrative duties, or buying or selling non-pharmaceutical merchandise.

EDUCATION

CREIGHTON UNIVERSITY OMAHA, NEBRASKA

*Pharm D, May 2001*

ROCKHURST UNIVERSITY KANSAS CITY, MISSOURI

*Completed coursework towards BS Biology, May 1997*

ADDITIONAL INFORMATION

- I spent 5/2012-5/2013 on a sabbatical traveling. I learned the history, language and cultures of many countries. I spent two months volunteering in a health clinic in Costa Rica.

\*PROFESSIONAL REFRENCES AVAILABLE BY REQUEST



# Special Site or Non-Pharmacist Preceptor Application

## SPECIAL SITE OR NON-PHARMACIST PRECEPTOR APPLICATION

STATE OF MISSOURI DIVISION OF PROFESSIONAL REGISTRATION MISSOURI BOARD OF PHARMACY  <i>NEW</i>	MAILING ADDRESS: MISSOURI BOARD OF PHARMACY PO BOX 625 JEFFERSON CITY, MO 65102	APPROVAL DATE NO. HOURS
	OVERNIGHT ADDRESS: 3605 MISSOURI BLVD. JEFFERSON CITY, MO 65109	DISAPPROVAL DATE
	RECEIVED DATE <b>RECEIVED</b> <b>OCT 7 2016</b>	

- KEEP COPY OF COMPLETED APPLICATION FOR YOUR RECORDS  
 - QUESTIONS: E-MAIL: [Interm@pr.mo.gov](mailto:Interm@pr.mo.gov) or call (673) 751-0092

**INSTRUCTIONS**

- ✓ Use this form to request approval of:
  - A preceptor that does not hold a pharmacist license issued by a U.S. state or territory, or;
  - An Intern training state that is not licensed as a pharmacy in the U.S. or a U.S. territory.
- ✓ After the special site/non-pharmacist preceptor has been approved by the Board, **interns must also file a Special Site/Non-Pharmacist Preceptor Notice of Employment Approval Application** before beginning their internship hours.
- ✓ **Missouri Pharmacy School Students:** If you are a student of a Missouri located pharmacy school/college, your school will submit an approval request for special sites/preceptors that will be used to earn Intern hours as part of your school/college curriculum. This form and the Intern Special Site/Non-Pharmacist Preceptor Notice of Employment form are only required if you will be independently earning hours outside of your school curriculum at a special site or with a non-pharmacist preceptor. *This allowance only applies to students attending a Missouri located pharmacy school/college.*

**REQUEST TYPE**

I AM REQUESTING APPROVAL OF:

Special Site and Non-Pharmacist Preceptor     
  Special Site     
  Non-Pharmacist Preceptor

**SITE APPROVAL**

NAME OF SPECIAL SITE  
 SSM Health Corporate Offices

SITE ADDRESS (STREET) (CITY) (STATE) (ZIP)  
 12312 Olive Boulevard St. Louis MO 63141

IS THE ENTITY AFFILIATED WITH A COLLEGE TRAINING AND/OR RESIDENCY PROGRAM?  YES  NO

IF YES, NAME OF SCHOOL/COLLEGE: St. Louis College of Pharmacy

DESCRIPTION OF BUSINESS ACTIVITIES (Attach additional sheets if necessary)  
 See attached



### Special Site or Non-Pharmacist Preceptor Application

PROVIDE A DETAILED DESCRIPTION OF THE PROPOSED INTERN JOB DUTIES/RESPONSIBILITIES (Attach additional sheets if necessary)

See attached

LIST THE LEARNING OBJECTIVE(S) FOR THE INTERN (Attach additional sheets if necessary)

See attached

#### PRECEPTOR APPROVAL

A Preceptor Affidavit Form (see attached) must be completed by each preceptor listed below.

Attach additional sheets if necessary.

PRECEPTOR NAME	Lindsay M. Reel, Pharm.D. (MO License 2006025351, Expires 10/31/18)			TITLE	Regional Director of Retail Pharmacies
PRECEPTOR MAILING ADDRESS (STREET)	12312 Olive Boulevard	(CITY)	St. Louis	(STATE)	MO 63141
PRECEPTOR NAME				TITLE	
PRECEPTOR MAILING ADDRESS (STREET)		(CITY)		(STATE)	(ZIP)
PRECEPTOR NAME				TITLE	
PRECEPTOR MAILING ADDRESS (STREET)		(CITY)		(STATE)	(ZIP)
PRECEPTOR NAME				TITLE	
PRECEPTOR MAILING ADDRESS (STREET)		(CITY)		(STATE)	(ZIP)

**PRECEPTOR QUALIFICATIONS:** To complete this application, a resume or curriculum vitae must be attached to this application that shows/ lists:

- All degrees obtained by the preceptor(s) listed above beyond high school/a general equivalency diploma; AND
- Preceptor employment history. Employment history must demonstrate the preceptor's experience/ability to train the intern in the proposed duties/responsibilities and should include the employer's name, employment dates and a description of job duties. Information must be submitted for each preceptor.

#### INTERN INFORMATION (List the names of interns that will be earning hours at the special site if known. Not required for Missouri located pharmacy schools/colleges. Attach additional sheets if necessary.)

INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER
INTERN NAME (LAST)	(FIRST)	(MIDDLE)	INTERN LICENSE NUMBER



### Special Site or Non-Pharmacist Preceptor Application

CONTACT PERSON (Please provide a contact person for questions regarding this application)			
CONTACT NAME Lindsay M. Reel, Pharm.D.		POSITION/TITLE Regional Director of Retail Pharmacies	
CONTACT MAILING ADDRESS (STREET) 12312 Olive Boulevard		(CITY) St. Louis	(STATE) (ZIP) MO 63141
E-MAIL ADDRESS Lindsay.Reel@SSMHealth.com	TELEPHONE NUMBER 314-523-8775	FAX NUMBER 314-523-8774	

AFFIDAVIT (to be completed by the sole representative of entity submitting this application)	
<p>I hereby request approval of the site and/or preceptor identified herein. All the information and answers contained in this application and any attachments are true and correct to my best knowledge and belief. I am making this affidavit knowing that any false statements or material omission subjects me to criminal penalties for making a false affidavit under Section 575.050, RSMo.</p> <p>I understand that I must comply with federal and state laws as well as the regulations of the Missouri Board of Pharmacy. I further understand that any intern hours earned at or credited by the proposed special site shall comply with 20 CSR 2220-7.030(1)(A). I hereby certify under penalty of perjury that the above statements, as well as all information provided herein, are true and accurate to the best of my knowledge and belief.</p>	
SIGNATURE OF APPLICANT 	PRINT NAME Lindsay M. Reel, Pharm.D.
TITLE Regional Director of Retail Pharmacies	DATE 10/7/16



## Special Site or Non-Pharmacist Preceptor Application

### PRECEPTOR'S AFFIDAVIT

A PRECEPTOR'S AFFIDAVIT MUST BE SUBMITTED BY ALL PRECEPTORS DESIGNATED IN THE SPECIAL SITE/NON-PHARMACIST PRECEPTOR APPLICATION.

I hereby attest that I have reviewed 20 CSR 2220-7.025 and agree to serve as a preceptor at the site listed below. I understand that intern practice experience must comply with 20 CSR 2220-7.030(1)(A)3. I certify that all preceptor information contained in this application is true and correct to my best knowledge and belief. I am making this affidavit knowing that any false statements or material omission subjects me to criminal penalties for making a false affidavit under Section 575.050, RSMO.

I understand that I must comply with federal and state laws as well as the regulations of the Missouri Board of Pharmacy. I agree to report intern hours to the Board as required by 20 CSR 2220-7.025. I hereby certify under the penalty of perjury that the above statements, as well as all information provided by me, are true and accurate.

NAME OF SPECIAL SITE

SSM Health Corporate Offices

SITE ADDRESS

(STREET)

(CITY)

(STATE)

(ZIP)

12312 Olive Boulevard

St. Louis

MO

63141

SIGNATURE OF PRECEPTOR

DATE

6/7/16

PRINT NAME

Lindsay M. Reel, Pharm.D.

TITLE

Regional Director of Retail Pharmacies

**SSM Health Corporate Offices  
Special Site Permit Application (Attachment)**

**Description of Business Activities:**

Manages five outpatient retail pharmacies at the following locations:

- SSM Health Cardinal Glennon Children's Hospital
- SSM Health Clayton Health Services (St. Mary's Hospital)
- SSM Health Pharmacy (DePaul Hospital)
- SSM St. Charles Clinic Medical Group Pharmacy
- SSM Health St. Joseph Hospital (Wentzville)

**Provide a detailed description of the job duties/responsibilities of the intern:**

The student will travel to the hospital pharmacies managed by the Regional Director of Retail Pharmacy and work with and have exposure to:

- Payroll reports
- P&L (profit and loss statements)
- Inventory
- 340b program and purchasing
- SSM Company goals
- HR issues, as much as possible without compromising employee privacy
- Pharmacy security and loss prevention techniques
- Pharmacy laws and licensing of retail facilities, inspections, etc.
- Interviews and hiring new employees
- MTM billable services
- Prescription reimbursement and 3<sup>rd</sup> party contracts

**List the Learning Objective(s) for the Intern:**

The student will learn:

- Payroll reports, how hours are figured, and how to adjust scheduling accordingly
- P&L (profit and loss statements), what we are able to leverage and what is fixed.
- Managing inventory and inventory days' supply turnover
- 340b program and purchasing
- SSM Company goals and means of meeting them
- Managing HR related issues
- Managing pharmacy security and loss prevention techniques
- Become familiar with pharmacy laws and licensing of retail facilities, inspections etc.
- Interviewing techniques and hiring new employees
- MTM billable services
- Prescription reimbursement and 3<sup>rd</sup> party contracts

**#C2 STLCOP and UMKC College of Pharmacy**

\*\*\*NO AGENDA MATERIALS AT THIS TIME\*\*\*

## **SECTION D – OPEN**

**#D1 FDA DQSA Guidance/Implementation**

- FDA September 2016 Inter-Governmental Meeting Update
- 21 CFR—Part 216 (Compounding of Drug Products Withdrawn or Removed From The Market)
- FDA Guidance (Insanitary Conditions at Compounding Facilities)

# Code of Federal Regulations

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## Title 21 - Food and Drugs

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Volume: 4

Date: 2011-04-01

Original Date: 2011-04-01

Title: PART 216 - PHARMACY COMPOUNDING

Context: Title 21 - Food and Drugs. CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED). SUBCHAPTER C - DRUGS: GENERAL.

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### Pt. 216

#### PART 216—PHARMACY COMPOUNDING

##### Subpart A—General Provisions [Reserved]

##### Subpart B—Compounded Drug Products

###### Sec.

216.23 [Reserved]

216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

**Authority** 21 U.S.C. 351, 352, 353a, 355, and 371.

**Source:** 64 FR 10944, Mar. 8, 1999, unless otherwise noted.

##### Subpart A—General Provisions [Reserved]

##### Subpart B—Compounded Drug Products

§ 216.23 [Reserved]

§ 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

The following drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective. The following drug products may not be compounded under the exemptions provided by section 503A(a) of the Federal Food, Drug, and Cosmetic Act:

*ADENOSINE PHOSPHATE:* ALL DRUG PRODUCTS CONTAINING ADENOSINE PHOSPHATE.

*ADRENAL CORTEX:* ALL DRUG PRODUCTS CONTAINING ADRENAL CORTEX.

*AZARIBINE:* ALL DRUG PRODUCTS CONTAINING AZARIBINE.

*BENOXAPROFEN:* ALL DRUG PRODUCTS CONTAINING BENOXAPROFEN.

*BITHIONOL:* ALL DRUG PRODUCTS CONTAINING BITHIONOL.

*BROMFENAC SODIUM:* ALL DRUG PRODUCTS CONTAINING BROMFENAC SODIUM.

*BUTAMBEN:* ALL PARENTERAL DRUG PRODUCTS CONTAINING BUTAMBEN.

*CAMPHORATED OIL:* ALL DRUG PRODUCTS CONTAINING CAMPHORATED OIL.

*CARBETAPENTANE CITRATE:* ALL ORAL GEL DRUG PRODUCTS CONTAINING CARBETAPENTANE CITRATE.

*CASEIN, IODINATED:* ALL DRUG PRODUCTS CONTAINING IODINATED CASEIN.

*CHLORHEXIDINE GLUCONATE*: ALL TINCTURES OF CHLORHEXIDINE GLUCONATE FORMULATED FOR USE AS A PATIENT PREOPERATIVE SKIN PREPARATION.

*CHLORMADINONE ACETATE*: ALL DRUG PRODUCTS CONTAINING CHLORMADINONE ACETATE.

*CHLOROFORM*: ALL DRUG PRODUCTS CONTAINING CHLOROFORM.

*COBALT*: ALL DRUG PRODUCTS CONTAINING COBALT SALTS (EXCEPT RADIOACTIVE FORMS OF COBALT AND ITS SALTS AND COBALAMIN AND ITS DERIVATIVES).

*DEXFENFLURAMINE HYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING DEXFENFLURAMINE HYDROCHLORIDE.

*DIAMTHAZOLE DIHYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING DIAMTHAZOLE DIHYDROCHLORIDE.

*DIBROMSALAN*: ALL DRUG PRODUCTS CONTAINING DIBROMSALAN.

*DIETHYLSTILBESTROL*: ALL ORAL AND PARENTERAL DRUG PRODUCTS CONTAINING 25 MILLIGRAMS OR MORE OF DIETHYLSTILBESTROL PER UNIT DOSE.

*DIHYDROSTREPTOMYCIN SULFATE*: ALL DRUG PRODUCTS CONTAINING DIHYDROSTREPTOMYCIN SULFATE.

*DIPYRONE*: ALL DRUG PRODUCTS CONTAINING DIPYRONE.

*ENCAINIDE HYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING ENCAINIDE HYDROCHLORIDE.

*FENFLURAMINE HYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING FENFLURAMINE HYDROCHLORIDE.

*FLOSEQUINAN*: ALL DRUG PRODUCTS CONTAINING FLOSEQUINAN.

*GELATIN*: ALL INTRAVENOUS DRUG PRODUCTS CONTAINING GELATIN.

*GLYCEROL, IODINATED*: ALL DRUG PRODUCTS CONTAINING IODINATED GLYCEROL.

*GONADOTROPIN, CHORIONIC*: ALL DRUG PRODUCTS CONTAINING CHORIONIC GONADOTROPINS OF ANIMAL ORIGIN.

*MEPAZINE*: ALL DRUG PRODUCTS CONTAINING MEPAZINE HYDROCHLORIDE OR MEPAZINE ACETATE.

*METABROMSALAN*: ALL DRUG PRODUCTS CONTAINING METABROMSALAN.

*METHAMPHETAMINE HYDROCHLORIDE*: ALL PARENTERAL DRUG PRODUCTS CONTAINING METHAMPHETAMINE HYDROCHLORIDE.

*METHAPYRILENE*: ALL DRUG PRODUCTS CONTAINING METHAPYRILENE.

*METHOPHOLINE*: ALL DRUG PRODUCTS CONTAINING METHOPHOLINE.

*MIBEFRADIL DIHYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING MIBEFRADIL DIHYDROCHLORIDE.

*NITROFURAZONE*: ALL DRUG PRODUCTS CONTAINING NITROFURAZONE (EXCEPT TOPICAL DRUG PRODUCTS FORMULATED FOR DERMATOLOGIC APPLICATION).

*NOMIFENSINE MALEATE*: ALL DRUG PRODUCTS CONTAINING NOMIFENSINE MALEATE.

*OXYPHENISATIN*: ALL DRUG PRODUCTS CONTAINING OXYPHENISATIN.

*OXYPHENISATIN ACETATE*: ALL DRUG PRODUCTS CONTAINING OXYPHENISATIN ACETATE.

*PHENACETIN*: ALL DRUG PRODUCTS CONTAINING PHENACETIN.

*PHENFORMIN HYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING PHENFORMIN HYDROCHLORIDE.

*PIPAMAZINE*: ALL DRUG PRODUCTS CONTAINING PIPAMAZINE.

*POTASSIUM ARSENITE*: ALL DRUG PRODUCTS CONTAINING POTASSIUM ARSENITE.

*POTASSIUM CHLORIDE*: ALL SOLID ORAL DOSAGE FORM DRUG PRODUCTS CONTAINING POTASSIUM CHLORIDE THAT SUPPLY 100 MILLIGRAMS OR MORE OF POTASSIUM PER DOSAGE UNIT (EXCEPT FOR CONTROLLED-RELEASE DOSAGE FORMS AND THOSE PRODUCTS FORMULATED FOR PREPARATION OF SOLUTION PRIOR TO INGESTION).

*POVIDONE*: ALL INTRAVENOUS DRUG PRODUCTS CONTAINING POVIDONE.

*RESERPINE*: ALL ORAL DOSAGE FORM DRUG PRODUCTS CONTAINING MORE THAN 1 MILLIGRAM OF RESERPINE.

*SPARTEINE SULFATE*: ALL DRUG PRODUCTS CONTAINING SPARTEINE SULFATE.

*SULFADIMETHOXINE*: ALL DRUG PRODUCTS CONTAINING SULFADIMETHOXINE.

*SULFATHIAZOLE*: ALL DRUG PRODUCTS CONTAINING SULFATHIAZOLE (EXCEPT THOSE FORMULATED FOR VAGINAL USE).

*SUPROFEN*: ALL DRUG PRODUCTS CONTAINING SUPROFEN (EXCEPT OPHTHALMIC SOLUTIONS).

*SWEET SPIRITS OF NITRE*: ALL DRUG PRODUCTS CONTAINING SWEET SPIRITS OF NITRE.

*TEMAFLOXACIN HYDROCHLORIDE*: ALL DRUG PRODUCTS CONTAINING TEMAFLORACIN.

*TERFENADINE*: ALL DRUG PRODUCTS CONTAINING TERFENADINE.

*3,3',4',5-TETRACHLOROSALICYLANILIDE*: ALL DRUG PRODUCTS CONTAINING 3,3',4',5-TETRACHLOROSALICYLANILIDE.

*TETRACYCLINE*: ALL LIQUID ORAL DRUG PRODUCTS FORMULATED FOR PEDIATRIC USE CONTAINING TETRACYCLINE IN A CONCENTRATION GREATER THAN 25 MILLIGRAMS/MILLILITER.

*TICRYNAFEN*: ALL DRUG PRODUCTS CONTAINING TICRYNAFEN.

*TRIBROMSALAN*: ALL DRUG PRODUCTS CONTAINING TRIBROMSALAN.

*TRICHLOROETHANE*: ALL AEROSOL DRUG PRODUCTS INTENDED FOR INHALATION CONTAINING TRICHLOROETHANE.

*URETHANE*: ALL DRUG PRODUCTS CONTAINING URETHANE.

*VINYL CHLORIDE*: ALL AEROSOL DRUG PRODUCTS CONTAINING VINYL CHLORIDE.

*ZIRCONIUM*: ALL AEROSOL DRUG PRODUCTS CONTAINING ZIRCONIUM.

*ZOMEPIRAC SODIUM*: ALL DRUG PRODUCTS CONTAINING ZOMEPIRAC SODIUM.

# Insanitary Conditions at Compounding Facilities

## Guidance for Industry

### *DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Office of Compliance**

**August 2016  
Compounding and Related Documents**

# Insanitary Conditions at Compounding Facilities

## Guidance for Industry

*Additional copies are available from:  
Office of Communications, Division of Drug Information  
Center for Drug Evaluation and Research*

*Food and Drug Administration*

*10001 New Hampshire Ave., Hillandale Bldg., 4<sup>th</sup> Floor*

*Silver Spring, MD 20993-0002*

*Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353*

*Email: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)*

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Office of Compliance**

**August 2016  
Compounding and Related Documents**

*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

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*Contains Nonbinding Recommendations*

*Draft — Not for Implementation*

**Guidance for Industry<sup>1</sup>**

**Insanitary Conditions at Compounding Facilities**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

**I. INTRODUCTION**

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), a drug is deemed to be adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.”<sup>2</sup> Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act, compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section 503A nor section 503B provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs prepared, packed, or held (hereinafter referred to as “produced”) under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the Act.<sup>3</sup> Any drug that is produced under insanitary conditions is adulterated under the Act, including compounded human and animal drugs; repackaged drug products; compounded or repackaged radiopharmaceuticals; and mixed, diluted, or repackaged biological products. The policies described in this guidance document specifically address pharmacies, Federal facilities, physicians’ offices (including veterinarians’ offices), and outsourcing facilities that compound or repackage human or animal drugs (including radiopharmaceuticals); or that mix, dilute, or repackage biological products. For purposes of this guidance, we refer to such entities as “compounding facilities.”

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<sup>1</sup> This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs and the Center for Veterinary Medicine at the Food and Drug Administration.

<sup>2</sup> Insanitary conditions are conditions that could cause a drug to become contaminated with filth or rendered injurious to health; the drug need not be actually contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substance is deemed to be adulterated under section 501(a)(1) of the FD&C Act.

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36 FDA is issuing this guidance to assist compounding facilities in identifying insanitary conditions  
37 so that they can implement appropriate corrective actions. This guidance is also intended to  
38 assist State regulatory agencies in understanding some examples of what FDA considers to be  
39 insanitary conditions that could cause a drug to become contaminated or rendered injurious to  
40 health.

41  
42 In general, FDA's guidance documents do not establish legally enforceable responsibilities.  
43 Instead, guidances describe the Agency's current thinking on a topic and should be viewed only  
44 as recommendations, unless specific regulatory or statutory requirements are cited. The use of  
45 the word *should* in Agency guidances means that something is suggested or recommended, but  
46 not required.

## **II. BACKGROUND**

### **A. Public Health Risk of Insanitary Conditions**

51  
52 FDA has investigated numerous outbreaks of infections and deaths found to be the result of drug  
53 products that were contaminated because they were produced under insanitary conditions. Most  
54 notably, in 2012, injectable drug products produced by a compounding facility and shipped  
55 across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and  
56 750 cases of infection. FDA has investigated numerous other serious adverse events, including  
57 deaths, associated with contaminated drug products produced by compounding facilities, and it is  
58 likely that such adverse events are underreported.

59  
60 Since the 2012 fungal meningitis outbreak, FDA has identified insanitary conditions at many of  
61 the compounding facilities that it has inspected, and numerous compounding facilities have  
62 voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased  
63 sterile operations as a result of those findings. However, FDA does not inspect the vast majority  
64 of compounding facilities in the United States because they generally do not register with FDA  
65 unless they elect to become outsourcing facilities.<sup>4</sup> Therefore, FDA is often not aware of these  
66 facilities and potential problems with their drug products, or conditions and practices, unless it  
67 receives a complaint, such as a report of a serious adverse event or visible contamination. It is  
68 critical that compounding facilities avoid the presence of insanitary conditions and identify and  
69 remediate any insanitary conditions at their facilities before the conditions result in drug  
70 contamination and patient injury.

71  
72 In addition, to protect the public health, it is critical that both FDA and State regulatory agencies  
73 take appropriate action when compounders produce drugs under insanitary conditions. Based on  
74 its inspections, FDA determines whether compounding facilities produce drugs under insanitary  
75 conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may  
76 initiate regulatory action. However, compounding facilities that are not registered with FDA as  
77 outsourcing facilities are primarily overseen by the States and, as explained above, generally are  
78 not routinely inspected by FDA. Therefore, FDA encourages State regulatory agencies to assess  
79 during inspections whether compounding facilities that they oversee engage in poor practices,

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<sup>4</sup> See section 503B of the FD&C Act.

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80 including those described below, and if so, to take action, as appropriate, consistent with State  
81 laws and regulations, and to contact FDA.

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### **III. POLICY**

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85 Section III.A of this guidance describes examples of conditions that would be considered  
86 insanitary conditions under section 501(a)(2)(A) of the FD&C Act. FDA has observed each of  
87 these conditions in one or more of the compounding facilities it has inspected. **These are only**  
88 **examples and are not an exhaustive list. Other conditions not described in this guidance**  
89 **may be considered insanitary.**

90

91 Section III.B of this guidance describes procedures that compounding facilities should employ to  
92 ensure that they do not have insanitary conditions and that they are capable of producing sterile  
93 drug products, and section III.C describes actions that compounding facilities should take if they  
94 identify insanitary conditions at their facilities. Finally, section III.D of this guidance describes  
95 potential FDA regulatory actions if insanitary conditions are not adequately corrected.

96

97 FDA intends to consider the entire set of conditions at the facility, including whether the facility  
98 engages in the procedures described in section III.B, when prioritizing regulatory action against a  
99 compounding facility for producing drugs under insanitary conditions.

100

#### **A. Examples of Insanitary Conditions<sup>5</sup>**

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##### *1. Insanitary Conditions Applicable to the Production of Sterile and/or Non-Sterile 104 Drugs*

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106 Although maintaining sterility is not a requirement for non-sterile drugs, non-sterile drugs can  
107 become contaminated with microorganisms of a type or at a level that can cause patient harm.  
108 Non-sterile aqueous solutions are particularly susceptible to microbial growth if contaminated.  
109 Contamination may also include non-viable filth and the presence of unintended drug  
110 components. The following are examples of insanitary conditions that are applicable to both  
111 sterile and non-sterile drug production.

112

- 113 • Vermin (e.g., insects, rodents) observed in production areas or areas immediately  
114 adjacent to production.
- 115 • Visible microbial contamination (e.g., bacteria, mold) in the production area.
- 116 • Non-microbial contamination in the production area (e.g., rust, glass shavings, hairs).
- 117 • Handling beta-lactam, hazardous, or highly potent drugs (e.g., hormones) without  
118 providing adequate containment, segregation, and cleaning of work surfaces, utensils, and  
119 personnel to prevent cross-contamination.
- 120 • Production of drugs while construction is underway in an adjacent area without adequate  
121 controls to prevent contamination of the production environment and product.

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<sup>5</sup> For definitions of some of the terms used in this section, refer to United States Pharmacopeia (USP) Chapter <797>.

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### *2. Insanitary Conditions in a Sterile Operation*

#### *a. Aseptic Practices*

- Putting on gowning apparel improperly, in a way that may cause the gowning apparel to become contaminated. This includes, for example, gowning in non-classified areas, gowning apparel touching the floor, or putting on sterile gloves improperly (e.g., touching the outside of a glove with bare hands).
- Failing to disinfect or change gloves frequently enough given the nature of the operations to prevent contamination.
- Engaging in aseptic processing wearing non-sterile gloves. This could contaminate the critical area.<sup>6</sup>
- Engaging in aseptic manipulations with exposed hands, wrists, legs, hair, or mouth, for example.
- Performing aseptic manipulations outside of an International Organization for Standardization Class 5 (ISO 5) area.
- Exposing unprotected sterile product, including stock solutions, to lower than ISO 5 quality air (e.g., removing it from the ISO 5 area without a robust and intact container closure system).
- Engaging in aseptic processing after leaving the cleanroom and re-entering from a non-classified area without first replacing gowning apparel (e.g., sterile gloves, gowns, mask, foot covers). Movement of personnel in and out of the cleanroom without regowning may bring contaminants from the non-classified areas into the cleanroom.
- Moving quickly in the vicinity of open containers or instruments (e.g., needles). While conducting aseptic manipulations, ISO 5 airflow must be unidirectional to protect the product from contaminating particles. Quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.
- Conducting aseptic manipulations or placing equipment/supplies in an area that blocks the movement of first pass air around an open container, whether before or after it is filled with sterile product. If unidirectional air over the critical surface is blocked, the area is no longer protected. If it is blocked by personnel conducting aseptic manipulations, contamination on personnel, particularly on exposed skin, could be introduced to the critical area.
- Using a non-sterile tool or manually contacting the inner surface of the container or closure. For example, during manual stoppering (e.g., hand stoppering), personnel touching the top of open containers, or the lower side or bottom of closures. This could contaminate the drug in the vials.
- Touching equipment or other surfaces (e.g., walls, telephone, floors) located outside of the ISO 5 area with gloved hands and then proceeding with aseptic manipulations without changing or sanitizing gloves.

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<sup>6</sup> A *critical area* is an area designed to maintain sterility of sterilized materials. Sterilized product, containers or closures, and equipment may be exposed in critical areas. The ISO 5 area is the critical area, and the terms are used interchangeably throughout this guidance.

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- Storing open sterile vials within the critical area without protective cover longer than needed for the process of filling drug product. The longer a vial is open to the environment, the greater the risk of contamination.
  - Failure to disinfect container closure systems of sterile drug components immediately prior to opening for use.
- b. Equipment/ Facilities
- Actionable microbial contamination of the ISO 5 area or in adjacent areas.
  - Cleanroom with unsealed, loose ceiling tiles.
  - ISO classified areas with difficult to clean (e.g., porous), particle-generating, or visibly dirty (e.g., rusty) equipment or surfaces such as shelving, floors, walls, doors, window sills, and ceilings. For example, wood is both difficult to clean and particle-generating.
  - Classified areas and segregated production areas surrounding the ISO 5 area that contain dust-collecting overhangs (e.g., utility pipes or ledges, such as windowsills).
  - ISO 5 area open to the surrounding cleanroom with minimal or no physical barriers separating it from non-aseptic activities (e.g., non-aseptic weighing materials, gowning, container labeling).
  - ISO 5 area open to non-classified rooms (segregated production area). Lower quality air from the surrounding room entering the ISO 5 area increases the risk of introducing microbial contamination into drug products being manipulated.
  - A facility designed and/or operated in a way that permits poor flow of personnel or materials, or allows the influx of poor quality air into a higher classified area. Examples include:
    - materials flow into the ISO 7 area directly from an unclassified area;
    - air return located next to the high efficiency particulate arrestance (HEPA) filter rather than near the floor;
    - an air vent between classified and unclassified areas;
    - a door opened between the unclassified area and the ISO 8 anteroom while the door between the ISO 7 and ISO 8 areas is also open;
    - inadequate pressure differentials between areas of higher quality air and lower quality air.
  - A lack of HEPA-filtered air, or inadequate HEPA filter coverage or airflow, over the area to which sterile product is exposed.
  - HEPA filters that are not sealed around each perimeter to the support frame. The air entering the cleanroom must be HEPA filtered to remove airborne particles. If HEPA filters are not sealed, air that is not HEPA filtered could enter the cleanroom.
  - The presence of sinks or drains in the cleanroom where the ISO 5 area is located. Sinks and drains are sources of microbial contamination.
  - Use of non-sterilized or non-depyrogenated equipment (e.g., transfer tubing, temporary bulk containers). Use of such equipment can introduce or increase bioburden and endotoxins.
  - Use of non-sterilized or non-depyrogenated final containers/closures. Use of such container/closures could contaminate the drug product after it has been sterilized.

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### c. Sterilization

- The “sterilizing filter” is not adequate to accomplish sterilization and is not pharmaceutical grade.
- Temperature and time conditions used for heat sterilization are not lethal to heat-resistant microorganisms.

### d. Cleaning and Disinfecting

- Non-sterile disinfecting agents and cleaning pads or wipes are used in the aseptic processing areas, especially the ISO 5 area. Non-sterile cleaning and disinfecting items could spread microbial spores.
- No, improper, or infrequent, use of a sporicidal agent in the facility’s cleanrooms and ISO 5 area.
- No disinfection of equipment and/or supplies entering the aseptic processing areas. Disinfection should occur at each transition from areas of lower quality air to areas of higher quality (e.g., from non-classified to first classified room, from anteroom to buffer room, from buffer room to ISO 5 area).
- Disinfectant contact time (also known as “dwell time”) and coverage of the item being disinfected are insufficient to achieve adequate levels of disinfection. The use, including contact time, of commercially-obtained disinfectants should follow the manufacturer’s instructions.

## **B. Identifying Insanitary Conditions**

Certain procedures are critical to ensuring that compounding facilities do not have insanitary conditions that could compromise drug sterility and that they are capable of producing sterile drug products. FDA recommends that compounding facilities that produce drugs that are intended to be sterile routinely employ these procedures to help ensure that they can produce sterile products. A non-exhaustive list of such procedures follows.

1. Conduct routine<sup>7</sup> environmental monitoring, including a) nonviable airborne particulate sampling; b) viable airborne particulate sampling; c) personnel sampling (including glove fingertip sampling); and d) surface sampling, including but not limited to equipment, work surfaces, and room surfaces. Environmental monitoring provides information on the quality of the aseptic processing environment and, if problematic, the compounding

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<sup>7</sup> For compounding facilities that are not registered with FDA as outsourcing facilities, see USP Chapter <797>. For outsourcing facilities, see FDA’s draft guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (“interim CGMP draft guidance”). Once final, this guidance will represent FDA’s current thinking regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until FDA promulgates CGMP regulations that are more specific to outsourcing facilities.

This interim CGMP draft guidance states that outsourcing facilities should conduct environmental monitoring of the ISO 5 area at least daily. FDA recommends that compounding facilities that are not registered as outsourcing facilities also conduct daily environmental monitoring during operations.

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244 facility should promptly identify potential routes of contamination and perform corrective  
245 actions.

- 246
- 247 2. Certify the ISO 5 area every six months. If the ISO 5 area is not certified every six  
248 months or does not pass all certification requirements, there is no assurance that the ISO  
249 5 area is working properly (e.g., generating unidirectional ISO 5 airflow). Smoke studies  
250 should be conducted as part of the certification to assess the airflow patterns necessary to  
251 maintain unidirectional flow from areas of higher air quality (e.g., ISO 5) to areas of  
252 lower air quality (e.g., ISO 7) to prevent microbial contamination of the sterile drug  
253 products during processing. Conducting smoke studies under dynamic conditions helps  
254 to ensure that unidirectional airflow is maintained while personnel are working in the ISO  
255 5 area.
- 256
- 257 3. Measure pressure differentials during operations to help ensure proper airflow (i.e., from  
258 areas of higher quality air to adjacent areas with lower quality air).
- 259
- 260 4. Conduct media fill studies to closely simulate aseptic production operations incorporating, as  
261 appropriate, worst-case activities and conditions that provide a challenge to aseptic  
262 operations.
- 263

### **C. Corrective Actions**

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265 A compounding facility should immediately assess the impact of insanitary conditions on drug  
266 products produced, which should include an evaluation of how widespread the insanitary  
267 conditions are and over what period of time the conditions existed.

268  
269 The compounding facility also should determine whether to cease production of drug products  
270 until the conditions have been corrected and initiate a recall of all potentially affected lots on the  
271 market.

272  
273 For example, FDA considers the following insanitary conditions to be particularly serious, and if  
274 any one of these conditions exists, FDA strongly recommends that a compounding facility  
275 immediately initiate a recall of purportedly sterile drugs and cease sterile operations until the  
276 condition(s) have been corrected:

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278
- 279 • Vermin (e.g., insects, rodents) observed in ISO 5 areas or in immediately adjacent  
280 areas.
  - 281 • Visible microbial contamination (e.g., bacteria, mold) in the ISO 5 area or in  
282 immediately adjacent areas.
  - 283 • Non-microbial contamination in the ISO 5 area (e.g., rust, glass shavings, hairs).
  - 284 • Performing aseptic manipulations outside of the ISO 5 area.
  - 285 • Exposing unprotected sterile product, including stock solutions, to lower than ISO 5  
286 quality air (e.g., removing it from the ISO 5 area without a robust and intact container  
287 closure system).
  - 288 • Cleanroom areas with unsealed, loose ceiling tiles.

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- 289 • Production of drugs while construction is underway in an adjacent area without  
290 adequate controls to prevent contamination of the production environment and  
291 product.
- 292 • Consistent and frequent pressure reversals from areas of less clean air to areas of  
293 higher cleanliness.
- 294 • The “sterilizing filter” is not adequate to accomplish sterilization and is not  
295 pharmaceutical grade.
- 296 • Temperature and time conditions used for heat sterilization are not lethal to heat-  
297 resistant microorganisms.

298  
299 If a compounding facility decides to initiate a recall, it should notify its local FDA District recall  
300 coordinator as soon as the decision to recall is made.<sup>8</sup> The compounding facility should also  
301 notify the applicable State regulatory body in the State(s) to which the facility ships drugs,  
302 consistent with State laws and guidance.

303  
304 In addition to the immediate actions recommended above, if a compounding facility has  
305 insanitary conditions, it should undertake a comprehensive assessment of its operations,  
306 including, as applicable, facility design, procedures, personnel, processes, materials, and  
307 systems, and should consider consulting a third party with relevant drug production expertise to  
308 conduct this comprehensive evaluation and to assist in implementing appropriate corrective  
309 actions.

310  
311 Compounding facilities producing purportedly sterile drug products under insanitary conditions  
312 should not rely on a passing sterility test as an indication of sterility assurance because microbial  
313 contamination, when present, is not uniformly distributed within a batch and may not be  
314 identified by a sterility test. Furthermore, compounding facilities must correct all insanitary  
315 conditions at their facility,<sup>9</sup> regardless of whether the drugs pass a sterility test.<sup>10</sup>

### **D. Regulatory Action**

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317  
318  
319 If a compounding facility produces drugs under insanitary conditions, the facility and responsible  
320 individuals may be subject to Federal regulatory actions including, but not limited to, a warning  
321 letter, seizure of product, and/or injunction. FDA may also recommend that the facility initiate a  
322 recall of some or all of its drugs and cease operations until the insanitary conditions have been  
323 adequately addressed. In addition, the applicable State regulatory agency may pursue regulatory  
324 action against the facility under applicable State authorities.

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<sup>8</sup> See the FDA guidance, *Product Recalls, Including Removals and Corrections*.

<sup>9</sup> See section 501(a)(2)(A) of the FD&C Act.

<sup>10</sup> USP Chapter <71> concerning sterility testing states, “these Pharmacopeial procedures are not by themselves designed to ensure that a batch of product is sterile or has been sterilized. This is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures.”

**#D2 Review of 20 CSR 2220-6.040**

- Rule Review Calendar
- Section 536.175 (Rule Review Statute)
- 20 CSR 2220-6.040 (Administration by Medical Prescription Order)
- Hospital Advisory Committee Comments



# MISSOURI BOARD OF PHARMACY ADMINISTRATIVE RULE REVIEW CALENDAR

*This calendar may be subject to change. Submit a comment online at [www.pr.mo.gov/pharmacists-proposed.asp](http://www.pr.mo.gov/pharmacists-proposed.asp)*

## OCTOBER 2016

Immunization/Administration		<i>*Last effective date</i>
20 CSR 2220-6.040	Administration by Medical Prescription Order	11/30/2008
20 CSR 2220-6.050	Administration of Vaccines Per Protocol	5/30/2008
20 CSR 2220-6.055	Non-Dispensing Activities	6/30/2010
20 CSR 2220-2.650	Standards of Operation for a Class J: Shared Services Pharmacy	8/28/2006

## JANUARY 2017

General Pharmacy Standards		<i>*Last effective date</i>
20 CSR 2220-2.005	Definitions	8/30/2011
20 CSR 2220-2.010	Pharmacy Standards of Operation	8/30/2008
20 CSR 2220-2.015	Termination of Business as a Pharmacy	12/30/1995
20 CSR 2220-2.016	Pharmacy Operating Procedures During Declared Disasters	12/30/1995
20 CSR 2220-2.020	Pharmacy Permits	4/30/2007
20 CSR 2220-2.025	Nonresident Pharmacies	1/30/2003
20 CSR 2220-2.090	Pharmacist-in-Charge	6/30/2001
20 CSR 2220-2.700	Pharmacy Technician Registration	3/30/2010
20 CSR 2220-2.900	Automated Dispensing and Storage Systems	8/30/2007
20 CSR 2220-2.080	Electronic Prescription Records	8/30/2013
20 CSR 2220-2.083	Electronic Record-Keeping Systems	11/30/2001

## APRIL 2017

Long-Term Care		<i>*Last effective date</i>
20 CSR 2220-2.140	Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities	1/30/2001
20 CSR 2220-2.085	Electronic Transmission of Prescription Data	11/30/2001
20 CSR 2220-2.145	Minimum Standards for Multi-Med Dispensing	6/30/2012
Medication Therapy Services		<i>*Last effective date</i>
20 CSR 2220-6.060	General Provisions	8/30/2012
20 CSR 2220-6.070	Certificate of MT Plan Authority	8/30/2012
20 CSR 2220-6.080	MT Services By Protocol	8/30/2012



# MISSOURI BOARD OF PHARMACY ADMINISTRATIVE RULE REVIEW CALENDAR

## JULY 2017

Specialty Pharmacy Services		<i>*Last effective date</i>
20 CSR 2220-2.400	Compounding Standards of Practice	7/30/2003
20 CSR 2220-2.600	Standards of Operation for a Class F: Renal Dialysis Pharmacy	8/30/1998
20 CSR 2220-2.675	Standards of Operation/Licensure for Class L Veterinary Pharmacies	3/30/2012
20 CSR 2220-6.100	Pharmacy Standards for Dispensing Blood-Clotting Products	5/30/2013
Nuclear Pharmacy		<i>*Last effective date</i>
20 CSR 2220-2.500	Nuclear Pharmacy- Minimum Standards for Operation	1/30/2001

## OCTOBER 2017

Medication Dispensing		<i>*Last effective date</i>
20 CSR 2220-2.013	Prescription Delivery Requirements	11/30/2012
20 CSR 2220-2.110	PRN Refills	3/11/1985
20 CSR 2220-2.120	Transfer of Prescription Information for the Purpose of Refill	8/30/2008
20 CSR 2220-2.130	Drug Repackaging	8/30/2003
20 CSR 2220-2.800	Vacuum Tube Drug Delivery System	2/28/1999
20 CSR 2220-2.950	Automated Filling Systems	1/30/2014
20 CSR 2220-2.190	Patient Counseling	4/30/2007

## JANUARY 2018

Drug Distributor		<i>*Last effective date</i>
20 CSR 2220-5.010	Drug Distributor Advisory Committee	4/26/1990
20 CSR 2220-5.020	Drug Distributor Licensing Requirements	4/30/2007
20 CSR 2220-5.025	Termination of Business as a Drug Distributor	12/30/1995
20 CSR 2220-5.030	Definitions and Standards for Drug Wholesale and Pharmacy Distributors	8/30/2008
20 CSR 2220-5.040	Drug Distributor Inspection Exemptions	6/10/1991
20 CSR 2220-5.050	Out-of-State Distributor License/Registration Requirements	9/30/2000



# MISSOURI BOARD OF PHARMACY ADMINISTRATIVE RULE REVIEW CALENDAR

APRIL 2018

GENERAL LICENSING/MISC.		<i>*Last effective date</i>
20 CSR 2220 Chapter 7	Board Licensing Rules	4/26/1990
20 CSR 2220-2.018	Prescription Requirements	8/30/2013
20 CSR 2220-2.050	Public Complaint Handling and Disposition Procedure	10/30/2005
20 CSR 2220-2.060	Gold Certificates	8/28/2006
20 CSR 2220-2.080	Electronic Prescription Records	8/30/2013
20 CSR 2220-2.083	Electronic Record-Keeping Systems	8/30/2013
20 CSR 2220-2.150	Mandatory Reporting Rule	1/29/1988
20 CSR 2220-2.160	Definition of Disciplinary Actions	1/30/2000
20 CSR 2220-2.165	Licensure Disciplinary Agreements	1/13/1992
20 CSR 2220-2.170	Procedure for Impaired Pharmacists	3/11/1989
20 CSR 2220-2.175	Well-Being Program	3/30/2010
20 CSR 2220-2.180	Public Records	2/25/1996
20 CSR 2220-2.300	Record Confidentiality and Disclosure	7/30/2004

\*\*\*\*The Board filed an emergency and amended rule to amend 20 CSR 2220-2.2000 (Sterile Compounding) in August of 2016. Further review/comment on this rule will be conducted as part of the rulemaking process. Additional information on the emergency/amended sterile compounding rule is available online at <http://pr.mo.gov/pharmacists-proposed.asp>\*\*\*\*

# Missouri Revised Statutes

## Chapter 536 Administrative Procedure and Review

August 28, 2016

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### **Periodic review required by state agencies, schedule, procedure.**

536.175. 1. Each state agency shall periodically review all of its rules according to the following review schedule:

(1) Rules contained in titles 1 through 6 of the code of state regulations shall begin the review process no later than July 1, 2015, and every five years thereafter;

(2) Rules contained in titles 7 through 10 of the code of state regulations shall begin the review process no later than July 1, 2016, and every five years thereafter;

(3) Rules contained in titles 11 through 14 of the code of state regulations shall begin the review process no later than July 1, 2017, and every five years thereafter;

(4) Rules contained in titles 15 through 19 of the code of state regulations shall begin the review process no later than July 1, 2018, and every five years thereafter; and

(5) Rules contained in titles 20 and higher of the code of state regulations shall begin the review process no later than July 1, 2019, and every five years thereafter.

2. The joint committee on administrative rules shall cause a notification of agency review to be published in the Missouri Register indicating rules being reviewed under this section and shall contain:

(1) Which titles of the code of state regulations will be under review;

(2) A notice that anyone may file comments concerning the rules being reviewed no later than sixty days after publication of the notice in the Missouri Register;

(3) A notice that all comments must identify the commenter, must specify the rule being commented upon, and must contain comments directly associated to that rule;

(4) A listing of agency designee assigned to receive comments on rules under review.

3. State agencies shall provide the joint committee on administrative rules contact information for the agency designee assigned to receive comments under subsection 2 of this section.

4. Each agency with rules being reviewed shall prepare a report containing the results of its periodic rule review. The report shall consider and include the following:

(1) Whether the rule continues to be necessary, taking into consideration the purpose, scope, and intent of the statute under which the rule was adopted;

(2) Whether the rule is obsolete, taking into consideration the length of time since the rule was modified and the degree to which technology, economic conditions, or other relevant factors have changed in the subject area affected by the rule;

(3) Whether the rule overlaps, duplicates, or conflicts with other state rules, and to the extent feasible, with federal and local governmental rules;

(4) Whether a less restrictive, more narrowly tailored, or alternative rule could adequately protect the public or accomplish the same statutory purpose;

(5) Whether the rule needs amendment or rescission to reduce regulatory burdens on individuals, businesses, or political subdivisions or eliminate unnecessary paperwork;

(6) Whether the rule incorporates a text or other material by reference and, if so, whether the text or other material incorporated by reference meets the requirements of section 536.031;

(7) For rules that affect small business, the specific public purpose or interest for adopting the rules and any other reasons to justify its continued existence; and

(8) The nature of the comments received by the agency under subsection 2 of this section, a summary of which shall be attached to the report as an appendix and shall include the agency's responses thereto.

5. Each agency with rules subject to review shall cause their report to be filed electronically with the joint committee on administrative rules and the small business regulatory fairness board no later than June thirtieth of the year after publication of agency review in the Missouri Register under subsection 2 of this section. The reports shall also be made available on the state agency's website. If the state agency fails to file the report as required by this section for any rule and has not received an extension for good cause from the joint committee on administrative rules, the joint committee on administrative rules shall notify the secretary of state to publish a notice as soon as practicable in the Missouri Register as to which rules the delinquency exists. The rule shall be void and of no further effect after the first sixty legislative days of the next regular session of the general assembly unless the state agency corrects the delinquency by providing the required review within ninety days after publication. Upon determination that the agency has complied with the requirements of this section regarding any delinquency that resulted in notice being published, the joint committee on administrative rules shall notify the secretary of state to remove the rule from the notice of rules scheduled to become null and void.

(L. 2012 H.B. 1135 merged with S.B. 469)

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 6—Pharmaceutical Care  
Standards**

**20 CSR 2220-6.040 Administration by Medical Prescription Order**

*PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices pursuant to medical prescription orders.*

- (1) A pharmacist may administer drugs pursuant to a medical prescription order.
- (2) The pharmacist may not delegate the administration to another person, except to a pharmacist intern who has met qualifications under subsections (3)(B), (C), and (E) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order.
- (3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must—
  - (A) Hold a current, unrestricted license to practice pharmacy in this state;
  - (B) Hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
  - (C) Successfully complete a certificate program in the administration of drugs accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. The certificate program must cover all routes of administration the pharmacist utilizes;
  - (D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;
  - (E) Maintain documentation of the above requirements; and
  - (F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.
- (4) General Requirements.
  - (A) A pharmacist shall administer drugs in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.
  - (B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State Board of Pharmacy or authorized representative.

(5) Requirements of Medical Prescription Order. The medical prescription order from a licensed prescriber must contain at a minimum the following:

- (A) The name of the licensed prescriber issuing the order;
- (B) The name of the patient to receive the drug;
- (C) The name of the drug and dose to be administered;
- (D) The route of administration;
- (E) The date of the original order;
- (F) The date or schedule, if any, of each subsequent administration; and
- (G) A statement that the drug is to be administered by a pharmacist.

(6) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

- 1. The name, address, and date of birth of the patient;
- 2. The date, route, and anatomic site of the administration;
- 3. The name, dose, manufacturer, lot number, and expiration date of the drug;
- 4. The name and address of the patient's primary health care provider, as identified by the patient;
- 5. The name or identifiable initials of the administering pharmacist; and
- 6. The nature of an adverse reaction and who was notified, if applicable.

(B) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives.

(7) Notification Requirements.

(A) A pharmacist administering drugs pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours after administration of the following:

- 1. The identity of the patient;
- 2. The identity of the drug administered;
- 3. The route of administration;
- 4. The anatomic site of the administration;
- 5. The dose administered; and
- 6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007.\* Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 6—Pharmaceutical Care  
Standards**

**20 CSR 2220-6.040 Administration by Medical Prescription Order**

*PURPOSE: This rule establishes procedures for pharmacists to administer drugs and devices, including ~~devices~~ vaccines, pursuant to medical prescription orders.*

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices, including vaccines, pursuant to a medical prescription order.

(2) Definitions. The following definitions shall apply for purposes of this rule:

(A) “Health Clinic or Facility”- A clinic or facility under the common control, management, or ownership of the same hospital or hospital system.

(B) “Hospital”- A hospital as defined in section 197.020.

(C) “Medical Prescription Order”- A lawful order for drugs or devices issued by an authorized practitioner within the scope of his/her professional practice which is to be dispensed or administered to the ultimate user or recipient.

~~(2)~~(3) The pharmacist may not delegate the administration to another person, except to an ~~pharmacist intern~~ intern pharmacist who has met the qualifications under subsections ~~(3)(B), (C), and (E)~~ (4)(B) - (D) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order. The pharmacist and pharmacist intern shall maintain proof of the intern’s compliance with this subsection.

~~(3)~~(4) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the state Board of Pharmacy. To file a Notification of Intent, a pharmacist must—

(A) Hold a current, ~~unrestricted~~ license to practice pharmacy in this state;

(B) Hold a current ~~provider level cardiopulmonary resuscitation (CPR)~~ Basic Life Support certification (BLS) issued by the American Heart Association, ~~or~~ the American Red Cross or an equivalent organization. The certificate program must include a live training component;

(C) Successfully complete a certificate program in the administration of drugs ~~accredited provided by: the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy~~ (1) a continuing education provider accredited by the Accreditation Council for Pharmacy Education (ACPE) or (2) a governmental entity, healthcare professional organization or educational institution approved by the Board. To obtain Board approval, the training program must **be taught by qualified instructors/a licensed healthcare professional and** provide instruction in: . ~~The certificate program must cover a~~

1. Physiology and techniques for routes of administration which must include hands-on training in all routes of administration the pharmacist utilizes;
2. Drug storage and handling;
3. Informed consent requirements, if applicable;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including, anaphylactic reactions and needle sticks.

(D) ~~Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;~~

~~(E) Maintain documentation of the above requirements; and.~~

~~(F) On a yearly basis prior to administering drugs, notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section. (E) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist shall first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized~~

to administer medication. Documentation of the required training shall be maintained at the pharmacy and available to the Board upon request.

~~(4)~~ (5) General Requirements.

(A) A pharmacist shall administer ~~drugs~~ vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention (CDC) ~~or in accordance with manufacturer's guidelines.~~ In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs by medical prescription order, ~~including the disposal of used and contaminated supplies and appropriate handling of acute adverse events.~~ The manual Policies and procedures shall be reviewed annually by the pharmacist-in-charge. Policies and procedures must be available for inspection by the State Board of Pharmacy or other authorized Board representative. Documentation of the annual review must be maintained in the pharmacy's records. At a minimum, the required policies and procedures must include provisions governing:

1. Drug administration procedures, including, authorized routes of administration,
2. Drug storage;
3. Pre- and post- administration assessment and counseling, including, providing vaccine information statements when applicable;
4. Biohazard waste disposal and disposal of used/contaminated supplies;
5. Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions; and
6. Recordkeeping requirements, including, providing notification to the prescriber and primary health care providers, as required by law.

(D) Drugs must be stored within the manufacturer's labeled requirements at all times, including when performing administrations outside of a pharmacy. Vaccines shall be stored in accordance with CDC guidelines at all times.

(E) Pharmacists shall request that a patient remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

~~(F) For pharmacists administering drugs in a, the policy and procedure review required by this subsection may be performed by the pharmacist in charge or by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the responsible for reviewing clinical practices.~~

~~(5)~~ (6) Requirements of Medical Prescription Order. The medical prescription order from a ~~licensed prescriber~~ an authorized practitioner must contain at a minimum the following:

- (A) The name of the ~~licensed prescriber~~ authorized practitioner issuing the order;
- (B) The name of the patient to receive the drug;
- (C) The name of the drug and dose to be administered;
- (D) The route of administration;
- (E) The date of the original order; and
- (F) The date or schedule, if any, of each subsequent administration; ~~and~~
- ~~(G) A statement that the drug is to be administered by a pharmacist.~~

~~(6)~~ (7) Record Keeping.

(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, ~~lot number,~~ and expiration date of the drug. The lot number shall be documented and recorded for vaccines and biologics;
4. For vaccines, ~~the~~ the name and address of the patient's primary health care provider, as identified by the patient. The pharmacist shall document in the patient's immunization record if a patient's primary health care provider is unknown or not designated by the patient;
5. The ~~name or identifiable initials~~ identity of the administering pharmacist. If administered by an intern pharmacist, the identity of the intern and the supervising pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable;
7. A patient's refusal or failure to remain in or return to the pharmacy as requested after vaccine administration to observe any adverse reactions; and
8. Written or electronic documentation that required notifications have been sent.

(B) All records required by this ~~regulation~~ rule shall be kept by the pharmacist at the pharmacy where the prescription order is maintained and must be available for two (2) years from the date of such record for inspecting and copying by the State Board of Pharmacy and/or its authorized representatives. Records may be securely stored offsite at a location designated by the pharmacy, provided records must be produced as provided in section (7)(C) of this rule.

(C) Production of Records. Records required by this rule shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records maintained at the pharmacy shall be physically or electronically produced immediately or within two (2) hours of a request from the Board or the Board's authorized designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Board and/or its authorized designee.

~~(7)~~ (8) Notification Requirements.

(A) A pharmacist administering ~~drugs~~ a vaccine pursuant to a medical prescription order shall notify the ~~prescriber within seventy-two (72) hours~~ patient's primary health care provider, if provided by the patient, within fourteen (14) days after administration of the following:

1. The identity of the patient;
2. The identity of the ~~drug~~ vaccine administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) In the event of any adverse event or reaction experienced by the patient following administration of a drug, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction. The prescriber may not opt out of adverse event notification requirements.

(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

(D) Documentation that the required notifications have been sent must be kept at the pharmacy or other authorized location where the prescription order is maintained.

(9) Notification of Intent Refiling. A Notification of Intent to administer drugs by medical prescription order shall be refiled with the state board of pharmacy biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must:

(A) Hold a current Basic Life Support certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The certification program must include a live training component; and

(B) Have successfully completed four (4) hours of continuing education (0.4 CEU) related to drugs administration. The required continuing education (CE) shall be governed by the rules of the state Board of Pharmacy governing pharmacist CE and may be used to satisfy the pharmacist's biennial pharmacist renewal CE requirements. The initial training program required by subsection (4) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within twelve (12) months prior to refiling the pharmacist's Notification of Intent.

(10) Administration in a Hospital or a Health Clinic or Facility- Pharmacists administering medication under the jurisdiction of the Board on behalf of a hospital or a health clinic or facility shall comply with the requirements of this rule with the following exceptions:

(A) A pharmacist shall be deemed in compliance with the requirements of sections (7) and (8) of this rule if the pharmacist administers drugs for or on behalf of a hospital or a hospital clinic or facility in compliance with this section and the administration is lawfully recorded in a patient medical record that is required to be maintained by the hospital or the hospital clinic or facility pursuant to state or federal law.

(B) In lieu of completing a certificate program in the administration of drugs as required by section (4) of this rule, pharmacists administering in a hospital or a hospital clinic or facility shall be trained in administration and meet all competency, training and evaluation requirements required by the hospital or hospital clinic or facility and the Missouri Department of Health and Senior Services (DHSS). At a minimum, pharmacist administration training must be similar to or include the training components identified in section (4)(C).

(C) A pharmacist shall administer vaccines in accordance with current treatment guidelines and recommendations established by the Centers for Disease Control and Prevention

(CDC). In the event of a conflict between CDC and manufacturer guidelines, CDC recommendations shall control.

(E) The policy and procedure review required by section (5) may be performed by the clinical care committee, pharmacy and therapeutics committee or a reviewing body/committee of the hospital responsible for reviewing clinical practices. Required policies and procedures may be maintained in or included with the governing hospital's approved policies, procedures or protocols.

(F) This section is only applicable to pharmacy services under the jurisdiction of the Board and is not applicable to hospital pharmacy services or pharmacist medication administration under the jurisdiction of the Department of Health and Senior Services.

*AUTHORITY: sections 338.140 and 338.280, RSMo 2000 and section 338.010.1, RSMo Supp. 2007.\* Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

**#D3 Review of 20 CSR 2220-6.050**

- 20 CSR 2220-6.050 (Administration of Vaccines Per Protocol)
- Walgreens Comments
- Wal-Mart Comments

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 6—Pharmaceutical Care  
Standards**

**20 CSR 2220-6.050 Administration of Vaccines Per Protocol**

*PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.*

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine.

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(A) Hold a current, unrestricted license to practice pharmacy in this state;

(B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;

(C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering vaccines; and

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do

so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

1. The identity of the participating pharmacist and physician, including signatures;
2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;
11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(6) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and

2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

#### (7) Notification Requirement.

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the authorizing physician within seventy-two (72) hours after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.

(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.



Lorri Walmsley, RPh  
Senior Manager, Pharmacy Affairs  
Walgreen Company  
5330 E. Washington St, D-105  
Phoenix, AZ 85034  
P 602-214-6618

September 20, 2016

Kimberly A. Grinston, JD  
Executive Director  
P.O. Box 625  
Jefferson City, MO 65102-0625

Via email: [kimberly.grinston@pr.mo.gov](mailto:kimberly.grinston@pr.mo.gov)  
Re: Rule Review of 20 CSR 2220-6.050 – Administration of Vaccines per Protocol

Dear Executive Director Grinston,

On behalf of Walgreens, we would like to thank the Missouri State Board of Pharmacy for the opportunity to comment on proposed changes to 20 CSR 2220-6.050, Administration of Vaccines per Protocol. In general, such protocol agreements have improved access to vaccine services, and increased vaccine rates in populations less likely to be seen by clinicians. However, some of the stipulations set forth in the current rule have impeded the ability of this practice to be as successful as we have experienced in other states.

The current requirement in Missouri for a protocol physician and more specifically the requirement that the physician must be located within 50 miles places an undue burden on the pharmacies. Not only are pharmacies tasked with finding multiple physicians based on geography, it also increases the level of complexity to manage state specific and provider specific requirements. Missouri has some of the most challenging administrative requirements regarding physician protocol requirements. We recommend amending the current regulations regarding protocol physicians. This can be accomplished by providing pharmacists with independent authority based on CDC/ACIP and FDA guidelines. Or a single state protocol provided by Missouri that defines the parameters for pharmacists to administer vaccine that achieves this requirement.

Walgreens currently provides immunizations based on state specific rules in all states in which it operates. Thirteen states allow pharmacists to provide flu and other routine adult and adolescent vaccines via independent authority and another two states allow for flu only. In these states, pharmacists have demonstrated that they have the ability to safely provide vaccinations via independent authority eliminating the need for a protocol physician and decreasing the administrative burden for pharmacies, pharmacists and the Board of Pharmacy and increasing the access for immunizations in the state of Missouri. The increased administrative burden by the current regulations, when compared to other states, hinders the ability of pharmacists and protocol physicians to provide quality patient care services to the citizens of Missouri. In comparison Oregon has some of the most permissive language for pharmacists to provide immunizations through independent authority and correspondingly has the highest adult immunization rate in the United States based on CDC collected data from 2014.

If your state feels strongly that a protocol physician should remain in place for patient safety, we would recommend the suggested language below in order to create a more straightforward process to safely deliver vaccine services across the state of Missouri.

## 20 CSR 2220-6.050 Administration of Vaccines per Protocol

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine:

(A) A pharmacist shall administer vaccines in accordance with treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer's guidelines, provided that a pharmacist shall not administer vaccines to persons under twelve (12) years of age.

(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(2) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer vaccines.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(4) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, must:

(A) Hold a current, unrestricted license to practice pharmacy in this state;

(B) Hold a current cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;

(C) Successfully complete a certificate program in the administration of vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;

(D) Maintain documentation of the above certifications;

(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education as defined per calendar year related to administration of vaccines. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;

~~(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into protocol or administering vaccines; and~~

*Comment: Providing this information on an annual basis to the protocol physician is not necessary as long as the pharmacist meets the requirements of the board and the information is available upon request. Creating and maintaining this documentation creates an unnecessary administrative burden for the pharmacy, pharmacist and protocol physician, while providing little value to the healthcare system.*

(G) On a yearly basis prior to administering vaccines, establish a new protocol with the authorizing physician. ~~and notify the State Board of Pharmacy of their qualifications to do so. Additionally, upon license renewal the pharmacist shall provide This notification of intent to vaccinate and shall include the types of drugs being administered and~~ a statement that the pharmacist meets the requirements of subsections (A), (B), (C), ~~and (E), and (F)~~ of this section.

*Comment: Eliminating the annual notification of the pharmacist's intent to immunize will decrease the administrative burden for the Board of Pharmacy and eliminate the need for pharmacists to keep track of this requirement, which is not concurrent with their license renewal.*

(4) Administration by Written Protocol with a Missouri Licensed Physician.

(A) A pharmacist may enter into a written protocol with a physician for the administration of vaccines authorized by Chapter 338, RSMo, provided that a pharmacist shall be prohibited from administering vaccines to patients under twelve (12) years of age. ~~The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the vaccine.~~ The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:

*Comment: The mileage requirement increases the administrative burden for pharmacies to find multiple protocol physicians and makes record keeping for pharmacies more complex. By eliminating the mileage requirement and allowing one protocol physician for the entire state, it would bring the state in line with the majority of other states that require a protocol, since only two other states have geography considerations for protocol physicians.*

1. The identity of the participating ~~pharmacist pharmacy or organization and physician, including along with the name and signature of the protocol physician;~~

*Comment: The requirement of individual signatures of all participating pharmacists increases the amount of time and burden for the pharmacy, pharmacist and protocol physician to complete an administrative task, and can delay the delivery of vaccines services and hinder patient care. The same intent could be accomplished by stating that all certified pharmacists licensed and employed within that company/organization are able to administer vaccines under the protocol and would the administrative burden for the pharmacy, pharmacist, physician and Board of Pharmacy to collect and store all of this information.*

2. Time period of the protocol;
3. The identification of the vaccines which may be administered;
- ~~4. The identity of the patient or groups of patients to receive the authorized vaccine(s);~~

- ~~5. The identity of the authorized routes and anatomic sites of administration allowed;~~
- ~~6. A provision to create a prescription for each administration under the authorizing physician's name;~~
- ~~7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;~~
- ~~8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;~~
- ~~9. A provision establishing the disposal of used and contaminated supplies;~~
- ~~10. The street addresses of the pharmacy or other locations at which the pharmacist may administer the authorized vaccine;~~

*Comment: Since vaccine administration has a defined standard of care, this information should not be required. The intent could be captured by requiring policy and procedures to be documented, reviewed, and updated annually, and made available upon request of the protocol physician and Board of Pharmacy. Additionally, the requirement listed in this section of providing all addresses where immunizations are being administered hinders the ability of pharmacists to provide immunizations in non-traditional environments, for example community based immunization clinics. Eliminating this requirement would also allow the pharmacist to aid the State of Missouri in cases of outbreaks of vaccine preventable diseases, by allowing them to more quickly and efficiently provide needed vaccinations both in their stores and in community based immunization clinics.*

11. Record-keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

~~(B) The protocol, and any subsequent amendments or alterations, shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol.~~ The authorizing physician and pharmacist-pharmacy shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

#### (6) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule shall maintain a record of each administration which shall include:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule shall be maintained securely and confidentially as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the prescription files of the pharmacy. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the administering pharmacist at an address that shall be identified in the protocol prior to administering the vaccine; and
2. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the State Board of Pharmacy and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

#### (7) Notification Requirement.

(A) A pharmacist administering vaccines authorized by Chapter 338, RSMo, shall notify the ~~authorizing physician patient's primary care provider if identified by the patient~~ within ~~seventy-two (72) hours~~ 14 days after administration of the following:

1. The identity of the patient;
2. The identity of the vaccine(s) administered;
- ~~3. The route of administration;~~
- ~~4. The anatomic site of the administration;~~
- ~~5. The dose administered; and~~
6. The date of administration.

*Comment: Since vaccines have a defined standard of care, this specific information should not be required and is an unnecessary burden for both the pharmacy and physician taking time away from patient care for to*

*complete this administrative task. Additionally, this information is provided to the Missouri State Immunization Registry, ShowMeVax, as required.*

~~(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.~~

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider ~~and authorizing physician~~, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

***Comment:** The protocol physician, if different than the patient's primary care provider, does not have a direct physician-patient relationship. It is unlikely that the protocol physician would oversee additional follow up-care, this care would most likely be overseen by the patient's primary care provider.*

(D) A pharmacist administering vaccine(s) shall report the administration to all entities as required by state or federal law.  
(E) Documentation that notifications required by this rule have been sent must be maintained as provided in section (6) of this rule.

Walgreens thanks the Missouri State Board of Pharmacy for considering our comments on this matter. We hope that the Board will consider our suggestions to amend the current administration of vaccines per protocol language. Please do not hesitate to contact me with any questions about the provided comments.

Sincerely,

A handwritten signature in black ink that reads "Lorri Walmsley". The signature is written in a cursive, flowing style.

Lorri Walmsley, RPh  
Senior Manager, Pharmacy Affairs  
Lorri.Walmsley@walgreens.com

**From:** [Grinston, Kimberly](#)  
**To:** [Grinston, Kimberly](#)  
**Subject:** FW: Missouri Immunization Changes recommended  
**Date:** Friday, October 14, 2016 3:45:16 PM

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**From:** Shelley Tustison  
**Sent:** Tuesday, September 13, 2016 9:47 AM  
**To:** Tim Koch - t0koch; JoLynn Coleman  
**Cc:** Debbie Mack; Kim Reitnauer; Cynthia Perez  
**Subject:** RE: Missouri Immunization Changes recommended

JoLynn/Tim,

I would add, too, that it would be more convenient to have 1 protocol for all immunizations (both standing order and patient specific prescriptions). Currently in MO, we have to have the standing order, then a separate protocol for administration of immunizations pursuant to patient specific prescriptions.

Thank you,

**Shelley Tustison, PharmD, CHC, Director, U.S. Ethics & Compliance**

U.S. Ethics & Compliance  
702 SW 8<sup>th</sup> St.  
Bentonville, AR 72716-0230  
**Save money. Live better.**

---

**From:** Tim Koch - t0koch  
**Sent:** Monday, September 12, 2016 10:38 AM  
**To:**  
**Cc:**  
**Subject:** Re: Missouri Immunization Changes recommended

On Sep 12, 2016, at 7:51 AM, JoLynn Coleman <[Jo.Coleman@walmart.com](mailto:Jo.Coleman@walmart.com)> wrote:

Hi Tim,

Someone alerted us to the fact that Missouri is asking for any recommended changes to their regulations as it relates to Immunizations. Here are the changes we would like to call out:

- 1) Remove the 50 mile radius limitation for physician supported standing orders. Routinely if there is an issue with an immunization that is administered, pharmacy would engage the patient's primary care physician.
  - Recommendation—allow for a state wide protocol or prescriptive authority where pharmacists can administer immunizations following a state wide protocol or CDC/ACIP guidelines.
- 2) Remove the requirement for off-site addresses to be added to the standing order.

- 3) Add additional vaccines allowed by pharmacist using a protocol: MMR, HPV, Varicella
  - There have been recent outbreaks in states where there was a need in the community for pharmacists to support the healthcare team and provide certain vaccines, like MMR.
- 4) Consider decreasing the age to 7-8 years of age for pharmacist to administer vaccines.
- 5) Allow patient specific prescriptions for immunizations like Zostavax to go below the CDC/ACIP guidelines for age if the physician writes a prescription.

Thanks

JoLynn

**JoLynn Coleman**

Walmart

702 Southwest 8th Street

Bentonville, AR 72716-0435

**Save money. Live better.**

**#D4 Review of 20 CSR 2220-6.055**

- 20 CSR 2220-6.055 (Current Rule)

1 Title 20—DEPARTMENT OF  
2 INSURANCE, FINANCIAL  
3 INSTITUTIONS AND  
4 PROFESSIONAL REGISTRATION  
5 Division 2220—State Board of Pharmacy  
6 Chapter 6—Pharmaceutical Care  
7 Standards

8  
9 **20 CSR 2220-6.055 Non-Dispensing Activities**

10 *PURPOSE: This rule establishes procedures and requirements for the performance of non-*  
11 *dispensing activities outside of a pharmacy.*

12 (1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-  
13 dispensing activities outside of a licensed pharmacy:

14 (A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist  
15 shall be obligated to comply with 20 CSR 2220-2.190, when applicable;

16 (B) Obtain patient history/information;

17 (C) Review patient records/medical histories;

18 (D) Patient assessment/evaluation, as authorized by Missouri law;

19 (E) Billing and insurance claim submissions/review;

20 (F) Drug utilization review;

21 (G) Assess health plan and medication eligibility/coverage;

22 (H) Pharmacy compliance audits/evaluations;

23 (I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the  
24 board;

25 (J) Peer review/peer consultations;

26 (K) Review, select, and develop formularies or plan/practice guidelines;

27 (L) Review compliance with benefit guidelines;

28 (M) Manage inventory, including purchasing and ordering;

29 (N) Manage/review information systems;

30 (O) Patient medication review;

31 (P) Consultation with other health care professionals;

32 (Q) Patient referrals;

33 (R) Prescription order entry/review, provided that a pharmacist shall only be authorized to  
34 accept a prescription on the premises of a Missouri licensed pharmacy, as required by  
35 section 338.095.5, RSMo; and

36 (S) Medication therapy management, pursuant to and as authorized by Chapter 338,  
37 RSMo, and the rules of the board.

38 (2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule  
39 shall comply with all applicable state and federal confidentiality laws and regulations and  
40 shall provide sufficient storage and security for confidential documents and electronic data  
41 processing hardware. In addition, data processing systems must utilize sufficient security  
42 software to ensure confidentiality and prevent unauthorized access. Any breach in the  
43 security or confidentiality of the data processing systems or confidential documents shall be  
44 documented and reported to the board in writing within seven (7) days of the breach.

45 (3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with  
46 patients in the pharmacist's residence or living quarters.

47 (4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure  
48 compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this  
49 rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-  
50 keeping, confidentiality, or security requirements otherwise imposed by Chapter 338,  
51 RSMo, or the rules of the board. Violations of this section shall constitute grounds for  
52 discipline.

53 (5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized  
54 practice of medicine or to conduct any activity for which a license is required pursuant to  
55 Chapters 330, 331, 332, 334, or 337, RSMo.

56 (6) A pharmacy permit shall be required for performing non-dispensing activities if the  
57 pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the  
58 location where non-dispensing activities are being performed, provided that a pharmacy  
59 permit shall not be required for sites used solely by the pharmacist for administering  
60 vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy  
61 technicians shall only be authorized to work under the direct supervision of a pharmacist as  
62 provided by section 338.013, RSMo, and 20 CSR 2220-2.700.

63 *AUTHORITY: sections 338.010 and 338.220, RSMo Supp. 2009 and 338.140, RSMo 2000.\**  
64 *Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expired April 30, 2010. Original*  
65 *rule filed Oct. 22, 2009, effective June 30, 2010.*

66 *\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009;*  
67 *338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.220, RSMo 1951, amended*  
68 *1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009.*

69  
70

**#D5 Review of 20 CSR 2220-2.650**

- 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy)
- 2015 Draft Proposed Rule\*\*

*\*\*The draft was presented to the Board for discussion purposes and has not been approved by the Board.*



38 4. The provision of adequate security to protect the confidentiality and integrity of patient  
39 information;

40 5. The maintenance of a quality assurance program for pharmacy services designed to  
41 objectively and systematically monitor and evaluate the quality and appropriateness of patient  
42 care, pursue opportunities to improve patient care and resolve identified problems.

43 *AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220,*  
44 *RSMo Supp. 2001.\* This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30,*  
45 *2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to*  
46 *20 CSR 2220-2.650, effective Aug. 28, 2006.*

47 \*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951,  
48 amended 2001; 338.220, RSMo 1951; amended 1969, 1981, 1989, 1997, 1999, 2001; 338.240,  
49 RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.

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51  
52

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION  
Division 2220—State Board of Pharmacy  
Chapter 2—General Rules**

**PROPOSED AMENDMENT**

**20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy**

*PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy.*

(1) Definitions. For purposes of this rule, the following definitions shall apply:

(A) Administration- Applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion or other means.

(B) Dispensing Pharmacy- The pharmacy that provides the medication to the patient.

(2) Class J: Shared Services: A Class J Shared Services permit shall be required if two or more pharmacies have or are in an arrangement to provide functions necessary to or involved in the practice of pharmacy for or on behalf of the other pharmacy. These functions may include, but are not limited to: prescription/order receipt, prescription/order clarification or modification, obtaining prescriber authorization, data entry, compounding, dispensing, pharmacist verification, patient counseling, patient profile maintenance, medication therapy services, medication administration, drug utilization review (DUR), claims adjudication, obtaining refill authorization and therapeutic interventions. Both pharmacies participating in the shared services arrangement shall be required to obtain a Class J permit.

(A) Pharmacies may perform Class J shared services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain separate licenses with a Class J classification for each location involved in providing shared services; and

3. Either share a common database or allow access to each pharmacy's separate database to allow both pharmacies to access the patient's complete profile. The access must provide real-time online access to the patient's complete pharmacy for all pharmacies involved.

(B) Pharmacies meeting the above requirements are exempt from the requirements of 20 CSR 2220-2.120 and 20 CSR 2220-6.030(4) when transferring prescription information between themselves. A Class J permit shall not be required to transfer an individual prescription as authorized by 20 CSR 2220-2.120 pursuant to a request by the patient or the patient's authorized designee.

(C) The parties performing Class J shared services shall maintain a detailed written description of all authorized shared services that includes the name, address and permit number(s) of the pharmacies involved. The parties shall also maintain a written policy and procedures manual that includes, but is not limited to, the following:

1. Policies and procedures that identify the duties of each pharmacy, including, the pharmacy responsible for drug utilization review, verifying or obtaining prescriber authorization/clarification, prescription/order data entry and verification, patient profile maintenance, medication/prescription labeling and obtaining refill authorization;

2. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;

3. The provision of adequate security to protect the confidentiality and integrity of patient information;

4. Policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP), given normal and customary delivery times. Medication shall be stored and transported in a manner that does not compromise medication integrity or stability; and

5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

(D) Policy and procedure manuals shall be annually reviewed for accuracy and compliance with this rule.

(E) Compounding may only be performed pursuant to a Class J arrangement in response to a patient specific prescription or in anticipation of a patient specific prescription as authorized by 20 CSR 2220-200 and 20 CSR 2220-2.400. **Preparations made in anticipation of a patient specific prescription may be prepared in advance but shall not be dispensed until a patient specific prescription is received.**

(3) The identity of the pharmacist(s) responsible for compounding, dispensing, product verification and data entry verification shall be maintained by the pharmacy where such services are performed.

(4) If medication is dispensed or provided pursuant to a Class J shared services arrangement, the name of the dispensing pharmacy shall be identified on the prescription label.

(5) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration to the patient on the same premises or physical location as the pharmacy by a pharmacist or other licensed health care professional who is authorized to administer medication by law.

(A) The exemption recognized in this subsection shall only apply if a completed and labeled prescription is delivered to the receiving pharmacy that is ready for administration to the patient, provided that additional manipulation or compounding of the medication may be performed if necessary for proper administration. Medication administered by a pharmacist shall be performed in compliance with all applicable provisions of law.

(B) The receiving pharmacy shall maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt and the patient's name. If additional manipulation or compounding of the medication is performed, the product shall be treated as a prescription by the dispensing pharmacy and shall comply with all applicable prescription requirements, including, all record keeping, compounding and labeling requirements.

(C) The dispensing pharmacy shall be responsible for ensuring compliance with all patient counseling requirements.

(6) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

(7) All records required by this rule, including, all policy and procedure manuals, contracts or other agreements shall be maintained for two (2) years and shall be made available to the Board or its representative upon request.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001.\* This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006.*

\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.220, RSMo 1951; amended 1969, 1981, 1989, 1997, 1999, 2001; 338.240, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.

**#D7 2016 NIOSH HAZARDOUS DRUGS LIST**

- NIOSH List of Antineoplastic and Other Hazardous Drugs in Health Settings, 2016

# NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health





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# **NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health

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## Suggested Citation

NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138).

NIOSH evaluation of hazardous drugs does not cover NIOSH classification of chemical carcinogens. Although NIOSH hazardous drug evaluation includes consideration of carcinogenicity and genotoxicity, this evaluation is tailored to identify and evaluate data from human toxicity profiles, animal studies and in vitro studies unique to evaluating therapeutic agents. For example, NIOSH consults a variety of resources including, but not limited to, safety data sheets, product labeling approved by the U.S. Food and Drug Administration and databases such as DailyMed and DrugBank. For more information on NIOSH classification of chemical carcinogens see "NIOSH Chemical Carcinogen Policy," <http://www.cdc.gov/niosh/index.htm>.

DHHS (NIOSH) Publication No. 2016-161

September 2016

## List of Acronyms

AHFS	American Hospital Formulary Service
ASHP	American Society of Health-System Pharmacists (formerly, American Society of Hospital Pharmacy)
BCG	Bacillus Calmette–Guérin
BSC	Biological safety cabinet
CACI	Compounding aseptic containment isolator
CFR	Code of Federal Regulations
CSTD	Closed system drug-transfer device
DPI	Drug package insert
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HEPA	High-efficiency particulate air
HIPEC	Heated intraperitoneal chemotherapy
IARC	International Agency for Research on Cancer
IV	Intravenous
MRHD	Maximum Recommended Human Dose
MSHG	Manufacturer’s safe handling guidance
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational exposure limit
OSHA	Occupational Safety and Health Administration
ONS	Oncology Nursing Society
PPE	Personal protective equipment
SC	Subcutaneous
SDS	Safety Data Sheet (formerly Material Safety Data Sheet)
USP	United States Pharmacopeial Convention



**Preamble:** The *National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings* was published in September 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>). In Appendix A of the Alert, NIOSH identified a sample list of hazardous drugs. The list was compiled from information provided by four institutions that had generated lists of hazardous drugs for their respective institutions, as well as a list from the Pharmaceutical Research and Manufacturers of America (PhRMA). The 2004 list was updated in 2010, 2012, and 2014. The current update (2016) adds 34 drugs, five of which have safe-handling recommendations from the manufacturers. In 2014, a new format was developed for the list of hazardous drugs, as described below. The review process for the addition of the new listings is described in the Federal Register: [http://www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a\\_2015-12857.pdf](http://www.cdc.gov/niosh/docket/review/docket233a/pdfs/233a_2015-12857.pdf).

## Drugs Considered Hazardous

### I. General Approach to Handling Hazardous Drugs

Early concerns about occupational exposure to antineoplastic drugs first appeared in the 1970s. Although the antineoplastic drugs remain the principal focus of the Alert, other drugs may also be considered hazardous because they are potent (small quantities produce a physiological effect) or cause irreversible effects. As the use and number of these potent drugs increase, so do opportunities for hazardous exposures among healthcare workers. For example, antineoplastic drugs such as cyclophosphamide and methotrexate have proved beneficial for treating nonmalignant diseases such as rheumatoid arthritis and multiple sclerosis.

In the Alert (NIOSH 2004) and updates to the hazardous drug list (NIOSH 2010 and 2012), NIOSH had previously recommended standard precautions (universal precautions) be taken in handling hazardous drugs. Given the addition of new drug formulations and drugs in tablet and/or capsule form to the list, no single approach can cover the

diverse potential occupational exposures to the drugs. All listed drugs are considered hazardous, but safe-handling precautions can vary with the activity and the formulation of the drug. Table 5 provides some guidance on engineering controls and personal protective equipment (PPE) that applies to all listed drugs. The current NIOSH approach involves three groups of drugs:

- Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2016]. Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 1).
- Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug. Note that some of these drugs may also pose a reproductive risk for susceptible populations (Table 2).
- Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk (Table 3).

All hazardous drugs, regardless of the formulation, should be labeled as such to prevent improper handling. The majority of the reproductive risks associated with the drugs listed in Table 3 apply to women, but some can apply to men only (such as reduced fertility or sperm count) or to both men and women. Although all hazardous drugs should be handled according to recommended procedures, especially if they must be prepared aseptically, some populations of workers may not be at reproductive risk from handling drugs in Group 3. These include workers who are excluded from the susceptible populations for specific reasons such as age or infertility. In addition, drugs for which the manufacturer includes safe-handling guidance in the DPI are indicated. NIOSH carries out a hazard identification on each drug on the basis of the NIOSH criteria for a hazardous drug. No attempt has been made to perform risk assessments on each drug or to propose exposure limits. NIOSH has provided guidance for personal protective equipment and ventilated engineering controls for some of the various scenarios in which a drug may be handled in healthcare settings (Table 5). This guidance does not cover all possible situations but provides general recommendations for the typical handling situations in healthcare.

With the increased availability of oral antineoplastic and other hazardous drugs, additional precautions are required in order to prevent worker exposure to these formulations. Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, coated tablets or capsules—solid, intact medications that are administered to patients without modification of the formulation). However, they may pose a risk if the formulations are altered, such as by crushing tablets or making solutions from them outside a ventilated cabinet [Simmons 2010; Goodin et al. 2011]. Uncoated tablets may present a risk of exposure from dust by skin contact and/or inhalation when the tablets are counted [Shahsavarani et al. 1993; Ahmad et al. 2014]. Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area [Fent et al. 2014]. Counting and pouring of hazardous drugs should be done carefully, and clean equipment should be

dedicated for use with these drugs. Crushing tablets or opening capsules should be avoided and liquid formulations should be used whenever possible.

During the compounding of hazardous drugs (e.g., crushing, dissolving, or preparing a solution or an ointment), workers should wear nonpermeable gowns and double gloves (Table 5). Guidelines for the safe compounding, administration, and disposal of hazardous drugs have been developed by several organizations [NIOSH 2004; ASHP 2006; ONS 2011; USP 2016, OSHA 2016]. However, the lack of proper training for handling antineoplastic drugs in other specialty areas may be an issue that needs to be addressed [Abel 2000; Polovich and Giesker 2011; Menonna-Quinn et al. 2013].

## II. Defining Hazardous Drugs

Hazardous drugs include those used for cancer chemotherapy, antiviral drugs, hormones, some bioengineered drugs, and other miscellaneous drugs. The NIOSH definition of hazardous drugs used in the Alert is based on a definition originally developed in 1990 by the American Society of Hospital Pharmacists [ASHP 1990], currently known as the American Society of Health-System Pharmacists. Thus, the NIOSH definition may not accurately indicate the potential toxicity criteria associated with some of the newer-generation pharmaceuticals used in healthcare. For example, bioengineered drugs target specific sites in the body, and although they may or may not pose a risk to healthcare workers, some may pose a risk to patients.

NIOSH and other organizations are still gathering data on the potential toxicity and health effects related to highly potent drugs and bioengineered drugs. Therefore, when working with any hazardous drug, healthcare workers should follow the approaches described in Table 5, along with any recommendations included in the manufacturer's Safety Data Sheet (SDS) or the drug package inserts (DPIs).

### A. ASHP Definition of Hazardous Drugs

ASHP defines hazardous drugs in its 1990 revision of the Technical Assistance Bulletin on Handling

Hazardous Drugs<sup>†</sup> [ASHP 1990]. The bulletin gives criteria for identifying potentially hazardous drugs that should be handled in accordance with an established safety program [ASHP 2006; Massoomi et al. 2008; Eisenberg 2009; ONS 2011]. The criteria are prioritized to reflect the hierarchy of potential toxicity described below. Since the hazardous drugs covered by the Alert were designed as therapeutic agents for humans, human toxicity profiles should be given more weight than data from animal models or in vitro systems. Additional guidance for defining hazardous drugs is available from the following sources: carcinogenicity [61 Fed Register 17960–18011 (1996b); IARC 2014], teratogenicity [56 Fed Register 63798–63826 (1991)], developmental toxicity [56 Fed Register 63798–63826 (1991)], and reproductive toxicity [61 Fed Register 56274–56322 (1996a)].

## B. NIOSH Revision of ASHP Definition

1. The 1990 ASHP definition of hazardous drugs was revised by the NIOSH Working Group on Hazardous Drugs for the Alert. Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity<sup>†</sup>

\*ASHP [1990] definition of hazardous drugs:

1. Genotoxicity (i.e., mutagenicity and clastogenicity in short-term test systems)
2. Carcinogenicity in animal models, in the patient population, or both, as reported by the International Agency for Research on Cancer (IARC)
3. Teratogenicity or fertility impairment in animal studies or in treated patients
4. Evidence of serious organ or other toxicity at low doses in animal models or treated patients.

<sup>†</sup>All drugs have toxic side effects, but some exhibit toxicity at low doses. The level of toxicity reflects a continuum from relatively nontoxic to production of toxic effects in patients at low doses (for example, a few milligrams or less). For example, a daily therapeutic dose of 10 mg/day or a dose of 1 mg/kg per day in laboratory animals that produces serious organ toxicity, developmental toxicity, or reproductive toxicity has been used by the pharmaceutical industry to develop occupational exposure limits (OELs) of less than 10 µg/m<sup>3</sup> after applying appropriate uncertainty factors [Sargent

- Reproductive toxicity<sup>†</sup>
- Organ toxicity at low doses<sup>†</sup>
- Genotoxicity<sup>‡</sup>
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

### 2. Determining Whether a Drug is Hazardous

Many hazardous drugs used to treat cancer (for example, alkylating agents) bind to or damage DNA. Other antineoplastic drugs, some antivirals, antibiotics, and bioengineered drugs interfere with cell growth or proliferation, or with DNA synthesis. In some cases, the nonselective actions of these drugs disrupt the growth and function of both healthy and diseased cells, resulting in toxic side effects for treated patients and their offspring. These nonselective actions can also cause adverse effects in healthcare workers who are inadvertently exposed to hazardous drugs. However, drugs other than those used to treat cancer may have toxic properties similar to those of the antineoplastic drugs. For some other drugs, adverse reproductive effects are the primary characteristic of concern for occupational exposure. NIOSH evaluates the potential of proposed additions to the list on the basis of these and other characteristics of the drugs.

This document presents criteria and sources of information for determining whether a drug is hazardous. When a drug has been judged to be hazardous, the various precautions outlined in the Alert should be applied when handling that drug. Also included is a list of drugs that should be handled as hazardous. When applying the criteria for a hazardous drug as outlined above, NIOSH takes the following approach.

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and Kirk 1988; Naumann and Sargent 1997; Sargent et al. 2002]. OELs in this range are typically established for potent or toxic drugs in the pharmaceutical industry. Under all circumstances, an evaluation of all available data should be conducted to protect healthcare workers.

<sup>‡</sup>In evaluating mutagenicity for potentially hazardous drugs, responses from multiple test systems are needed before precautions can be required for handling such agents. The EPA evaluations include the type of cells affected and in vitro versus in vivo testing [51 Fed Register 34006–34012 (1986)].

### ***Reproductive and Developmental Toxicity***

NIOSH takes into account the dose for animal testing of reproductive and developmental toxicity. If adverse effects are observed in animal testing near, at, or below the maximum recommended human dose (MRHD), NIOSH considers it to be highly relevant. If doses producing an adverse effect are many times the MRHD, usually NIOSH does not consider them in its evaluation.

For reproductive and developmental effects, NIOSH notes if there was maternal toxicity, in addition to the dose. Effects on the fetus in the absence of maternal toxicity are considered relevant. Many drugs with an FDA pregnancy category X rating meet the criteria for a hazardous drug and are listed, but each drug is evaluated individually. Similarly, for Category D, these drugs are often listed because many meet the criteria for being hazardous. Any available human data are considered significant. In June 2015, the FDA removed the pregnancy letter categories (A, B, C, D, and X) in prescription drug labeling. The new labeling was renamed “Pregnancy,” “Lactation,” and “Females and Males of Reproductive Potential” [FDA 2015]. The plan for the new labeling is to be phased in gradually for drugs approved on or after June 2001, but it went into effect immediately for drugs and biologic products submitted after June 2015. Therefore, the pregnancy letter categories are still in effect for most of the drugs described in this document, for the immediate future.

### ***Carcinogenicity***

In addition to dose, for carcinogenicity testing NIOSH looks for tumors in more than one species and sex. It looks for tumors in multiple organs and for tumors that are not rodent-specific. Any available human data are considered significant.

### ***Genotoxicity***

For effects of genotoxicity, NIOSH gives greater weight to in vivo testing than in vitro testing. However, adverse outcomes in several in vitro tests will be considered in its evaluation.

### ***Organ Toxicity***

For organ toxicity, the low-dose criterion in the definition (a daily therapeutic dose of 10 mg/day or

a dose of 1 mg/kg per day in laboratory animals) is used as a benchmark.

### ***Other***

Drugs with safe-handling guidelines from the manufacturer are automatically put on the list because the manufacturer has determined their properties warrant special handling.

A NIOSH internal committee performs an initial review of all new FDA drug approvals and new warnings on existing drugs for a two-year period. Following this review, an expert panel consisting of peer reviewers and stakeholders reviews the proposed additions (and deletions, when applicable), using information in DrugBank, DailyMed, and the DPs and SDSs. Additionally, a Federal Register Notice is published requesting comments on the proposed changes to the list. A final review of all information is performed by NIOSH, and the updated list is published on the NIOSH Hazardous Drug Topic Page (<http://www.cdc.gov/niosh/topics/hazdrug/>) and in the Federal Register.

In addition to using the list of hazardous drugs presented here, each organization should create its own list of drugs considered to be hazardous, based on drugs in its formulary. This document presents guidance for making such a facility-specific list (see section entitled How to Generate Your Own List of Hazardous Drugs). Subsequently, newly purchased drugs should be evaluated against the organization’s hazardous drug criteria and added to the list if they are deemed hazardous. Organizations have developed various approaches to identifying and classifying hazardous drugs [Chaffee et al. 2010; Badry et al. 2013; Kaestli et al. 2013]. Although the classification schemes may differ somewhat, the drugs listed as hazardous are quite similar.

Individual organizations may not have adequate resources for determining their own list of hazardous drugs. If so, the list of hazardous drugs in this document will help employers and workers to determine when precautions are needed. However, reliance on such a published list is a concern because it quickly becomes outdated as new drugs continually enter the market or listed drugs are removed when additional information becomes available. NIOSH will update this list periodically by adding

drugs that meet its criteria and removing those that no longer meet its criteria. This hazardous drug list will be posted on the NIOSH website at [www.cdc.gov/niosh/topics/hazdrug/](http://www.cdc.gov/niosh/topics/hazdrug/). In addition, drugs that have safe-handling guidance from the manufacturers in the DPIs will be posted on this website after they are approved by the FDA.

### III. How to Generate Your Own List of Hazardous Drugs

#### A. OSHA Hazard Communication

The OSHA hazard communication standard [29 CFR 1910.1200] requires employers to develop a hazard communication program appropriate for their unique workplaces. An essential part of the program is the identification of all hazardous chemicals a worker may encounter in the facility. Compliance with the OSHA hazard communication standard entails developing a list of hazardous chemicals (in this case, drugs) as part of the written hazardous communication program and informing workers where that list can be obtained. The criteria OSHA uses to identify hazardous chemicals, including hazardous drugs, are provided in that standard. Institutions may wish to compare their lists to the listing in this document or on the NIOSH website.

It is not likely that every healthcare provider or facility will use all drugs that have received U.S. Food and Drug Administration (FDA) approval. Instead, compliance requires practice-specific assessments for drugs used at any one time by a facility. However, hazardous drug evaluation is a continual process. Each facility must assess each new drug that enters its workplace to determine if it needs to be included in the Hazard Communication program and, when appropriate, reassess its list of hazardous drugs when new toxicological data become available. Toxicological data are often incomplete or unavailable for investigational drugs. However, if their mechanism of action suggests that there may be a concern, it is prudent to handle them as hazardous drugs until adequate information becomes available to exclude them.

#### B. NIOSH List of Hazardous Drugs

The following list (Tables 1–3) contains those drugs that NIOSH has reviewed according to the criteria in the NIOSH definition of a hazardous drug. The list was compiled from the following:

- the 2014 NIOSH update to the list
- the NIOSH 2016 update to the list, for which 34 drugs were added (including five with the manufacturers' safe-handling warnings).

The OSHA hazard communication standard requires a written program including a list of chemicals that meet the Hazard Communication definitions for hazardous, labelling, and employee training. The mandate applies not only to health-care professionals who provide direct patient care but also to others who support patient care by participating in product acquisition, storage, transportation, housekeeping, and waste disposal. Institutions may want to adopt this list or compare theirs with the list on the NIOSH website.

**CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. Therefore, this list may not be all-inclusive.**

If you use a drug that is not included in the list of hazardous drugs, check the available literature to see whether the unlisted drug should be treated as hazardous. Check the SDS from the manufacturer or the DPI. You may also check with other institutions that might be using the same drug. If any of the documents mention carcinogenicity, genotoxicity, teratogenicity (Section 13 in the DPI), or reproductive or developmental toxicity (Section 8), or if the DPI contains safe-handling warnings (Section 16), then use the precautions stipulated in the Alert. If the drug meets one or more of the criteria for hazardous drugs in the NIOSH definition, handle it as hazardous.

The list of hazardous drugs will be updated periodically on the website <http://www.cdc.gov/niosh/topics/hazdrug/>.

This list supersedes the lists from 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>), 2010, 2012, and 2014 (<http://www.cdc.gov/niosh/docs/2014-138/>).

### C. Where to Find Information Related to Drug Toxicity

Practice-specific lists of hazardous drugs (usually developed by pharmacy or nursing departments) should be comprehensive, including all hazardous medications routinely used or very likely to be used by a local practice. Here are some of the resources that employers can use to evaluate the hazard potential of a drug:

- Safety Data Sheets (SDSs, formerly Material Safety Data Sheets)
- Product labeling approved by the U.S. FDA (DPIs)
- International Agency for Research on Cancer (IARC): <http://www.iarc.fr>
- DrugBank: <http://www.drugbank.ca/>
- DailyMed: <http://dailymed.nlm.nih.gov/dailymed/>
- Special health warnings from drug manufacturers, FDA, and other professional groups and organizations
- Reports and case studies published in medical and other healthcare profession journals
- Evidence-based recommendations from other facilities that meet the criteria defining hazardous drugs

### References

Abel EA [2000]. Immunosuppressant and cytotoxic drugs: unapproved uses or indications. *Clin Dermatol* 18:95–101.

Ahmad N, Simanovski V, Hertz S, Klaric G, Kaizer L, Krzyzanowska MK [2015]. Oral chemotherapy practices at Ontario cancer centres. *J Oncol Pharm Pract* 21:249–257.

ASHP (American Society of Hospital Pharmacists) [1990]. ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs. *Am J Hosp Pharm* 47:1033–1049.

ASHP (American Society of Health-System Pharmacists) [2006]. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm* 63:1172–1193.

ASHP/AHFS DI (American Hospital Formulary Service Drug Information) [2016]. AHFS drug information online updates, [www.ahfsdruginformation.com](http://www.ahfsdruginformation.com).

Badry N, Fabbro J, de Lemos ML [2014]. Hazards in determining whether a drug is hazardous. *J Oncol Pharm Pract* 20:312–315.

Chaffee BW, Armistead JA, Benjamin BE, Cotugno MC, Forrey RA, Hintzen BL, Pfeiffenberger T, Stevenson JG [2010]. Guidelines for the safe handling of hazardous drugs: consensus recommendations. *Am J Health-Syst Pharm* 67:1545–1546.

Eisenberg S [2009]. Safe handling and administration of antineoplastic chemotherapy. *J Infus Nurs* 32(1):23–32.

FDA [2015]. Content and format of labeling for human prescription drug and biological products: requirements for pregnancy and lactation labeling. Silver Spring, MD: U.S. Food and Drug Administration, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm>.

Fent K, Mueller C. Pharmaceutical dust exposure at pharmacies using automatic dispensing machines: a preliminary study [2014]. *J Occup Environ Hyg* 11:695–705.

Goodin S, Griffith N, Chen B, Chuk K, Daouphars M, Doreau C, Patel RA, Schwartz R, Tames MJ, Terkola R, Vadnais B, Wright D, Meier K [2011]. Safe handling of oral chemotherapeutic agents in clinical practice: recommendations from an international pharmacy panel. *J Oncol Pract* 7(1):7–8.

IARC [2016]. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. Lyon, France: World Health Organization, International Agency for Research on Cancer, [www.iarc.fr](http://www.iarc.fr).

Kaestli L-Z, Fonzo-Christe C, Bonfillon C, Desmuelles J, Bonnabry P [2013]. Development of a standardized method to recommend protective measures to handle hazardous drugs in hospitals. *Eur J Hosp Pharm* 20:100–105.

Massoomi F, Neff B, Rick A, Denekas P [2008]. Implementation of a safety program for handling hazardous drugs in a community hospital. *Am J Health-Syst Pharm* 65:861–865.

Menonna-Quinn D [2013]. Safe handling of chemotherapeutic agents in the treatment of non-malignant diseases. *J Infus Nurs* 36(3):198–204.

Naumann BD, Sargent EV [1997]. Setting occupational

- exposure limits for pharmaceuticals. *Occup Med* 12(1):67–80.
- NIOSH [2004]. NIOSH alert: preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.
- ONS [2011]. Safe handling of hazardous drugs. 2nd ed. M. Polovich, ed. Pittsburgh, PA: Oncology Nursing Society.
- OSHA [2016] Controlling occupational exposure to hazardous drugs, [http://www.osha.gov/SLTC/hazardousdrugs/controlling\\_occex\\_hazardousdrugs.html](http://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html).
- Polovich M, Giesker KE [2011]. Occupational hazardous drug exposure among non-oncology nurses. *Medsurg Nurs* 20(2):79–85, 97.
- Sargent EV, Kirk GD [1988]. Establishing airborne exposure control limits in the pharmaceutical industry. *Am Ind Hyg Assoc J* 49(6):309–313.
- Sargent EV, Naumann BD, Dolan DG, Faria EC, Schulman L [2002]. The importance of human data in the establishment of occupational exposure limits. *Hum Ecol Risk Assess* 8(4):805–822.
- Shahsavarani S, Godefroid RJ, Harrison BR [1993]. Evaluation of occupational exposure to tablet trituration dust [abstract]. Bethesda, MD: American Society of Health-System Pharmacists: ASHP Midyear Clinical Meeting, Document No. P-59(E).
- Simmons CC [2010]. Oral chemotherapeutic drugs: handle with care. *Nursing* 40(7):44–47.
- U.S. Pharmacopeia (USP) [2016]. Hazardous drugs: handling in healthcare settings. Chapter 800 (USP 39-NF 34), [www.usp.org/usp-nf](http://www.usp.org/usp-nf).

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# NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016

NIOSH performs a hazard identification for each of the drugs in the following tables, based on its criteria as described above. The actual risk to healthcare workers depends on toxicity of the drugs, how the drugs can enter the body (e.g., dermal, inhalation, or ingestion), and how the drugs are handled—how they are manipulated, how often they are handled, and the exposure controls in place, such as the type of engineering controls and personal protective equipment (PPE) (see Table 5). For example,

- Dispensing a single tablet to a patient may pose a relatively low risk to the healthcare worker. A single pair of gloves may be adequate.
- Repeatedly counting, cutting, or crushing tablets may pose a higher risk for worker exposure

than dispensing a single tablet and contamination to the workplace if exposure controls are not in place. If a containment device such as a BSC (Class II biological safety cabinet) or CACI (compounding aseptic containment isolator) is not available, then double gloves, a protective gown, respiratory protection, and a disposable pad to protect the work surface should be used.

- Preparing several intravenous doses of an antineoplastic drug typically poses a higher potential risk to the worker. In addition to double gloving and a protective gown, an engineering control such as a BSC or CACI, possibly supplemented with a CSTD (closed system drug-transfer device), is necessary to protect the drug, environment, and healthcare worker.

The drugs in **Table 1** meet one or more of the NIOSH criteria for a hazardous drug. In addition to many of these drugs being cytotoxic, the majority are hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

These drugs represent an occupational hazard to healthcare workers and should always be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation (IV [intravenous], SC [subcutaneous], topical, tablet, or capsule). Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe-handling recommendations.

*Abbreviations and footnotes.* AHFS = American Hospital Formulary Service; MRHD = maximum recommended human dose.

\*Drugs in red font were added in 2016.

National Toxicology Program classifications (<http://ntp.niehs.nih.gov/pubhealth/roc/index.html>): \*\*Known To Be Human Carcinogens; \*\*\*Reasonably Anticipated To Be Human Carcinogens.

†International Agency for Research on Cancer ([www.iarc.fr](http://www.iarc.fr)): Group 1, Carcinogenic to Humans; Group 2A, Probably Carcinogenic to Humans; Group 2B, Possibly Carcinogenic to Humans.

‡BCG, although classified as a vaccine, is used in the treatment of certain cancers. BCG should be prepared with aseptic techniques. To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared. A separate area for the preparation of BCG suspension is recommended. All equipment, supplies, and receptacles in contact with BCG should be handled and disposed of as biohazardous. If preparation cannot be performed in a containment device, then respiratory protection, gloves, and a gown should be worn to avoid inhalation or contact with BCG organisms.

‡‡MSHG was removed in 2015 by the manufacturer.

**Table 1. Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
abiraterone	10:00 antineoplastic agents		Women who are pregnant or may be pregnant should not handle without protection (e.g., gloves); FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ado-trastuzumab emtansine	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
afatinib*	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
altretamine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
amsacrine	NA antineoplastic agents	yes	IARC Group 2B <sup>†</sup>	<a href="#">DrugBank</a>
anastrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
arsenic trioxide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP <sup>**</sup> ; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
axitinib	10:00 antineoplastic agents		Teratogenic, embryotoxic and fetotoxic in mice at exposures lower than human exposures; FDA Pregnancy category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
azacitidine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP <sup>***</sup> ; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
Bacillus Calmette Guerin (BCG)	80:12 vaccines	yes	See special handling requirements <sup>†</sup> ; FDA Pregnancy Category C	<a href="#">DailyMed</a>
belinostat	10:00 antineoplastic agents	yes	May cause teratogenicity and/or embryo-fetal lethality because it is a genotoxic drug and targets actively dividing cells; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bendamustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bexarotene	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bicalutimide	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bleomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bortezomib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued) Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
bosutinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
busulfan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cabazitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cabozantinib	10:00 antineoplastic agents		Embryolethal in rats at exposures below the recommended human dose; FDA Pregnancy category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
capecitabine	10:00 antineoplastic agents	yes	Metabolized to 5-fluorouracil; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
carboplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
carfilzomib	10:00 antineoplastic agents		Special warnings on contraception while taking and 2 weeks post-treatment; FDA Pregnancy category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
carmustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
chlorambucil	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cisplatin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cladribine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
clofarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
crizotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cyclophosphamide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
cytarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dabrafenib	10:00 antineoplastic agents		Special warnings on contraception for females while taking and 2 weeks post-treatment; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dacarbazine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
dactinomycin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dasatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
daunorubicin	10:00 antineoplastic agents	yes	IARC Group 2B, AKA daunomycin; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
decitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
degarelix	10:00 antineoplastic agents	-**	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
docetaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
doxorubicin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
enzalutamide	10:00 antineoplastic agents		Embryo-fetal toxicity in mice at exposures that were lower than in patients receiving the recommended dose; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
epirubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
eribulin	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
erlotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
estramustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
etoposide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
everolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
exemestane	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
floxuridine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
fludarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
fluorouracil	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
flutamide	10:00 antineoplastic agents		Indicated only for men; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
fulvestrant	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
gemcitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
gemtuzumab ozogamicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
goserelin	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
histrelin	10:00 antineoplastic agents		Can cause fetal harm when administered to a pregnant patient, with the possibility of spontaneous abortion; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
hydroxyurea	10:00 antineoplastic agents	yes	Special warning on handling bottles and capsules; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
idarubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ifosfamide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
imatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
irinotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ixazomib	10:00 antineoplastic agents	yes	Male and female patients of childbearing potential must use effective contraceptive measures during and for 3 months following treatment	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ixabepilone	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
letrozole	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
leuprolide	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
lomustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mechlorethamine	10:00 antineoplastic agents	yes	NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
megestrol	10:00 antineoplastic agents	yes	Nursing should be discontinued if megestrol is required; women at risk of pregnancy should avoid exposure; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
melphalan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
mercaptopurine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
methotrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mitomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mitotane	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mitoxantrone	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
nelarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
nilotinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
omacetaxin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
oxaliplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
paclitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
panobinostat	10:00 antineoplastic agents	yes	Special warnings on contraception for females while taking and 1 month post-treatment;	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pazopanib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pemetrexed	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pentostatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pertuzumab	10:00 antineoplastic agents		Black Box warning on embryo-fetal death and birth defects; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
pomalidomide	10:00 antineoplastic agents	yes	Females of reproductive potential must use two forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping treatment; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ponatinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pralatrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
procarbazine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
regorafenib	10:00 antineoplastic agents		Black Box warning on severe and sometimes fatal hepatotoxicity; total loss of pregnancy at doses lower than recommended human dose; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
romidepsin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
sorafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
streptozocin	10:00 antineoplastic agents	yes	IARC Group 2B; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
sunitinib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
tamoxifen	10:00 antineoplastic agents		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
temozolomide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
temsirolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
teniposide	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
thioguanine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
thiotepa	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
topotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
toremifene	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
trametinib	10:00 antineoplastic agents		Embryotoxic and abortifacient at doses less than recommended human dose; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
trifluridine/tipiracil (combination only)	10:00 antineoplastic agents	yes	Embryo-fetal lethality and embryo-fetal toxicity at doses lower than or similar to exposures at the recommended human dose	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a> ; <a href="#">DrugBank</a>
triptorelin	10:00 antineoplastic agents		FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
valrubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vandetanib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vemurafenib	10:00 antineoplastic agents		FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vinblastine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vincristine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vinorelbine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 1 (Continued). Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
vismodegib	10:00 antineoplastic agents		Black Box warning on embryo-fetal death or severe birth defects; recommend effective contraception for females during therapy and for 7 months after treatment; present in semen; no sperm donation during and 3 months post-treatment; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vorinostat	10:00 antineoplastic agents	yes	Adverse embryo-fetal effects at less than the recommended human dose; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ziv-aflibercept	10:00 antineoplastic agents		Embryotoxic and teratogenic in rabbits at exposure levels lower than human exposures at the recommended dose, with increased incidences of external, visceral, and skeletal fetal malformations; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

The drugs in **Table 2** meet one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe-handling recommendations.

*Abbreviations and footnotes.* AHFS = American Hospital Formulary Service; MRHD = maximum recommended human dose.

\*Drugs in blue font meet one or more criteria for a hazardous drug and also pose a potential reproductive hazard. National Toxicology Program (<http://ntp.niehs.nih.gov/pubhealth/roc/index.html>): \*\*Known To Be Human Carcinogens; \*\*\*Reasonably Anticipated To Be Human Carcinogens.

†International Agency for Research on Cancer ([www.iarc.fr](http://www.iarc.fr)): Group 1, Carcinogenic to Humans; Group 2A, Probably Carcinogenic to Humans; Group 2B, Possibly Carcinogenic to Humans.

‡Drugs in red font were added in 2016.

**Table 2. Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
abacavir	8:18.08.20 nucleoside and reverse transcriptase inhibitors		FDA Pregnancy Category C; malignant tumors observed in male and female mice and rats; genotoxic in in vivo micronucleus test	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
alefacept	84:92 skin and mucous membrane agents, miscellaneous		Increased frequency of malignancies observed in treated patients; FDA Pregnancy Category B	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
carbamazepine	28:12:92 anticonvulsants, miscellaneous		Black Box warning for aplastic anemia; congenital malformations in offspring of mothers who took drug; rapid transplacental passage; FDA Pregnancy Category D*	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
apomorphine	28:36.20.08 non-ergot-derivative dopamine receptor agonists		FDA Pregnancy Category C; genotoxic in several in vitro assays	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
azathioprine	92:44 immunosuppressants	yes	IARC Group 1 carcinogen <sup>†</sup> ; NTP <sup>**</sup> ; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
chloramphenicol	8:12:08 chloramphenicols		IARC Group 2A carcinogen; NTP <sup>***</sup> ; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cidofovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cyclosporine	92:44 immunosuppressive agents		IARC Group 1 carcinogen; NTP <sup>**</sup> ; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
deferiprone	64:00 heavy metal antagonists		Genotoxic in vitro and in vivo; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dexrazoxane	92:56 protective agents	yes	FDA Pregnancy Category C; secondary malignancies observed in patients treated long term with Razoxane (a racemic mixture containing dexrazoxane); genotoxic in vitro and in vivo; in laboratory studies, testicular atrophy observed at or below the human dose	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
diethylstilbestrol	NA		IARC Group 1 carcinogen; NTP <sup>**</sup> ; FDA Pregnancy Category X	<a href="#">DrugBank</a>
divalproex	28:12:92 anticonvulsants, miscellaneous		Black Box warning for teratogenicity; FDA Pregnancy Category D; tumors seen in laboratory studies at doses below MRHD	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
entecavir	8:18:32 nucleosides and nucleotides		FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
estradiol	68:16:04 estrogens		Black Box warning for malignant neoplasms; increased risk of endometrial cancer, breast cancer, and ovarian cancer; in laboratory studies, increased frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver; present in breast milk; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
estrogen/ progesterone combinations	68:12 contraceptives		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category X	<a href="#">DailyMed</a>
estrogens, conjugated	68:16:04 estrogens		Black Box warning for endometrial cancer and cardiovascular risks; long-term use in women and laboratory studies increases frequency of several cancers; NTP**; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
estrogens, esterified	68:16:04 estrogens		Black Box warning for endometrial cancer and cardiovascular risks; NTP**; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
estropipate	68:16:04 estrogens		Black Box warning for endometrial carcinoma in postmenopausal women and use during pregnancy; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
fingolimod	92:20 biologic response modifiers		FDA Pregnancy Category C; in laboratory studies, increased malformations and embryofetal deaths at less than the recommended human dose; malignant lymphomas observed in male and female mice	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
flouxymesterone	68:08 androgens		Tumors in mice and rats and possibly humans; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
fosphenytoin	28:12.12 hydantoins		Metabolized to phenytoin; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ganciclovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
leflunomide	92:36 disease-modifying antirheumatic agents		Teratogenic in laboratory studies at 1/10 human dose (HD); marked postnatal survival at 1/100 HD; FDA Pregnancy Category X; severe liver injury reported in patients; carcinogenicity observed at doses below HD	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
lenalidomide	92:20 biologic response modulators	yes	Analog of thalidomide; FDA Black Box warnings for limb abnormalities; Pregnancy Category X; in laboratory studies, caused thalidomide-type limb defects in monkey offspring	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
liraglutide recombinant	68:20.06 incretin mimetics		FDA Pregnancy Category C; Black Box warning for thyroid C-cell tumors, with supporting evidence in laboratory studies; also in laboratory studies, teratogenic at or below the MRHD	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
medroxyprogesterone acetate	68:32 progestins	yes	IARC Group 2B; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
methimazole <sup>†</sup>	68:36:08 antithyroid agents		Appears in human breast milk; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mipomersen	24:06:92 antilipemic agents, miscellaneous		Black Box warning on hepatotoxicity; FDA Pregnancy Category B	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
mycophenolate mofetil	92:44 immunosuppressive agents		Black Box warning for embryo fetal toxicity, malignancies, and serious infections; increased risk of first-trimester pregnancy loss and increased risk of congenital malformations; FDA Pregnancy Category D; Special warning: Tablets should not be crushed and capsules should not be opened or crushed. Avoid inhalation or direct contact with skin or mucous membranes of the powder contained in capsules and oral suspension (before or after constitution). If such contact occurs, wash thoroughly with soap and water; rinse eyes with plain water.	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mycophenolic acid	92:44 immunosuppressive agents		Black Box warning for first trimester pregnancy loss and an increased risk of congenital malformations; FDA Pregnancy Category D; Black Box warning for lymphomas and other malignancies; genotoxic in vitro and in vivo	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
nevirapine	8:18.08.16 nonnucleoside reverse transcriptase inhibitors		FDA Pregnancy Category B; in laboratory studies, hepatocellular adenomas and carcinomas at doses lower than human dose	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ospemifene	68:16:12 estrogen agonists-antagonists		Black Box warning on increased risk of endometrial cancer in certain populations; risk of adverse outcomes during pregnancy and labor; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
oxcarbazepine	28:12:92 anticonvulsants, miscellaneous		Tumors observed in laboratory studies at 1/10 MRHD; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
palifermin	84:16 cell stimulants and proliferants		FDA Pregnancy Category C; potential for stimulation of tumor growth	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
paliperidone	28:16:08:04 atypical antipsychotics		Metabolite of risperidone; excreted in human breast milk; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
phenoxybenzamine	12:16:04:04 non-selective alpha-andrenergic blocking agents		IARC Group 2B; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
phenytoin	28:12.12 hydantoin		IARC Group 2B; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pipobroman	NA		FDA Pregnancy Category D	<a href="#">DrugBank</a>
progesterone	68:32 progestins		IARC Group 2B; NTP***	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
progestins	68:12 contraceptives		FDA Pregnancy Category X	<a href="#">DailyMed</a>
propylthiouracil	68:36.08 antithyroid agents		IARC Group 2B; NTP***; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
raloxifene	68:16:12 estrogen agonists-antagonists		Abortion and developmental abnormalities seen at low doses in laboratory studies; evidence of tumors at low doses in laboratory studies; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
rasagiline	28:36 antiparkinsonian agents		FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
risperidone	28:16:08:04 atypical anti-psychotics		Evidence of tumors at low doses in laboratory studies; may be prolactin-mediated; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
sirolimus	92:44 immunosuppressive agents		AKA rapamycin; increased risk of lymphomas and other malignancies; embryotoxic and fetotoxic at 0.2 human dose; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)**

Drug	AHFS classification	MSHG	Supplemental information	Links
spironolactone	24:32.20 mineralocorticoid receptor antagonists		FDA Pregnancy Category C; Black Box warning for tumorigenicity in laboratory studies	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
tacrolimus	92:44 immunosuppressive agents		Increased risk of lymphomas and other malignancies; reproductive effects seen in laboratory studies below the MRHD; excreted in breast milk; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
teriflunomide	92:20 immunomodulatory agents		Black Box warning on severe hepatotoxicity and teratogenicity, including major birth defects; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
thalidomide	92:20 biologic response modulators	yes	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
tofacitinib	92:36 disease modifying antirheumatic drugs		Black Box warning for lymphoma and other malignancies; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
uracil mustard	NA	yes	FDA Pregnancy Category D	<a href="#">DrugBank</a>
valganciclovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
zidovudine	8:18:08 antiretroviral agents		IARC Group 2B; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

The drugs in **Table 3** primarily meet the NIOSH criteria for reproductive hazards. They represent a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk. Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers. The manufacturer's safe-handling guidance (MSHG) is typically in Section 16 of the DPI. See Table 5 for safe handling recommendations.

\*Drugs in red font were added in 2016.

**Table 3. Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
acitretin	88:04 vitamin A	Black Box warning on adverse reproductive effects; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
alitretinoin	84:92 skin and mucous membrane agents, miscellaneous	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ambrisentan	24:12:92 vasodilating agents, miscellaneous	Black Box warning on adverse reproductive effects; reduced sperm counts in patients; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
bosentan	24:12:92 vasodilating agents, miscellaneous	Black Box warning on adverse reproductive effects; Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cabergoline	28:36:20:04 ergot-derivative dopamine receptor agonists	Inhibition of conception and embryo fetal effects at doses below recommended human dose; FDA Pregnancy Category B	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
cetrorelix	92:40 gonadotropin-releasing hormone antagonists	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
choriogonadotropin	68:18 gonadotropins	FDA Pregnancy Category X; may cause fetal harm when administered to a pregnant woman	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
clomiphene*	68:16:12 estrogen agonist-antagonists	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
clonazepam	28:12:08 benzodiazepines	Increased risk of congenital abnormalities when taken in first trimester; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
colchicine	92:16 anti-gout agents	FDA Pregnancy Category C; published animal reproduction and development studies indicate it causes embryofetal toxicity, teratogenicity, and altered postnatal development at exposures within or above the clinical therapeutic range	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dinoprostone	76:00 oxytocics	Hazardous only for women in late pregnancy; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dronedarone	24:04:04 antiarrhythmics	Teratogenic in laboratory studies at ½ MRHD; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
dutasteride	92:08 5-alpha reductase inhibitors	Women warned not to handle; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
eslicarbazepine	28:12:92 anticonvulsants, miscellaneous	Fetal malformations, fetal growth retardation, embryolethality, and reduced body weights observed in animal studies; excreted in human breast milk; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ergonovine/methylergonovine	76:00 oxytocics	Use is contraindicated during pregnancy because of its uterotonic effects; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a> ; <a href="#">DrugBank</a>
finasteride	92:08 5-alpha reductase inhibitors	Women should not handle crushed or broken finasteride tablets when they are pregnant or may potentially be pregnant, due to potential risk to a male fetus; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
fluconazole	8:18.08 azoles	FDA Pregnancy Category C; case reports describe congenital anomalies in infants exposed in utero to maternal fluconazole (400–800 mg/ day) during most or all of the first trimester, similar to those seen in animal studies	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
ganirelix	92:40 gonadotropin-releasing hormone antagonists	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
gonadotropin, chorionic	68:18 gonadotropins	Defects of forelimbs and central nervous system and alterations in sex ratio have been reported in laboratory studies; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
icatibant	92:32 complement inhibitors	FDA Pregnancy Category C; in laboratory studies, premature birth and abortion rates increased at a dose that was less than 1/40th the MRHD, and delayed parturition and fetal death occurred at 0.5 and 2-fold, respectively, the MRHD	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
lomitapide	24:06:92 antilipemic agents, miscellaneous	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
macitentan	48:48 vasodilating agents	Black Box warning for embryo-fetal toxicity; special warnings on contraception for females while taking and 1 month post-treatment; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mentropins	68:18 gonadotropins	FDA Pregnancy Category X	<a href="#">DrugBank</a>
methyltestosterone	68:08 androgens	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
mifepristone	76:00 oxytocics	When given to pregnant women, results in termination of pregnancy; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
misoprostol	56:28.28 prostaglandins	FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
nafarelin	68:18 gonadotropins	Note: Given only as nasal spray; no potential for occupational exposure; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
oxytocin	76:00 oxytocics	Hazardous only for women in 3 <sup>rd</sup> trimester; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
pamidronate	92:24 bone resorption inhibitors	Embryo-fetal toxicities at doses below the recommended human dose; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
paroxetine	28:16:04:20 selective serotonin uptake inhibitors	Increased risk of congenital abnormalities when taken in first trimester; complications in pregnancy when taken in third trimester; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pasireotide	68:29:04 somostatin agonists	Increased implantation loss and decreased viable fetuses, corpora lutea, and implantation sites at doses less than the human recommended dose; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
pentetate calcium trisodium	NA	Severe teratogenic effects in laboratory studies in dogs; supplied in ampule, which can lead to occupational exposure; FDA Pregnancy Category C	<a href="#">DailyMed</a>
peginesatide	20:16 hematopoietic agents	Adverse embryo-fetal effects, including reduced fetal weight, increased resorption, embryo-fetal lethality, and cleft palate, observed in doses below the recommended human dose; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
plerixafor	20:16 hematopoietic agents	Teratogenic in laboratory studies; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ribavirin	8:18:32 nucleosides and nucleotides	Teratogenic and embryotoxic effects in several laboratory studies; contraindicated in women who are pregnant and in the male partners of women who are pregnant; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
riociguat	48:48 vasodilating agents	Exclude pregnancy before the start of treatment, monthly during treatment, and 1 month after stopping treatment; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
telavancin	8:12:28 glycopeptides	Black Box warning for potential risk to fetus and adverse reproductive outcomes; reduced fetal weights and increased rates of digit and limb malformations in three species at clinical doses; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
temazepam	28:24:08 benzodiazepines	Increased risk of congenital malformations associated with treatment during the first trimester of pregnancy; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
testosterone	68:08 androgens	Children should avoid contact with unwashed or unclothed application sites on skin; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
topiramate	28:12:92 anticonvulsants, miscellaneous	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
tretinoin	84:16 cell stimulants and proliferants	Black Box warning for severe birth defects; Special FDA distribution system; FDA Pregnancy Category X	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ulipristal	68:12 contraceptives	FDA Pregnancy Category X	<a href="#">DailyMed</a>
valproate/valproic acid	28:12:92 anticonvulsants, miscellaneous	Black Box warning for teratogenicity; congenital malformations, including neural tube defects; teratogenic in multiple species; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
vigabatrin	28:12:92 anticonvulsants, miscellaneous	Malformations seen in laboratory studies below the MRHD; FDA Pregnancy Category C	<a href="#">DailyMed</a> ; <a href="#">Drugbank</a>
voriconazole	8:14:08 azoles	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

(Continued)

**Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects**

Drug	AHFS classification	Supplemental information	Links
warfarin	20:12.04.08 coumarin derivatives	FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
ziprasidone	28:16:08:04 atypical antipsychotics	Developmental toxicity, including possible teratogenic effects at doses similar to human therapeutic doses; an increase in the number of pups born dead and a decrease in postnatal survival at less than MRHD; FDA Pregnancy Category C*	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
zoledronic acid	92:24 bone resorption inhibitors	Number of stillbirths increased and survival of neonates decreased in laboratory studies at low doses; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>
zonisamide	28:12:92 anticonvulsants, miscellaneous	Teratogenic in multiple miscellaneous animal species; FDA Pregnancy Category D	<a href="#">DailyMed</a> ; <a href="#">DrugBank</a>

**Table 4** would list drugs that were deleted from the 2014 NIOSH hazardous drug list for the 2016 update; however, there are no deletions to report.

**Table 5** provides general guidance for some of the possible scenarios that may be encountered in healthcare settings where hazardous drugs are handled, but it cannot cover all possible situations.

*Abbreviations and footnotes.* BSC = Class II biological safety cabinet; CACI = compounding aseptic containment isolator; CSTD = closed system drug-transfer device; HIPEC = hyperthermic intraperitoneal chemotherapy.

\*This guidance applies to the drugs in Tables 1–3. For more detailed information on safe-handling practices, see the reference list [NIOSH 2004; ASHP 2006; ONS 2011; USP 2016; OSHA 2016].

†For nonsterile preparations, a ventilated engineering control such as a fume hood or Class I BSC or a HEPA-filtered enclosure (such as a powder hood) is sufficient if the control device exhaust is HEPA filtered or appropriately exhausted to the outside of the building. It is recommended that these activities be carried out in a control device, but it is recognized that under some circumstances, it is not possible. If the activity is performed in a ventilated engineering control that is used for sterile intravenous preparations, a thorough cleaning is required following the activity.

‡Required if patient may resist (infant, unruly patient, patient pre-disposed to spitting out, patient who has difficulty swallowing, veterinary patient) or if the formulation is hard to swallow.

§Sterile gloves are required for aseptic drug preparation in BSC or CACI.

¶Intravenous tubing already attached and primed.

**Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings\***

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes <sup>†</sup>
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up <sup>‡</sup>	no	N/A

(Continued)

**Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings\***

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Oral liquid drug or feeding tube	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes <sup>†</sup>
	Administration	yes	yes	yes, if vomit or potential to spit up <sup>†</sup>	no	N/A
Topical drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes <sup>†</sup> , BSC or CACI (Note: carmustine and mustargen are volatile)
	Administration	yes	yes	yes, if liquid that could splash <sup>†</sup>	yes, if inhalation potential	N/A
Subcutaneous/intra-muscular injection from a vial	Preparation (withdrawing from vial)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash <sup>†</sup>	no	N/A
Withdrawing and/or mixing intravenous or intramuscular solution from a vial or ampoule	Compounding	yes <sup>§</sup>	yes	no	no	yes, BSC or CACI; use of CSTD recommended
	Administration of prepared solution	yes	yes	yes; if liquid that could splash <sup>†</sup>	no	N/A; CSTD required per USP 800 if the dosage form allows

(Continued)

**Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings\***

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
Solution for irrigation	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; use of CSTD recommended
	Administration (bladder, HIPEC, limb perfusion, etc.)	yes	yes	yes	yes	N/A
Powder/solution for inhalation/ aerosol treatment	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Aerosol administration	yes	yes	yes	yes	yes, when applicable
	Administration	yes	yes	yes, if liquid that could splash <sup>†</sup>	yes, if inhalation potential	N/A
Drugs and metabolites in body fluids	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Drug-contaminated waste	Disposal and cleaning	yes	yes	yes, if liquid that could splash	yes, if inhalation potential	N/A
Spills	Cleaning	yes	yes	yes	yes	N/A





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DHHS (NIOSH) Publication No. 2016-161 (Supersedes 2014-138)

**#D8 JOINT LETTER ON USP CHAPTER 800**

- September 16, 2016 Correspondence from
  - American Pharmacists Association (APhA)
  - American Society of Consultant Pharmacists (ASCP)
  - College of Psychiatric and Neurologic Pharmacists (CPNP)
  - International Academy of Compounding Pharmacists (IACP)
  - National Alliance of State Pharmacy Associations (NASPA)
  - National Association of Chain Drug Stores (NACDS)
  - National Community Pharmacists Association (NCPA)

**From:** [Grinston, Kimberly](mailto:Grinston, Kimberly)  
**To:** [Grinston, Kimberly](mailto:Grinston, Kimberly)  
**Subject:** FW: USP  
**Date:** Friday, October 14, 2016 4:35:10 PM

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**From:** Klein, Fara [<mailto:Fara.Klein@ncpanet.org>]  
**Sent:** Friday, September 16, 2016 9:36 AM  
**To:** [MissouriBOP@pr.mo.gov](mailto:MissouriBOP@pr.mo.gov)  
**Subject:** USP

Dear Kimberly Grinston,

Our organizations are writing today in regards to a new general chapter from the U.S. Pharmacopeial Convention (USP), *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings*. The purpose of the chapter, per USP, is “to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection.”

Chapter <800> will apply to all healthcare personnel who handle hazardous drug preparations, including members of our organizations. Also impacted will be nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians and the entities where they practice.

General Chapter <800> utilizes the National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs to define a hazardous drug preparation. There are multiple commonly dispensed drugs on this list, including estrogen and progestin containing drugs, anticonvulsants, immunosuppressive agents, antifungal agents, atypical antipsychotics and warfarin. The impact of General Chapter <800> on our members is substantial from both an economic and operational perspective and compliance with the new general chapter will require changes such as the use of Personal Protective Equipment (PPE) and the potential for reconstruction of facilities.

General Chapter <800> was published on February 1, 2016. In recognizing that it will take facilities time to conform to the new requirements, USP extended the official implementation date until July 1, 2018. However, given such highly complex, resource intensive, and time consuming compliance requirements, we respectfully request that the Missouri Board of Pharmacy carefully consider any actions related to pharmacy compliance with the standards.

Employee safety must always be a top priority. Our members are currently held to and comply with regulations and guidelines from entities such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and The Joint Commission (TJC), which detail the handling of hazardous material that serve to protect employees. We appreciate the intent of the proposed chapter <800>, however, the impact on our members and their patients in relation to a 2018 enforcement date is too great at this time and full compliance would be extremely difficult to the vast majority of our members.

In order to give our members the opportunity to perform the proper analyses, including budget implications and the impact upon the delivery of services to patients, and to fully integrate General Chapter <800> into their practice settings, we feel that a delay in enforcement is

warranted, similar to the phased in approach that accompanied the introduction of USP *General Chapter <797> Pharmaceutical Compounding – Sterile*.

A delay in enforcement of USP <800> allows healthcare organizations sufficient time to plan and gradually implement changes. Budgeting capital expenses is a multistep, multi-year process that is not under the control of many pharmacies. Some organizations may have to justify their <800> project proposal to numerous organizational stakeholders, spread expenditures over more than one budget cycle, and integrate their project into existing organizational project timelines.

If the Missouri Board of Pharmacy agrees that a graduated approach to implementing General Chapter <800> is consistent with its mission and goals, we respectfully request that the Missouri Board of Pharmacy grant a five year delay in enforcement of General Chapter <800> until July 1, 2021. This grace period allows state-licensed practitioners to assess and plan for the significant operational and structural changes needed as well as budget and obtain the necessary resources in an already strained financial environment.

We appreciate your thoughtful consideration of our comments regarding *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings*.

Sincerely,

American Pharmacists Association (APhA)  
American Society of Consultant Pharmacists (ASCP)  
College of Psychiatric and Neurologic Pharmacists (CPNP)  
International Academy of Compounding Pharmacists (IACP)  
National Alliance of State Pharmacy Associations (NASPA)  
National Association of Chain Drug Stores (NACDS)  
National Community Pharmacists Association (NCPA)

**#D9 Hospital Advisory Committee Update (Bert McClary, Chair)**

- June 3, 2016 Agenda
- June 3, 2016 Minutes
- July 15, 2016 Agenda
- August 26, 2016 Agenda
- September 28, 2016 Agenda

**TENTATIVE AGENDA  
Meeting Notice  
Missouri Board of Pharmacy  
Hospital Advisory Committee**

**June 3, 2016, 10:00 a.m.  
Missouri Hospital Association  
4712 Country Club Drive  
Jefferson City, MO 65109**

1. Approval of Minutes
2. Review of Administration by Medical Prescription Order Rule (20 CSR 2220-6.040)
3. Board Updates
4. DHSS Updates
5. Board of Pharmacy/DHSS Webinar
6. Potential Board Rules Governing Class-B Pharmacies
7. Pharmacy services in hospital-related entities
8. Board of Pharmacy Hospital/Health System Practice Guide
9. DHSS/Bd. Of Pharmacy Practice Questions
11. DHSS Hospital, Premises and Campus Rule(s)
12. 2016 Legislation
13. Future Meeting Dates/Topics

**OPEN MINUTES**  
**Missouri Board of Pharmacy**  
**Hospital Advisory Committee Meeting**

**June 3, 2016**

The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**

Bert McClary, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member  
Colby Grove, R.Ph., Member  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Committee Members Absent**

Kevin Kinkade, R.Ph.,

**Staff Present**

Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector

**Others Present**

Barbara Bilek, Board Member  
Sarah Willson, Missouri Hospital Association  
Julie Creach, Missouri DHSS  
David Wolfrath (MSHP liaison)

Chairman McClary opened the meeting at 10:01 a.m. and attendees were introduced.

**Agenda Item # 1:** Kimberly Grinston reported draft minutes from the April 11, 2016 and May 6, 2016 meetings have been included for review and approval. Greg Teale indicated Kevin Kinkade was incorrectly listed as chairman in the April minutes. No recommended changes were suggested to the May minutes. **A motion was made by James Gray, seconded by Greg Teale, to approve the April 11, 2016, minutes without the chairman designation for Kevin Kinkade. The motion passed 5:0:0:1 with roll call vote as follows:**

**James Gray – yes**

**Colby Grove- yes**

**Neil Schmidt- yes**

**Greg Teale – yes**

**Daniel Good – yes**

**Kevin Kinkade - absent**

**A motion was made by Neil Schmidt, seconded by Daniel Good, to approve the May 6, 2016, minutes as presented. The motion passed 5:0:0:1 with roll call vote as follows:**

**James Gray – yes**

**Colby Grove- yes**

**Neil Schmidt- yes**

**Greg Teale – yes**

**Daniel Good – yes**

**Kevin Kinkade - absent**

**Agenda Item # 2:** Bert McClary suggested discussing this agenda item with agenda items # 6 and #7.

**Agenda Item # 3:** Kimberly Grinston reported on recent Board activities. Ms. Grinston noted the Board was hosting a diversion conference and also a free ethics webinar for pharmacists. Greg Teale asked if regulators are seeing more diversion in retail pharmacy settings or in hospitals. Tom Glenski indicated the majority of diversion cases that the inspectors see are not hospital related. Neil Schmidt asked how soon does the Board contact a hospital when there's been a diversion. Tom Glenski indicated diversions are usually reported with an employee disciplinary action notice. Mr. Glenski commented that most inspectors will contact the hospital in two (2) weeks depending on their schedules and that the vast majority of investigations are completed within ninety (90) days. To avoid a conflict, Mr. Glenski indicated inspectors may wait to make contact if the hospital is conducting an internal investigation. Greg Teale reported hospitals in other states have experienced significant losses; James Gray agreed that diversion is a high risk point for hospitals. Julie Creach asked if Mike Boeger from BNDD should be invited to speak to the group. General consensus was to invite Mr. Boeger to a future meeting.

**Agenda Item # 4:** Julie Creach reported the DHSS rule revision working group met on May 5, 2016, and reviewed the Committee's suggested changes. Ms. Creach reported some of the suggested changes were not addressed in the hospital pharmacy rule because the suggestion was included/addressed in the proposed DHSS definitions rule. Ms. Creach indicated DHSS General Counsel still needs to review the proposed rules before they are forwarded to the Governor's office for final approval. Ms. Creach reported the proposed rules would likely be reviewed by the new Governor.

Ms. Creach also reported that DHSS may be modifying the hospital construction requirements based on recently passed 2016 legislation. Bert McClary asked for additional information on the construction changes. Sarah Willson with MHA indicated the changes were suggested before her tenure but noted the current construction standards are outdated and may not have been revised since 1982. Ms. Willson indicated MHA worked with DHSS on the language and noted the current legislation requires the most updated life safety requirements from the National Fire Protection Association and is consistent with CMS' most recent updates to the 2012 safety codes.

Ms. Willson also reported MHA felt it could not adopt/endorse all of the Facility Guideline Institute's (FGI) hospital design and construction standards at this time. MHA will work with DHSS and the Missouri Society for Healthcare Engineering to review FGI

standards and find a solution. Julie Creach indicated DHSS previously intended on adopting the FGI standards but will now need to draft a rule that may incorporate all or portions of the FGI standards. Sarah Willson commented that nothing prevents an entity from voluntarily following the FGI guidelines or a more current standard which is what many entities have done. However, Ms. Willson spoke favorably of DHSS being able to enforce and survey to newest standards.

Mr. McClary noted the new standards may affect sterile compounding areas and medication rooms but noted that sterile compounders should not be detrimentally impacted given that DHSS proposed rules adopt and require compliance with USP Chapter 797.

**Agenda Item # 5:** Tom Glenski reported the webinar is currently scheduled for August 25, 2016. Greg Teale commented that he's recently received inquiries regarding what falls under the hospital's license and what is considered a Class-B activity. Sarah Willson indicated that defining the hospital premises is still a major area of confusion and suggested that DHSS or the Board create a "top 10" list of things to look for when trying to make the distinction.

Greg Teale commented that many times pharmacy may not be informed in a timely manner when new buildings are being added and noted that hospital administration may not be aware of the legalities/licensing issues surrounding the hospital premises. Tom Glenski cautioned that pharmacies should contact DHSS to verify what areas are part of the licensed hospital premises. Mr. Glenski noted that buildings/areas do not automatically qualify as part of the licensed premises just because they meet the statutory definition. Instead, Mr. Glenski noted DHSS has to be notified and the building/area has to be officially recognized by DHSS as part of the licensed area. Bert McClary commented the hospital premises question has been an issue for some time and suggested the Board and DHSS create some form of guidance document.

Bert McClary asked if the Board/DHSS wanted the Committee to review the proposed webinar questions and answers. Kimberly Grinston indicated proposed webinar questions could be brought to a future meeting.

**Agenda Items # 6 and #7:** Bert McClary indicated these items could be grouped with the administration rule and once again suggested that the Board draft a guidance document that gives criteria for determining what pharmacy services are under the Board's jurisdiction. Mr. McClary suggested the guidance document also address areas of conflict/inconsistency between DHSS standards and Board standards. Mr. McClary indicated further guidance on the Board's regulatory jurisdiction is needed for not just hospitals/health systems but also other health care entities. Mr. McClary noted the previous MHA case against the Board did not address other practice settings and asked how entities like long-term care facilities who may want their own pharmacy would be regulated. Mr. McClary also inquired about Board jurisdiction over ambulatory surgical centers where pharmacy services are provided. Greg Teale noted that with current

reimbursement issues, the jurisdictional question may become more common. Sarah Willson agreed especially for acute and post-acute care providers.

Additional discussion was held. Greg Teale commented that the dual licensure requirements have become problematic and that pharmacy services must be safe and efficient to practice. Sarah Willson indicated that having a pharmacist involved in dispensing activities is the safest practice and that removing the pharmacist is not in the patient's best interest. Bert McClary once again suggested that the Committee focus on the appropriate rules for hospital related entities and noted the administration rule is a good example of Board rules that may impact different licensing settings. Mr. McClary noted these practice settings could be simply identified as "health care entities" if defined properly.

Kimberly Grinston suggested that defining "health care entity" too broadly could slow down Board resolution of the issue. Neil Schmidt indicated he previously preferred the term "health system." Sarah Willson suggested that representatives from these other practice settings may need to be added to the discussion.

The following additional discussion was held on the administration by medical prescription order rule:

- Bert McClary asked if the definition of "health care entity" in the rule was sufficient or if it should be limited to just licensed entities. Mr. McClary indicated he always presumed that any place that offers or practices onsite direct patient care/clinical services would need to be licensed. Kimberly Grinston asked if the Committee was attempting to address pharmacists administering under the hospital's authority. James Gray advised the Committee should not make the rule too broad and suggested referencing "health system" as an umbrella term. However, Mr. Gray cautioned the definition should not be so complicated that it couldn't be enforced. Sarah Willson commented that the reason for exempting hospitals from Board requirements is because they are extensively regulated by the Joint Commission and CMS. Ms. Willson suggested that other practice settings in newer business models may not have a proven track record. Ms. Willson commented that exemptions for emerging business models outside of a hospital setting may be too broad of an application at this time. However, Bert McClary commented Missouri's rules should not impose harsher restrictions on pharmacists than other healthcare practitioners that may be handling or administering medication in the same setting.
- In further discussion, Kimberly Grinston noted the current draft administration rule focuses on who the practitioner is operating on behalf of. Tom Glenski suggested limiting section (10) of the draft to individuals operating on behalf of a health care entity. James Gray alternatively suggested including persons operating on behalf of a health care entity "or as determined by the Board" to give the Board discretion. Bert McClary asked if the rule should include the definition of hospital and hospital clinic or facility from SB 808 enacted in 2014.

Consensus to add the definitions of hospital and hospital clinic and facility from SB 808 and to add “other facilities recognized by the Board.”

- Committee members asked that the rule clarify that administration policies and procedures can be maintained as part of the hospital’s policies/procedures. A suggestion was also made that the rule allow the required administration notifications to be maintained in a common electronic record.
- Additional suggested changes are highlighted in Appendix A.

**Agenda Item #8:** Kimberly Grinston reported the office is working on a draft guidance to address many of the jurisdictional and practice concerns the Committee previously discussed. Ms. Grinston indicated the draft guidance would be returned to the Committee for additional review/comment at a future meeting. Greg Teale indicated he surveyed his peers and asked them to rate their pharmacy related concerns by priority/level of importance. Mr. Teale indicated the following concerns were submitted:

1. Labeling: Concerns were raised that the Class-A labeling requirements were inappropriate for hospital facilities- many of whom are dispensing for immediate use. It was reported that entities such as infusion clinics may be using the hospital’s labeling system and wouldn’t have information like the pharmacy’s address or phone number on the label.
2. Filing Orders: Concerns were raised that medication orders are not kept in a regular prescription file as required for retail pharmacies.
3. Medication Therapy Services/Collaborative Drug Therapy Agreements: Concerns were raised that the MTS rules require an agreement between the pharmacist and physician although some Class-B pharmacies may be using a P&T protocol. Concerns were also expressed about the inconsistent standards for pharmacists who may be fluctuating between DHSS regulated settings and Board regulated settings. Greg Teale commented the current requirements are both burdensome and confusing when providing patient care.
4. Automated Cabinets: Concerns were raised that pharmacy controlled automated cabinets may be the primary means of distribution for some Class-B pharmacies in lieu of transferring stock to a cabinet for physician dispensing. James Gray noted these medications stay under the control of the pharmacy. Greg Teale indicated the automated cabinets use technology to enhance accuracy and prevent diversion and that cabinet activity is verified by a pharmacist. Mr. Teale asked the Board to consider how these cabinets may be operated lawfully and still stay under pharmacy control.

Additional discussion was held regarding remote/video monitoring of technician activities. Tom Glenski reported the Board has previously indicated that remote final product verification is not allowed. James Gray suggested that the Board reconsider this issue and asked what the Board’s concerns would be if the data shows a higher degree of accuracy with remote/electronic verification. Tom Glenski added the Board has been reluctant to address expanded duties for technicians until technician education or training requirements are in place.

5. Pharmacy Access: Concerns were raised regarding access to the pharmacy by other healthcare practitioners. Greg Teale indicated there may be a need for nurses to access the pharmacy to draw doses or access medication when the pharmacy is closed. Tom Glenski indicated Missouri law says these nurses may need to be a technician but noted the Board has never officially addressed this topic for nurses entering Class-B pharmacies. Bert McClary suggested there would be value in allowing access for nursing staff and other healthcare practitioners in lieu of stocking medication outside of the pharmacy.
6. Concerns were raised regarding USP chapters 797 and 800. However, Greg Teale indicated this may not need priority consideration at this time. Tom Glenski noted the Board's requirements are generally stricter than DHSS' requirements. Mr. Glenski mentioned the previously discussed white-bagging issue and indicated the Board wrote a rule that may address this. James Gray commented there is general confusion about what is allowed under a Class-J arrangement.
7. Mr. Teale noted he will discuss the proposed webinar questions with his contact group and will try to have feedback before June 20<sup>th</sup>.

James Gray suggested that compounding issues are also a topic of concern that should be addressed. As an example, Mr. Gray indicated there may be surgery centers using compounded topicals during surgery that may ask the pharmacy to prepare a batch that is non-patient specific. Mr. Gray commented that pharmacists cannot prepare non-patient specific batches but noted that hospital-owned surgical centers can prepare non-patient specific batches without pharmacist involvement. Tom Glenski said the Board may reconsider this issue given the one (1) mile limit indicated in the most recent FDA Guidance and asked Committee members to identify other scenarios hospitals may be dealing with. James Gray suggested hospitals may need to know that pharmacies in a Class-J arrangement can compound and send non-patient specific prescription to another pharmacy.

**Agenda Item #9:** Bert McClary suggested the Committee could be a resource for practice questions that the Board and DHSS may receive on a regular basis. Tom Glenski said planned to review a list of questions on the webinar. Bert McClary asked Mr. Glenski to compile a list of common questions for Committee review and or guidance.

Committee Member Greg Teale left the meeting at 2:38 p.m.

**Agenda Item #11:** Bert McClary indicated this topic was previously discussed and asked the group to send hospital premises related questions/examples to DHSS.

**Agenda Item # 12:** Kimberly Grinston reported on pending legislation listed in the agenda and noted there have been extensive discussions regarding the value of a PDMP. Neil Schmidt inquired about proposed legislation that would allow pharmacists

to dispense contraceptives; Kimberly Grinston reported she does not believe the legislation passed but will update the Committee if different.

**Agenda Item # 13:** Bert McClary asked if Committee members still wanted to meet monthly. Committee consensus to continue monthly meetings and to schedule the next conference call on July 15, 2016 from 2:00 – 4:00 p.m. and the next full meeting for August 26, 2016, in Jefferson City.

**A motion was made by Neil Schmidt, seconded by Colby Grove, to adjourn the meeting. Chairman McClary adjourned the meeting by consensus at approximately 2:59 p.m.**

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KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved:

**REVISED TENTATIVE AGENDA**  
**July 15, 2016 2:00 p.m.**  
**Missouri Board of Pharmacy**  
**Hospital Advisory Committee Conference Call**

**Missouri Division of Professional Registration**  
**3605 Missouri Boulevard**  
**Jefferson City, MO 65102**

1. Board Updates/Potential Board Guidance Documents
2. Board/DHSS Joint Webinar on Hospital Pharmacy/Class-B Hospital Questions
  - a. Access to Class-B pharmacies by other healthcare professionals
  - b. Immunization Notifications
  - c. Labeling
3. MSHP/MHA Survey
4. FDA Hospital Compounding Guidance
5. Future Meeting Dates/Discussion Topics

**TENTATIVE AGENDA**  
**Meeting Notice**  
**Missouri Board of Pharmacy**  
**Hospital Advisory Committee**

**August 26, 2016, 10:00 a.m.**  
**Missouri Hospital Association**  
**4712 Country Club Drive**  
**Jefferson City, MO 65109**

1. Approval of Minutes
2. Review of Administration by Medical Prescription Order Rule (20 CSR 2220-6.040)
3. Board Updates
4. DHSS Updates
5. Potential Class-B Pharmacy Rule Suggestions
6. Board of Pharmacy/DHSS Jurisdictional Conflicts/Questions
7. Use of Automated Devices in Class-B Settings
8. Access to Class-B Pharmacies by Other Healthcare Practitioners
9. Pharmacist Scope of Practice in Class-B v. Hospital Settings
  - a. MTS in dually regulated practice settings (Bd/DHSS)
  - b. Prescribing authority
  - c. Controlled substance authority
  - d. Advance practice pharmacist designation
10. Technician Scope of Practice in Class-B Pharmacies/Dually Regulated Settings
11. Regulation of other health care entities
12. BOP/DHSS Funded Pharmacist
13. Future Meeting Dates/Topics

**TENTATIVE AGENDA**  
**September 28, 2016 2:00 pm to 4:00 pm**

**Missouri Board of Pharmacy**  
**Hospital Advisory Group**  
**Meeting**

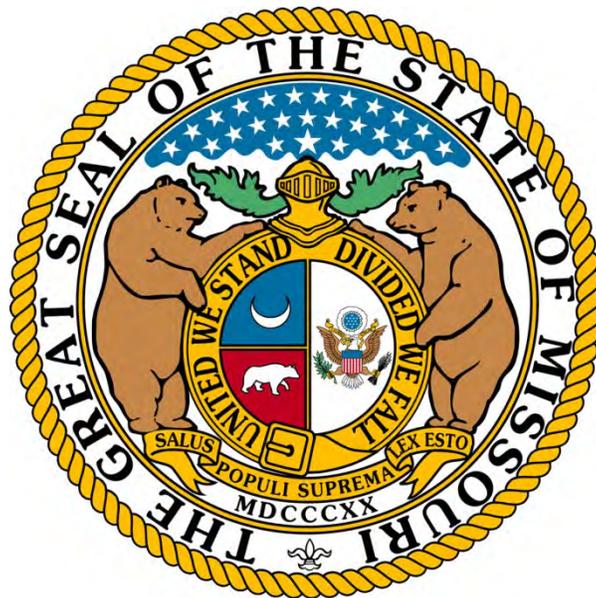
**Professional Registration**  
**3605 Missouri Blvd**  
**Jefferson City, MO 65109**

1. Welcome & Introductions
2. Approval of Minutes
3. Board Updates
4. Department of Health Updates
5. Review of Administration by Medical Prescription Order Rule
6. Class-B Guidance Document
7. Potential Hospital Guidance Document
8. Selection/Discussion of Future Agenda Topics
9. Future Agenda Meeting/Schedules
10. Public Questions/Comments

**#D10 Class-B Pharmacy Guidance**

- Class-B Pharmacy Draft Guidance Document

# MISSOURI BOARD OF PHARMACY



## CLASS-B HOSPITAL PHARMACY GUIDANCE

**\*\*\* THIS DRAFT HAS NOT BEEN REVIEWED OR APPROVED BY THE BOARD  
AND MAY NOT REFLECT THE BOARD'S CURRENT POSITION/GUIDANCE\*\*\***

# CLASS-B

## Hospital Pharmacy Guidance

This guidance document is being provided by the Missouri Board of Pharmacy to provide compliance information for Class-B Hospital pharmacies. **This guidance is not applicable to pharmacy services regulated by and under the jurisdiction of the Missouri Department of Health and Senior Services (DHSS).**

### OVERVIEW

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In 2014, the Missouri General Assembly enacted SB 808 which officially established a Class-B Hospital pharmacy permit for pharmacies located in Missouri licensed hospitals and also hospital clinics and facilities. Prior to the new law, only Missouri licensed hospitals were eligible for a Class B permit. As healthcare delivery models have evolved, Missouri hospitals indicated pharmacy services were increasingly being delivered via hospital owned clinics or satellite pharmacies that were not part of the licensed hospital. The Board was informed its general pharmacy rules conflicted or hindered compliance with accreditation and other reimbursement requirements, particularly for clinics/facilities not engaged in traditional “prescription” dispensing.

The Board subsequently convened a Hospital Pharmacy Advisory Group comprised of hospital representatives to assist the Board in addressing these concerns. The Advisory Group recommended establishing a single Class-B permit class for both hospitals and hospital related clinics and facilities along with enhanced distribution/dispensing standards for Class-B pharmacies under common control or ownership.

SB 808 was subsequently enacted which officially established the current Class-B Hospital Pharmacy permit classification. SB 808 also:

- Created additional dispensing and distribution allowances for Class-B pharmacies;
- Granted DHSS and the Board of Pharmacy authority to collaborate on rules governing medication distribution and medication therapy services performed by a pharmacist at or within a hospital. This allowance does not change DHSS’ current jurisdiction over hospital pharmacy but allows the agencies to collaborate on rulemaking, and
- Established a standing Hospital Advisory Committee to advise the Board. The Advisory Committee consists of hospital representatives designated by DHSS, the Missouri Hospital Association, the Missouri Society of Health System

Pharmacists and the Missouri Pharmacy Association and a Board appointed pharmacist with experience in hospital pharmacy.

## CLASS-B PERMIT REQUIREMENTS

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Section 338.220, RSMo, defines a “Class-B Hospital Pharmacy” as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3); § 338.220.6].

Eligible clinics/facilities may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (*this list is not exhaustive*). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction.

Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

Class-B applications and related fees are available on the Board’s website. *Note: Applicants must apply for and hold any required classification for specialty pharmacy services regulated by the Board (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).*

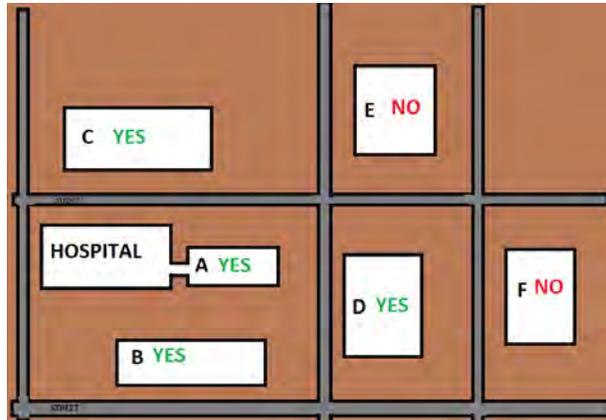
## CLASS-B LICENSURE FOR MISSOURI HOSPITALS

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Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “[licensed premises](#)” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of

pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [§ 338.220.6, RSMo]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: *“tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way.”* DHSS has provided the following examples of facilities considered “adjacent but for a common street or highway” to a hospital:



According to DHSS, buildings or areas that do not meet the above definition/ requirements would not qualify as part of the hospital's premises even though the building/area may be:

- Part of the hospital's campus
- Under the same CMS Certification Number (CCN), or
- Under the same ownership



Inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital's license. According to DHSS, this may be done in the hospital's initial DHSS license application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including, any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

DHSS has advised that the hospital premises may include more than just “inpatient” areas. For example, other hospital areas such as emergency departments, infusion clinics, urgent care facilities, ambulatory surgery centers, physical therapy departments or other “outpatient” service areas may be included, provided the facility or department meets the hospital premises definition above. *Note: Additional DHSS regulatory requirements may apply (e.g., DHSS construction standards/life safety requirements).*

Examples of pharmacy services under DHSS' jurisdiction would include, but are not limited to:

- Dispensing or distributing medication for use or administration to patients within the same DHSS licensed premises regardless of billing status ("inpatient" vs. "outpatient"). This includes dispensing or distributing to clinics or other hospital departments included within the DHSS licensed premises,
- Compounding medication within the DHSS licensed hospital premises for use or administration within the same licensed premises;
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment within the DHSS licensed hospital premises (e.g., DUR, medication reconciliation, order review/approval),
- Administering medication within the DHSS licensed hospital premises, and
- Initiating, modifying or dosing medication for use or administration within the DHSS licensed hospital premises (*a Board Certificate of Medication Therapeutic Plan Authority would still be required as described below*).

The Board has jurisdiction over pharmacy services provided outside of the licensed DHSS hospital premises. Examples would include, but are not limited to:

- Dispensing or distributing medication that will be used or administered outside of the DHSS licensed premises (e.g., "take-home" meds)
- Pharmacy services provided under a pharmacy's Class-B permit
- Compounding for use or administration outside of the DHSS licensed hospital premises or compounding medication outside of the DHSS licensed hospital premises regardless of patient location
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment outside of the DHSS licensed hospital premises (DUR, medication reconciliation, order review/approval)
- Administering medication outside of the licensed hospital premises,
- Modifying or initiating drug therapy that will be dispensed, distributed or administered outside of the DHSS licensed premises, and
- Pharmacy services provided at a clinic or facility that is not part of the DHSS licensed hospital premises. This would include any clinic/facility that has not been officially designated with DHSS as part of the hospital's license even if located within the hospital's building or on the hospital campus.

The Board has determined that "take-home" medication would not include a self-contained medication therapy course where administration is initially started within the DHSS licensed hospital premises and will leave with the patient. Examples would include intrathecal or 5-FU pumps that are started within the DHSS licensed hospital premises. The Board has also determine that medication sent with a patient to be used during an emergency transfer to

another facility would not be considered a “take home” medication. These services may be provided under DHSS’ jurisdiction; additional Board licensure is not required.

Additionally, DHSS rules allow licensed hospitals to send a limited supply of medication home with the patient from the hospital when pharmacy services are not reasonably available. A Board pharmacy permit is not required for these activities as authorized by DHSS rules.

All pharmacists, technicians and interns practicing in Missouri must hold an individual pharmacist, technician or intern license/registration issued by the Board regardless of practice setting. Pharmacist, technicians and interns practicing within a DHSS licensed hospital must be licensed with/registered by the Board.

## DUALLY REGULATED ENTITIES

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The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

DHSS licensed hospitals may choose to license all or a portion of the hospital as a Class-B pharmacy (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. The Board would only have jurisdiction over and regulate the Class-B pharmacy services.

## NON-DISPENSING ACTIVITIES

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Missouri law authorizes pharmacists to perform non-dispensing activities outside of a Missouri licensed pharmacy. Specifically, 20 CSR 2220-6.055 provides a pharmacist may perform the following activities at a non-pharmacy location:

- |  |  |
|--|--|
| (1) Administering medication or biologicals          | (6) Drug utilization review                                    |
| (2) Obtaining patient history/information            | (7) Pharmacy compliance audits/evaluations                     |
| (3) Reviewing patient records/medical reconciliation | (8) Peer review/peer consultations                             |
| (4) Patient assessment/evaluation                    | (9) Managing drug inventory, including purchasing and ordering |
| (5) Insurance billing and claims                     |  |

- (10) Consulting with other health care professionals
- (11) Patient referrals
- (12) Medication therapy management/medication therapy services, and

- (13) Prescription order entry/review, provided a pharmacist can only accept a prescription on the premises of a Missouri licensed pharmacy [§ 338.095.5]

A Class-B pharmacy permit would not be required for allowed non-dispensing activities, unless technicians will be assisting at the non-pharmacy location.<sup>1</sup>

The Board has been asked if pharmacists can maintain or monitor drug storage areas/units that are located in hospital areas/facilities that are not licensed with the Board or located in other unlicensed healthcare facilities such as a private physician's office, ambulatory surgical center or an infusion clinic. Class-B pharmacies cannot store medication outside of the licensed pharmacy area, except as allowed by 20 CSR 2220-2.900 for automated dispensing systems. However, 20 CSR 2220-6.055 would allow pharmacists to monitor/maintain medication or drug storage areas *belonging to other unlicensed entities* without a Board pharmacy permit. This would include non-dispensing activities such as checking drug storage, inventorying medication, performing drug utilization reviews, medication reconciliation and counseling patients (*this list is not exhaustive*).

## SCOPE OF CLASS-B ACTIVITIES

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Once licensed by the Board, sections [338.165.5 and .6](#), RSMo, grant two new allowances to Class B Hospital pharmacies. Specifically, Class-B Hospital pharmacies may:

- 1) Dispense medication by prescription or by medication order, and
- 2) Distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

## Dispensing by Prescription/Medication Order

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Class-B pharmacies may dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements, including, the required two-line format for Missouri prescribers.

A "medication order" is defined as an order for a legend drug or device that is:

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<sup>1</sup> A Board pharmacy permit would not be required if technicians are only assisting with administering vaccines. 20 CSR 2220-6.055(6).

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and
2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” [Section 338.165.1, RSMo](#)

Significantly, medication orders can only be used to dispense medication that will be distributed or administered at a hospital or at a qualifying “hospital clinic or facility.” A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

**BOARD NOTE: WE ARE ASKING THE BOARD TO DISCUSS THE AREAS HIGHLIGHTED IN ORANGE. ORANGE AREAS ARE POLICY POSITIONS THAT THE BOARD HAS NOT YET APPROVED.**

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration to the patient initially begins at the hospital or at a qualifying hospital clinic or facility.

Medication orders do not have to be in two-line format, however, orders must comply with all state/federal controlled substance requirements. Missouri law is silent on the pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance.

## Drug Distribution by Class-B Pharmacies

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Section [§ 338.165.6](#) provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system.

The following chart provides examples of distributions that are authorized for Class-B pharmacies without an additional Missouri drug distributor license:

Under federal law, a pharmacy may still be required to register with the DEA as a controlled substances distributor if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed by the pharmacy during the previous calendar year.

Significantly, a Class B pharmacy may not distribute compounded preparations to other entities or distribute repackaged medication to other practitioners without being registered with the FDA.

## Class-B Labeling Requirements

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Section 338.059, RSMO, provides a written label must be affixed to each prescription container dispensed to a consumer indicating:

- 1) The date the prescription was filled;
- 2) A prescription number or other unique identifier;
- 3) The patient's name;
- 4) The prescriber's directions for usage;
- 5) The prescriber's name;
- 6) The pharmacy's name and address;
- 7) The exact name and dosage of the drug dispensed, and;
- 8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy's records by name or abbreviation. [[§ 338.059](#)].<sup>2</sup>

For controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or a physician assistant (PA), the required label must also include the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [[§ 195.100, RSMo](#)].

If a unique identifier is used in lieu of a prescription number, the identifier must be able to retrieve the patient's specific medication order/prescription. Board inspectors have observed instances where a unique identifier could retrieve the patient's medical record but

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<sup>2</sup> Section 338.059, RSMo, does not apply to internal drug orders for hospital in-patients.

not the specific medication order/prescription. In some cases, the same identifier was used for multiple patients. Unique identifiers should be formatted to allow retrieval of the specific dispensing record for each individual patient (e.g. a unique identifier/order #).

The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board understands labeling may be a particular issue for hospital-owned clinics/satellite pharmacies that may not use prescriptions or have software to print a traditional "outpatient" prescription label.

The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059's labeling requirements if:

- 1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and
- 2) The medication/prescription container labeling is accurate and complies with DHSS' medication labeling requirements [see generally 19 CSR 30-20.100(21) which requires patient name, drug name, strength, expiration date, lot number when applicable and other pertinent information], and<sup>3</sup>
- 3) The medication/prescription container is not given to the patient for use/administration outside of the Class-B pharmacy location or DHSS licensed hospital premises. The Board will not consider a self-contained medication therapy course to have been "given to the patient for use/administration" offsite if administration is initiated within a Class-B pharmacy location or the DHSS licensed hospital premises but is continued or completed offsite (e.g., intrathecal and 5-FU pumps).

## Sterile Compounding

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Class-B pharmacies engaged in sterile compounding must also have a Class-H Sterile Compounding pharmacy permit. All sterile compounding for use or administration to patients outside of the DHSS licensed hospital premises must comply with the Board's sterile compounding rules (20 CSR 2220-2.200, 20 CSR 2220-2.400). Class-B pharmacies may share sterile compounding space/equipment with a DHSS hospital (e.g., the same clean room). However, the sterile compounding area will be inspected for compliance with Board requirements.

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<sup>3</sup> Radiopharmaceuticals must also comply with 19 CSR 30-20.100(18)

Licensees are reminded that Class-B pharmacies may only dispense compounded sterile preparations pursuant to a patient-specific prescription or a patient-specific medication order.

## Allowed Technician Activities

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Generally, a Missouri pharmacy technician registration is required for any person who has independent access to a pharmacy on a routine basis or who assists a pharmacist in the practice of pharmacy. Given the nature of hospital practice, the Board has determined that technician registration is not required for nurses and other healthcare practitioners who access Class-B pharmacy space or drug inventory that is shared with a DHSS regulated hospital pharmacy as part of their non-pharmacy job duties.

Pharmacy technicians may assist in any area of pharmacy practice that does not require the use of professional judgment by a pharmacist. [20 CSR 2220-2.700(1).] Technicians assisting in Class B pharmacy practice may not work independently and must be under the direct supervision and responsibility of a Missouri licensed pharmacist at all times. [20 CSR 2220-2.700]. All prescriptions prepared or compounded by a technician in a Class-B pharmacy must be finally verified/checked by a pharmacist, including, reconstituted products.

## Medication Therapy Services

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Under Missouri law, all pharmacists providing medication therapy services (MTS) must obtain a certificate of medication therapeutic authority from the Board, regardless of practice setting. [§ 338.010.4] Licensees should review the Missouri Pharmacy Practice Guide for additional MTS requirements.

As explained in the Practice Guide, an MTS certificate is not required to perform traditional pharmacist functions such as medication reconciliation or medication therapy management. A MTS certificate is only required if a pharmacist will be modifying drug/device therapy which includes:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Generally, pharmacists who are dosing, modifying or initiating medication that will be dispensed, distributed or administered outside of the DHSS licensed premises would be

regulated by the Board and required to comply with the Board's MTS rules and requirements. DHSS would regulate dosing, modifying or initiating medication within the DHSS licensed hospital premises (a Board MT certificate would still be required). *Note: This is a general guideline. A determination of DHSS/Board jurisdiction would depend on the specific facts.*

The Board has issued the following additional guidance for pharmacists performing MT services under the Board's jurisdiction:

1. Pharmacists must have a MT protocol with a Missouri physician that complies with 20 CSR 2220-6.080. A hospital protocol may be used to provide MT services if the protocol includes all information required by 20 CSR 2220-6.080(4) and authorizes the pharmacist to perform the services provided. A separate protocol would not be required. In lieu of individual signatures, 20 CSR 2220-6.080 allows the pharmacist and authorizing physician(s) to sign and date a statement agreeing to be governed by the hospital's protocol.
2. Pharmacists are required to notify the protocol physician within twenty-four (24) hours of modifying drug therapy or within 24-hours of an adverse event, adverse medical reaction or an adverse needle stick. The Board has determined that notifications may be maintained in an electronic medical record (EMR) that is required to be maintained by state or federal law, provided the EMR is accessible to and shared by both the physician and pharmacist.
3. In addition to a MT protocol, pharmacists performing MT services under the Board's jurisdiction must also have a prescription order from a physician authorizing them to provide MT services for the specific patient. The Board has determined that a protocol approved by a hospital's clinical care committee, pharmacy and therapeutics committee or an equivalent hospital reviewing body/committee may be used to initiate pharmacist MT services, provided the protocol is not restricted or limited to MT services within the DHSS licensed premises.<sup>4</sup> By statute, the prescription order/protocol must be initiated or issued by the physician and not a nurse or physician assistant. [§ 338.010.2]
4. Generally, the authorizing physician must review the pharmacist's MT services at least once every three (3) months. For pharmacists providing MT services for, or on behalf of, a licensed hospital, the required review may be conducted by the clinical care committee, the pharmacy and therapeutics committee or by an equivalent hospital reviewing body that includes a Missouri-licensed physician (e.g., the medical staff committee).<sup>4</sup>

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<sup>4</sup> Note: This allowance would also apply to pharmacists providing MT services for, or on behalf of, a state or federally licensed hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility or a habilitation center.

*The above requirements are for services provided under the Board's jurisdiction. Please consult DHSS requirements for services provided under their jurisdiction.*

**BOARD NOTE: WE ARE ASKING THE BOARD TO DISCUSS THE AREAS HIGHLIGHTED ABOVE IN ORANGE. ORANGE AREAS ARE POLICY POSITIONS THAT THE BOARD HAS NOT YET APPROVED.**

## Immunization/Administration of Medication

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Pharmacists immunizing or administering medication outside of the DHSS licensed premises must file a Notification of Intent to immunize and/or administer medication by prescription order with the Board and comply with rules 20 CSR 2220-6.040 and 20 CSR 2220-6.050.

Pharmacists immunizing by protocol are required to notify the authorizing protocol physician within seventy-two (72) hours after immunizing and notify the patient's primary care provider within fourteen (14) days after vaccination, if different. Additionally, pharmacists must notify the protocol physician within twenty-four (24) hours of an adverse event/reaction. Pending future Class-B rules, the Board has determined the required notifications may be documented in a common EMR that is accessible to both the pharmacist and physician. Proof of documentation/notification must be produced on inspection or as requested by the Board.

Licensees should review the Missouri Pharmacy Practice Guide for additional immunization/administration compliance information. The Board also has an Immunization/Administration Checklist available online at <http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization>. Pharmacists immunizing or administering medication within the DHSS licensed hospital premises must comply with DHSS requirements.

## Class-J Shared Services

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Class-B pharmacies engaged in shared services with another Board licensed pharmacy must also have a Class-J pharmacy permit, in addition to their Class-B permit. A Class-J permit is required if a pharmacy will be using, or assisting another pharmacy with:

- Filling or refilling a prescription drug order, or
- Performing or assisting in the performing of any function associated with the dispensing process. This would include drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions for another pharmacy.

Pharmacies may participate in a Class-J shared services arrangement if both pharmacies:

- 1) Have the same owner or have a written contract outlining the shared services to be provided by, and the responsibilities of, each party participating in the contract; and
- 2) Maintain separate pharmacy licenses for each shared services location; and
- 3) Share a common electronic file that allows access to sufficient information necessary or required to fill/refill a prescription drug order. The pharmacies must share a record keeping system that provides real time, on-line access to shared services by both pharmacies.

Class-J pharmacies must also maintain a policy and procedure manual that describes/includes procedures for: (a) how the parties will comply with state/federal requirements (b) identifying the pharmacist responsible for dispensing and counseling, (c) tracking the prescription drug order during each step in the process, (d) maintaining adequate security to protect the confidentiality and integrity of patient information and (e) maintaining a quality assurance program for pharmacy services that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems.

Once again, a Class-J permit is required for both pharmacies engaged in shared services. For example, a Class-B chemotherapy infusion pharmacy receives and fills a patient's prescription from a specialty mail order pharmacy (i.e., a manufacturer's indigent program). A Class-J permit would be required for both the Class-B chemotherapy infusion pharmacy and the specialty mail order pharmacy. Pharmacies may add a classification by filing a [Pharmacy Classification Change Application](#) with the applicable fee.

Transferring prescription information between Class-J pharmacies in a shared services arrangement that share a real-time, on-line database are not considered "prescription transfers" under, and are not subject to the requirements of, 20 CSR 2220-2.120. Other controlled substance laws may apply.

## Record-Keeping

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As a licensed pharmacy, Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. Licensees should review Missouri law and the Missouri Practice Guide for specific requirements. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board.<sup>5</sup>

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<sup>5</sup> Controlled substance records must still be separately maintained/retrievable as required by state/federal law.

## Future Rules

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The Board will be consulting with the Hospital Advisory Committee to develop future Class-B pharmacy rules. Interested parties should monitor the Board's website for meeting information; public comments are welcomed.

## Questions

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Questions regarding activities under DHSS' authority should be addressed to DHSS' Division of Hospital Licensure and Regulation at (573) . Questions regarding the Board's rules or requirements may be addressed to your Inspector or e-mailed to [compliance@pr.mo.gov](mailto:compliance@pr.mo.gov).

**#D11 2016 MISSOURI PHARMACY PRACTICE GUIDE**

- Draft Practice Guide (*For Discussion Purposes*)

**#D12 REVIEW OF NAPLEX/MPJE PASS RATES**

- NABP July 28, 2016 Memo re: NAPLEX Changes
- NABP September 8, 2016 Memo re: NAPLEX waiting periods
- Missouri MPJE Statistical Data



nabp

## National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014  
Tel: 847/391-4406 • Fax: 847/391-4502  
Web Site: [www.nabp.net](http://www.nabp.net)

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: July 28, 2016  
RE: NAPLEX Program Notification

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The National Association of Boards of Pharmacy (NABP) would like to notify the boards of pharmacy regarding the implementation of the upcoming changes to the North American Pharmacist Licensure Examination (NAPLEX) and the Association's efforts to alert candidates with open, active registrations for the current exam.

The NAPLEX program will transition to a new administration model in November 2016, and the upcoming changes were detailed in a memo sent to the member boards on March 3, 2016. Changes to the NAPLEX include an increase in the number of items from 185 to 250, an increase in testing time to six hours, and an increase in the registration fee from \$505 to \$575. In addition, effective November 1, 2016, the NAPLEX waiting period will be 45 days. Candidates must wait at least 45 days to schedule another attempt after obtaining a failing score on the NAPLEX.

Via email, NABP will be notifying candidates with open, active NAPLEX registrations of the following deadlines:

- The last day to take the current NAPLEX is October 22, 2016. Candidates wishing to take the current exam must:
  - Register by October 3, 2016,
  - Be granted eligibility and receive an Authorization to Test, and
  - Schedule and take the exam by October 22, 2016.
- The NAPLEX will not be administered October 24-31, 2016.
- The new NAPLEX will launch on November 1, 2016.

For candidates with open, active registrations who are unable to test by October 22, 2016, their registrations will remain active and they may schedule an appointment to take the new NAPLEX on or after November 1, 2016.

Candidates who graduate in 2017 should not register for the current NAPLEX since they are not eligible to sit for the current exam. Should any such candidates register for the current exam, their record will be closed and a partial refund granted per the NABP refund policy. The

EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

July 28, 2016

Page 2

candidate would then need to register for the new NAPLEX after November 1, 2016, and pay the new fee of \$575.

Detailed information on the changes to the exam and the above deadlines will be published the week of August 1, 2016 on the NABP website (in the NAPLEX section, under Programs) and in the *NAPLEX/MPJE Candidate Registration Bulletin*. This information has also been provided to the schools and colleges of pharmacy.

If there are any questions regarding the updates to the NAPLEX program, please contact Maria Incrocci, competency assessment senior manager, at [mincrocci@nabp.net](mailto:mincrocci@nabp.net) or 847/391-4400.

cc: NABP Executive Committee  
NABP Advisory Committee on Examinations



## National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014

Tel: 847/391-4406 • Fax: 847/391-4502

Web Site: [www.nabp.net](http://www.nabp.net)

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: September 8, 2016  
RE: NAPLEX Waiting Period Policy

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Effective November 1, 2016, the waiting period for the North American Pharmacist Licensure Examination (NAPLEX) will change from the current 91-day waiting period to 45 days. A waiting period is the time between a failed attempt on the NAPLEX and the next scheduled appointment to test. The National Association of Boards of Pharmacy (NABP) Advisory Committee on Examinations and NABP Executive Committee have revised the policy to reduce the waiting period, which also includes a provision that there shall be no more than three (3) attempts to pass the NAPLEX in a twelve (12)-month period. If a candidate fails the NAPLEX three (3) times in a twelve (12)-month period, the candidate shall be subject to eligibility approval by the board of pharmacy (or designated authority) and will not receive an authorization to test until the 12-month time frame has passed.

To reiterate the information in the memo sent to the NABP member boards on July 26, 2016, there shall be no consideration for waivers or the reduction of the waiting period time when the new NAPLEX waiting period becomes effective on November 1, 2016.

If you have any questions regarding the new NAPLEX waiting period, please contact Maria Incrocci, competency assessment senior manager, at [mincrocci@nabp.net](mailto:mincrocci@nabp.net) or 847/391-4426.

cc: NABP Executive Committee  
NABP Advisory Committee on Examinations

**From:** [Grinston, Kimberly](#)  
**To:** [Grinston, Kimberly](#)  
**Subject:** FW: Missouri Question  
**Date:** Friday, October 14, 2016 5:09:11 PM  
**Attachments:** [image001.png](#)

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**From:** Incrocci, Maria [mailto:[mincrocci@nabp.pharmacy](mailto:mincrocci@nabp.pharmacy)]  
**Sent:** Tuesday, October 11, 2016 9:55 AM  
**To:** Grinston, Kimberly  
**Subject:** RE: Missouri Question

Hello Kim

The following table shows five years of data for individuals who graduated from a pharmacy program in MO and took the MO MPJE in the same year. The data spans January through September for each year shown.

Right now, we are looking at a way to convey which competencies in the MPJE seem to be more difficult in terms of performance at a national level. Once we are ready to share that information, I can point you in the right direction.

You may recall that the national pass rate on the MPJE in 2016 for new graduates (shown at the forum last week) was ~86%

	2012	2013	2014	2015	2016
Pass	195	218	207	206	196
Fail	11	10	8	11	42
Total	206	228	215	217	238
Pass Rate	94.66%	95.61%	96.28%	94.93%	82.35%

Let me know if I can assist further and if you will need me for a call in to the board meeting.

Maria

Maria Incrocci, PhD, RPh  
Competency Assessment Senior Manager  
National Association of Boards of Pharmacy  
1600 Feehanville Drive  
Mount Prospect, IL 60056  
O- 847/ 391-4426

### **#D13 STERILE COMPOUNDING SURVEY**

- 2016 Non-Resident Sterile Compounding Survey
- Discussion: Should the Board survey resident sterile compounders?

# Report for 2016 Non-Resident Survey

## 1. Response Counts

Completion Rate:

100%

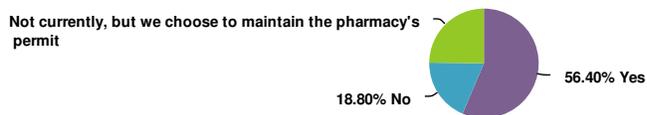


Complete  117

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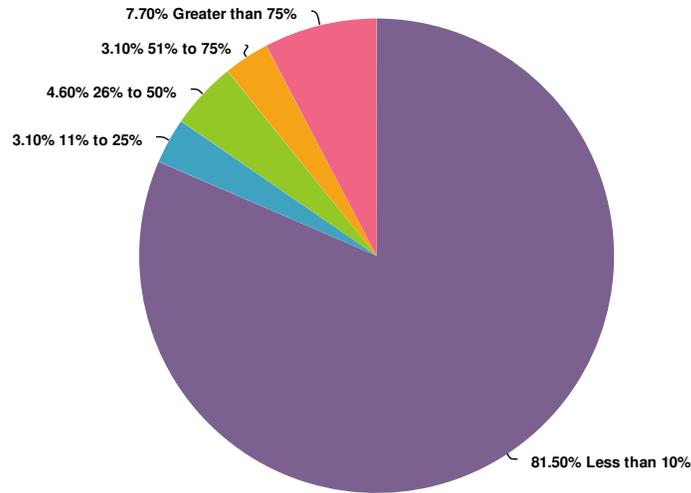
Total 117

### 3. Does the pharmacy compound sterile preparations for Missouri patients



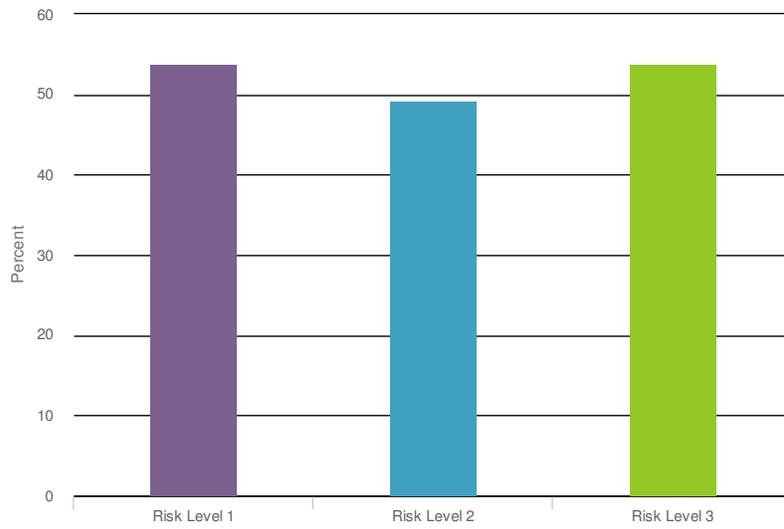
Value	Percent	Count
Yes	56.4%	66
No	18.8%	22
Not currently, but we choose to maintain the pharmacy's Class H permit	24.8%	29
<b>Total</b>		<b>117</b>

4. If yes, what percentage of the pharmacy's business is related to sterile compounding for Missouri patients?



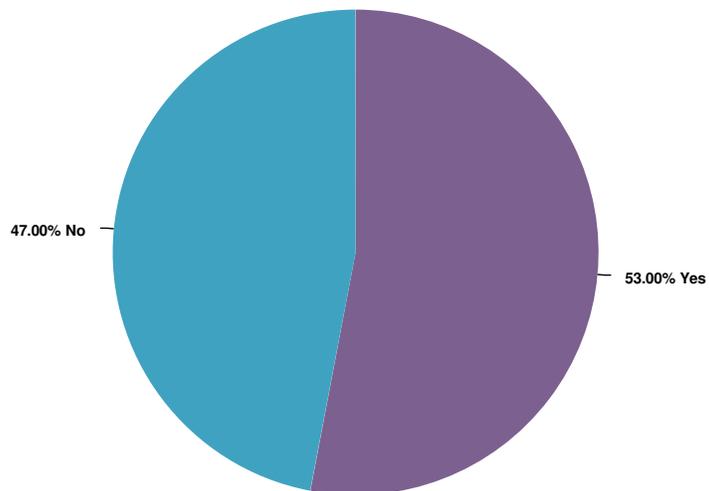
Value	Percent	Count
Less than 10%	81.5%	53
11 to 25%	3.1%	2
26 to 50%	4.6%	3
51 to 75%	3.1%	2
Greater than 75%	7.7%	5
<b>Total</b>		<b>65</b>

5. What type(s) of sterile products does the pharmacy compound for Missouri patients? Check all that apply.



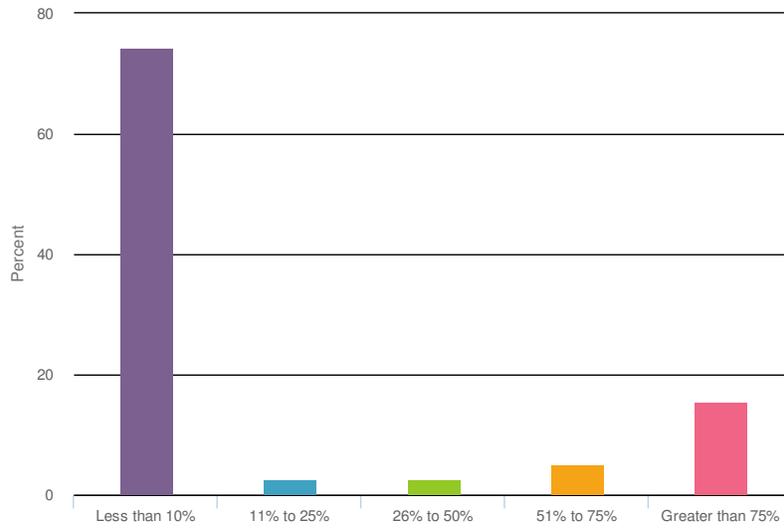
Value	Percent	Count
Risk Level 1	53.8%	35
Risk Level 2	49.2%	32
Risk Level 3	53.8%	35

6. Does the pharmacy compound RISK LEVEL 3 products for Missouri patients?



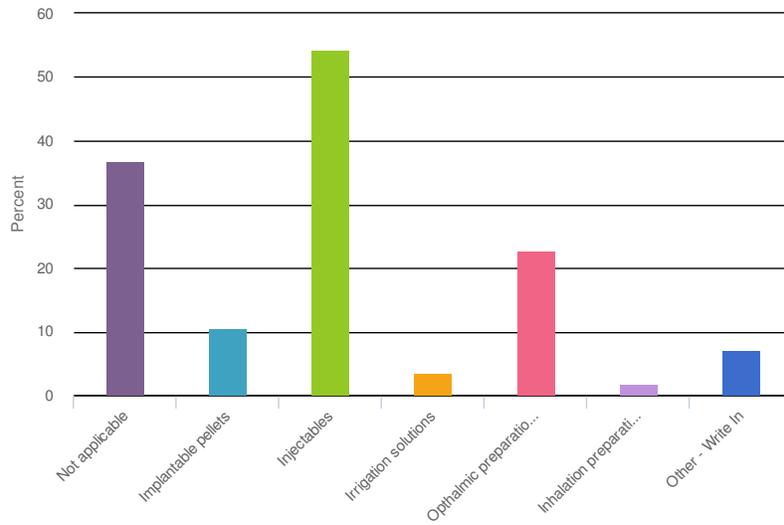
Value	Percent	Count
Yes	53.0%	35
No	47.0%	31
Total		66

7. If yes, what percentage of the pharmacy's business is related to compounding RISK LEVEL 3 products for Missouri patients?



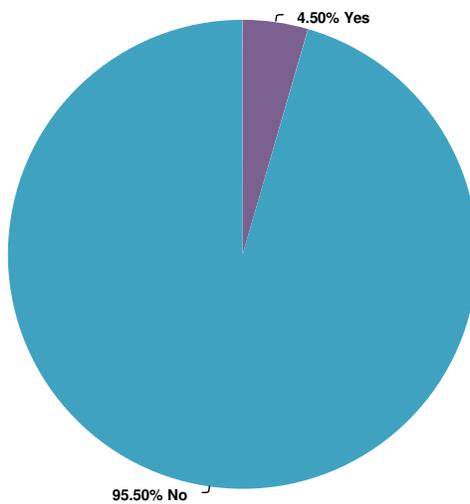
Value	Percent	Count
Less than 10%	74.4%	29
11% to 25%	2.6%	1
26% to 50%	2.6%	1
51% to 75%	5.1%	2
Greater than 75%	15.4%	6

8. What type(s) of RISK LEVEL 3 products does the pharmacy compound for Missouri patients? Check all that apply.



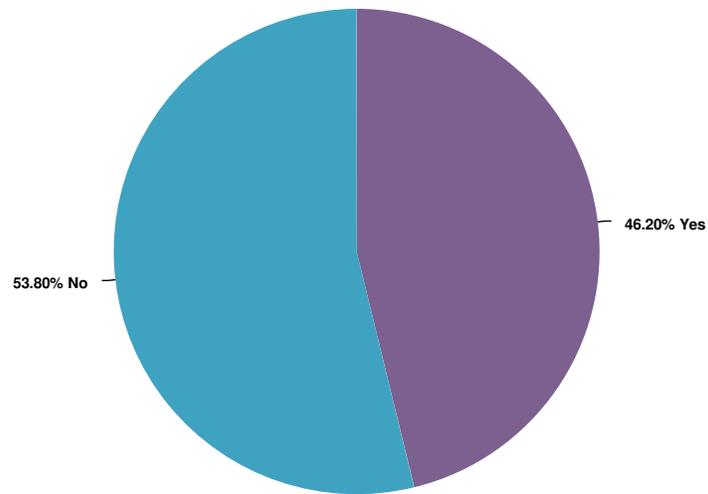
Value	Percent	Count
Not applicable	36.8%	21
Implantable pellets	10.5%	6
Injectables	54.4%	31
Irrigation solutions	3.5%	2
Ophthalmic preparations	22.8%	13
Inhalation preparations	1.8%	1
Other - Write In	7.0%	4

9. Does the pharmacy hold a Missouri Class-J Shares Services permit?



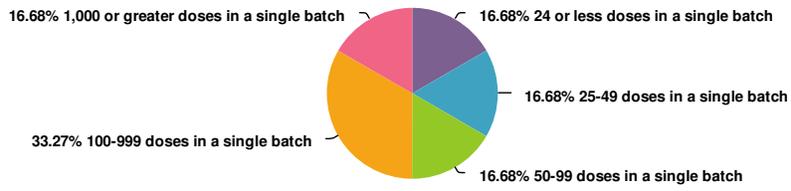
Value	Percent	Count
Yes	4.5%	3
No	95.5%	63
Total		66

10. Are compounded sterile preparations that are made via a batch process dispensed to Missouri patients (e.g., compounding multiple doses for more than one (1) patient)



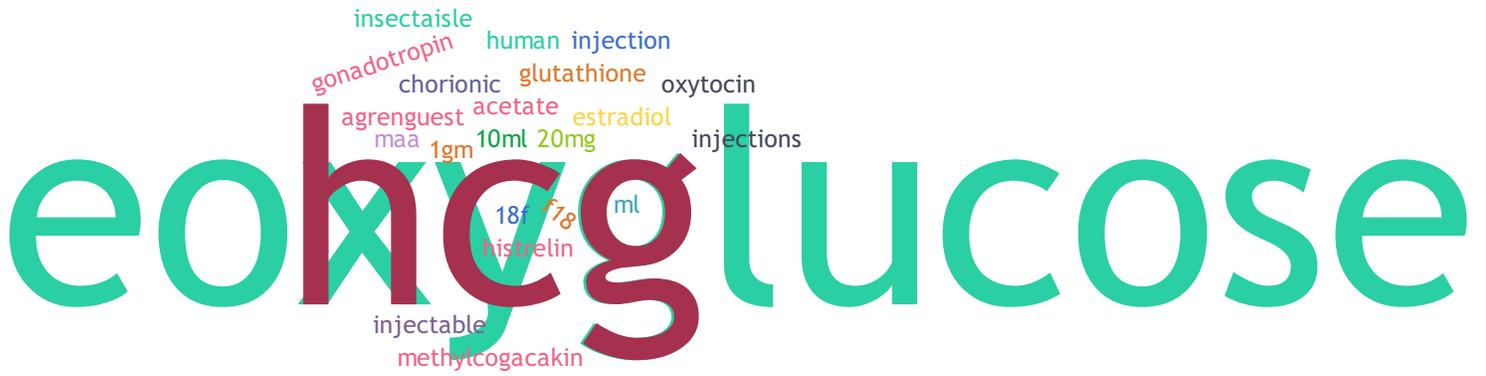
Value	Percent	Count
Yes	46.2%	30
No	53.8%	35
Total		65

11. If "yes", what would be the pharmacy's largest single batch in a typical week?



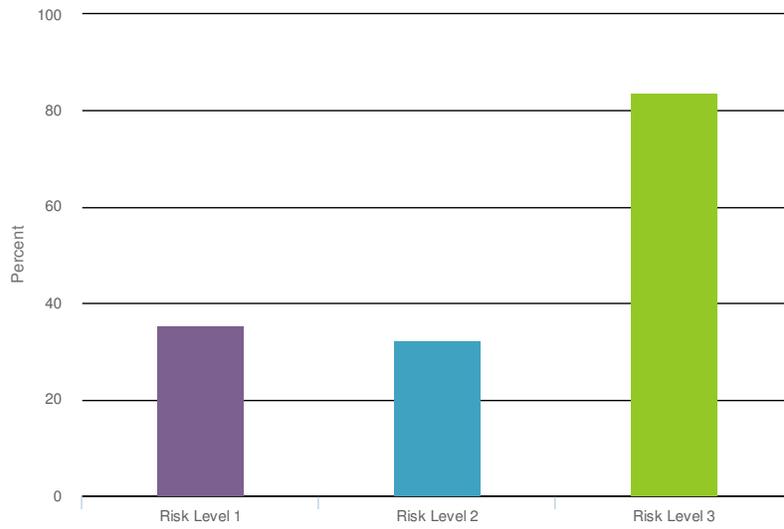
Value	Percent	Count
24 or less doses in a single batch	16.7%	5
25-49 doses in a single batch	16.7%	5
50-99 doses in a single batch	16.7%	5
100-999 doses in a single batch	33.3%	10
1,000 or greater doses in a single batch	16.7%	5
<b>Total</b>		<b>30</b>

12. What drug(s) do you compound in a batch process for Missouri patients?



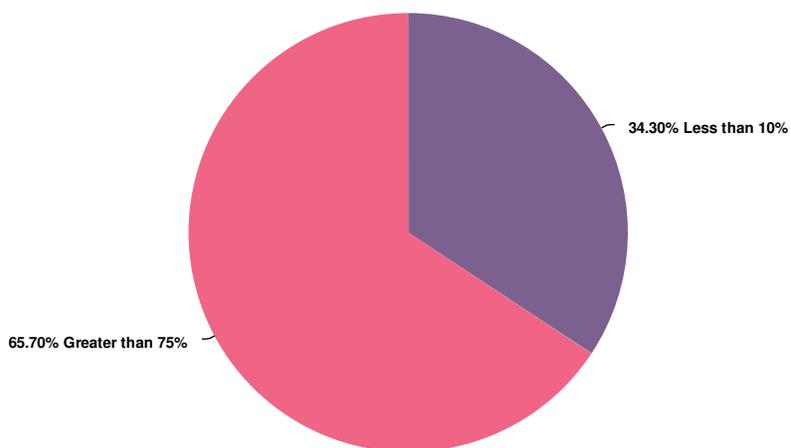
Count	Response
1	18F Sodium Fluoride 18F Fludeoxyglucose
1	Fludeoxyglucose F18 Injection, Sodium Fluoride F18 Injection MAA-Tc99m
1	Glutathione 1gm/10ml syringe methylcogacakin 20mg/ml syringe
1	HCG insectaisle, progesterone, injectable
1	HCG, Testosterone, Vitamin injections, sermorelin
1	Histrelin, Agrenguest, Progesterowe, Estradiol, Oxytocin
1	Human Chorionic Gonadotropin Semorelin Acetate

### 13. What risk level are your batch preparations?



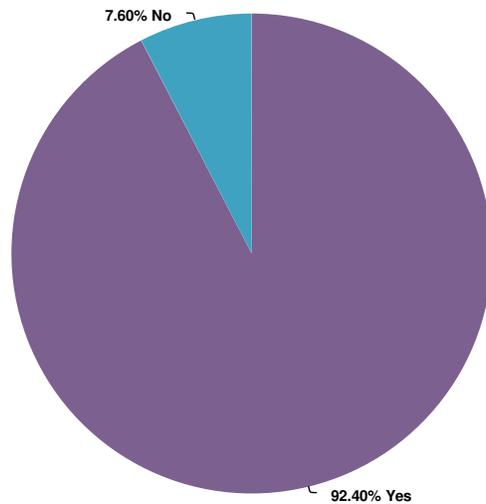
Value	Percent	Count
Risk Level 1	35.5%	11
Risk Level 2	32.3%	10
Risk Level 3	83.9%	26

14. What percentage of your sterile compounded preparations prepared in batch are high risk preparations (this would include non-sterile to sterile preparation)?



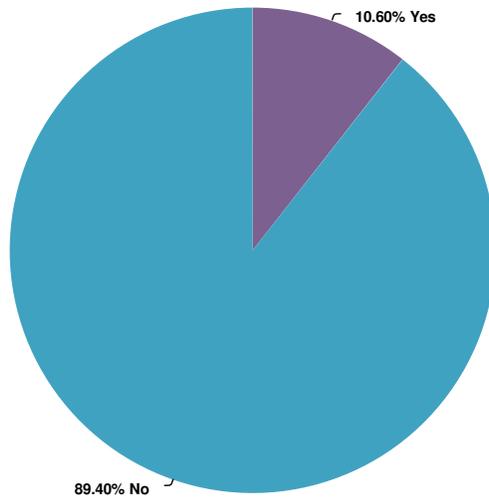
Value	Percent	Count
Less than 10%	34.3%	12
Greater than 75%	65.7%	23
<b>Total</b>		<b>35</b>

15. Is a patient specific prescription required prior to distributing or dispensing a sterile compound into Missouri?



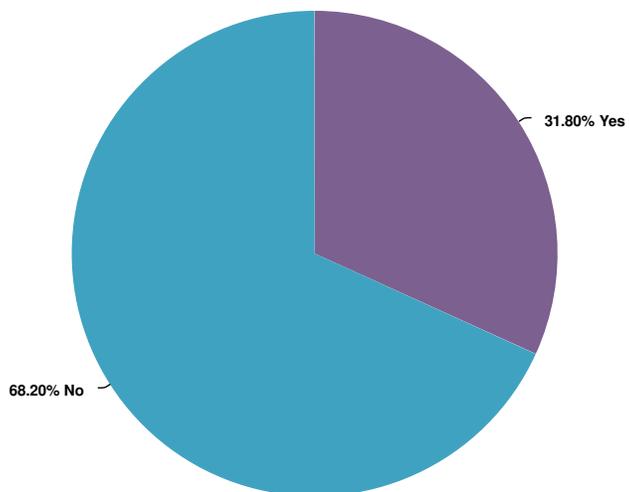
Value	Percent	Count
Yes	92.4%	61
No	7.6%	5
Total		66

16. Are you registered with the FDA as a 503(B) outsourcing facility?



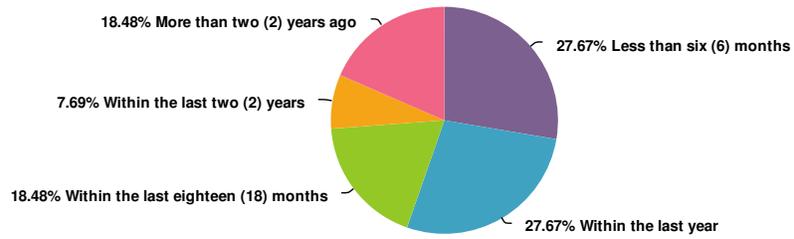
Value	Percent	Count
Yes	10.6%	7
No	89.4%	59
Total		66

17. If you are a registered 503(B) outsourcing facility, are you shipping or do you intend to ship non-patient specific compounds into Missouri?



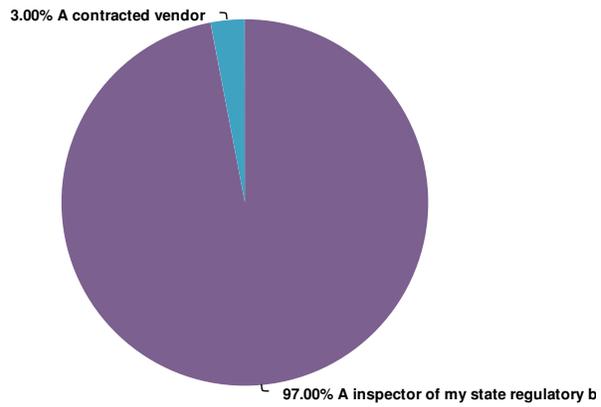
Value	Percent	Count
Yes	31.8%	7
No	68.2%	15
Total		22

18. When was the pharmacy last inspected by your state regulatory authority?



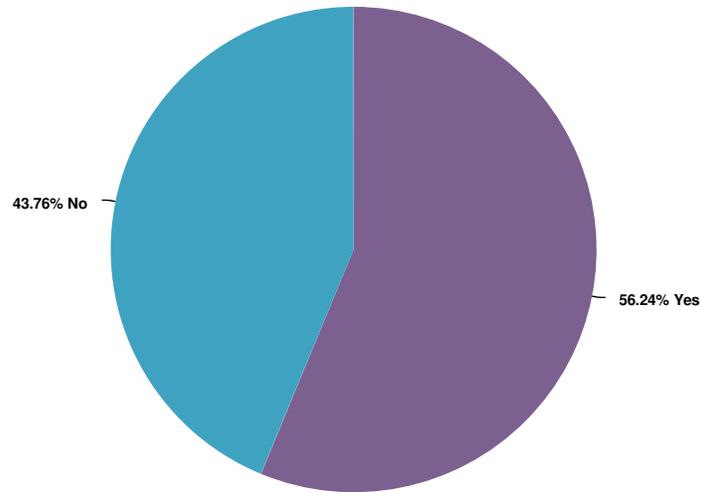
Value	Percent	Count
Less than six (6) months	27.7%	18
Within the last year	27.7%	18
Within the last eighteen (18) months	18.5%	12
Within the last two (2) years	7.7%	5
More than two (2) years ago	18.5%	12
<b>Total</b>		<b>65</b>

19. Was the inspector for your last state regulatory inspection an inspector from the state regulatory board of pharmacy or a contracted vendor?



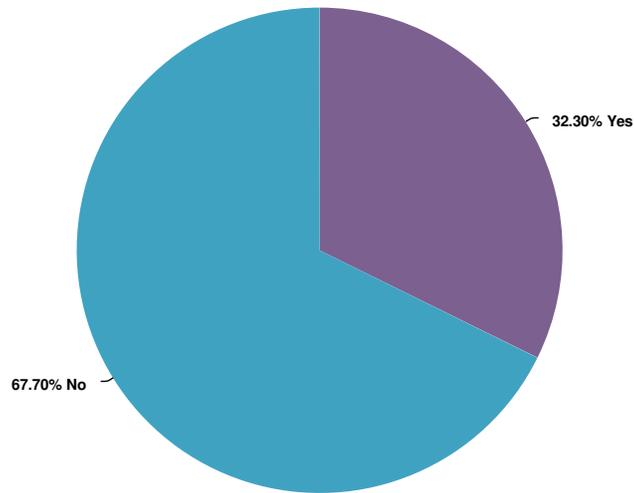
Value	Percent	Count
A inspector of my state regulatory board for pharmacy	97.0%	64
A contracted vendor	3.0%	2
<b>Total</b>		<b>66</b>

20. Has your pharmacy been inspected by a state regulatory board of pharmacy other than the state board of pharmacy where the pharmacy is located (e.g., an inspection by a non-resident state board of pharmacy)?



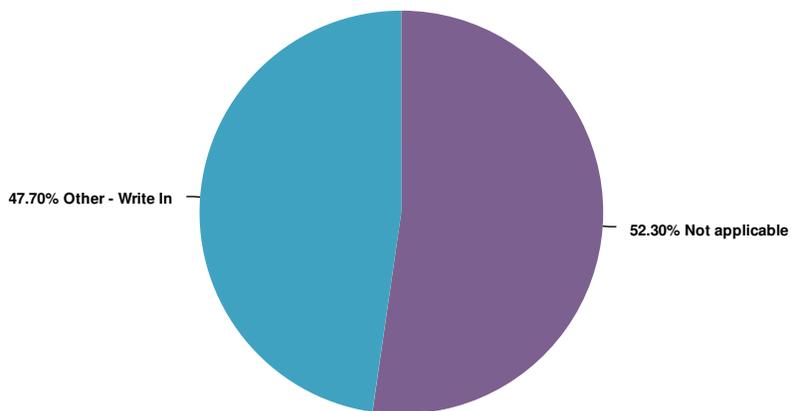
Value	Percent	Count
Yes	56.3%	36
No	43.8%	28
Total		64

21. Has the pharmacy been inspected by the FDA?



Value	Percent	Count
Yes	32.3%	21
No	67.7%	44
Total		65

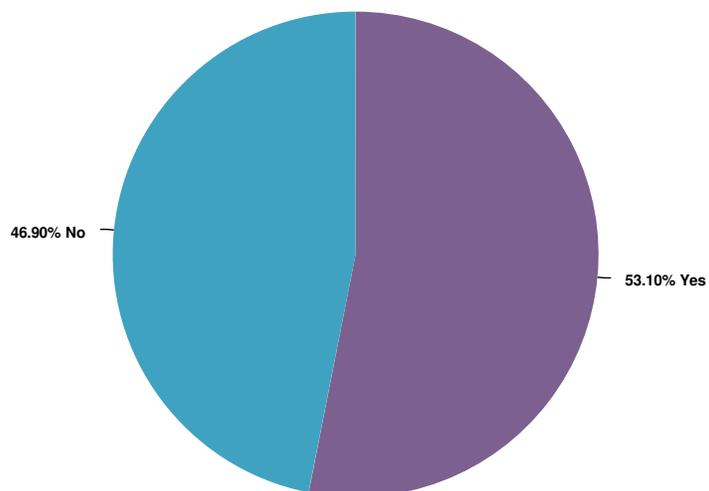
22. If so, when was the pharmacy inspected by the FDA?



Value	Percent	Count
Not applicable	52.3%	23
Other - Write In	47.7%	21
<b>Total</b>		<b>44</b>

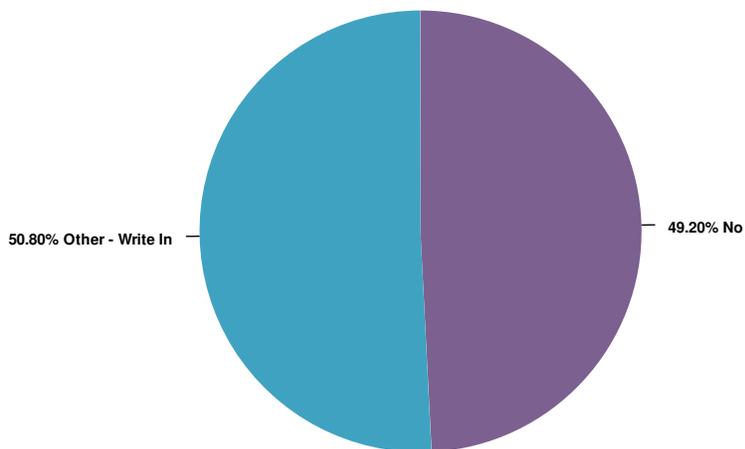
Other - Write In	Count
9-15-15	2
03-01-14	1
04-01-13	1
08-01-03	1
08-2014	1
08-2015	1
1-28-15	1
11-16-15	1
12-16-14	1
12-2014	1
2-11-15	1
4-20-16	1
4-22-15	1
5-22-15	1
6-1-15	1
6-25-13	1
8-11-15	1
8-26-15	1
9-15-14	1
<b>Total</b>	<b>20</b>

23. Did the FDA issue a Form 483 as a result of the inspection?



Value	Percent	Count
Yes	53.1%	17
No	46.9%	15
Total		32

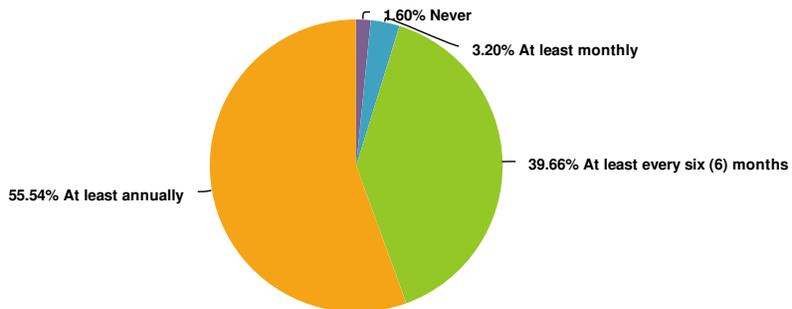
24. Has your pharmacy's sterile compounding activities been inspected by a third party vendor?



Value	Percent	Count
No	49.2%	32
Other - Write In	50.8%	33
<b>Total</b>		<b>65</b>

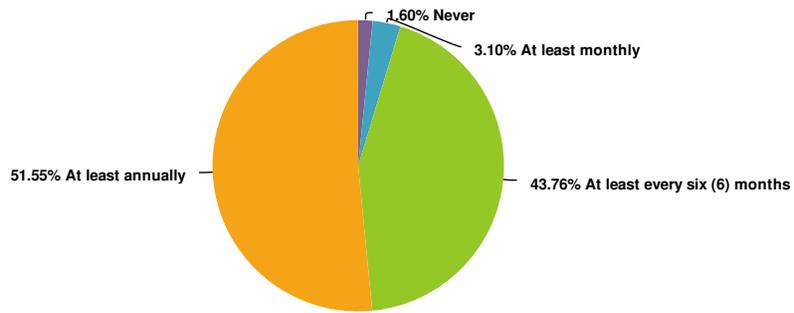
Other - Write In	Count
3-15-15	1
3-5-15	1
5-5-15	1
8-19-15	1
HQAA	1
<b>Total</b>	<b>5</b>

25. How often does the pharmacy require or provide aseptic technique training for technicians?



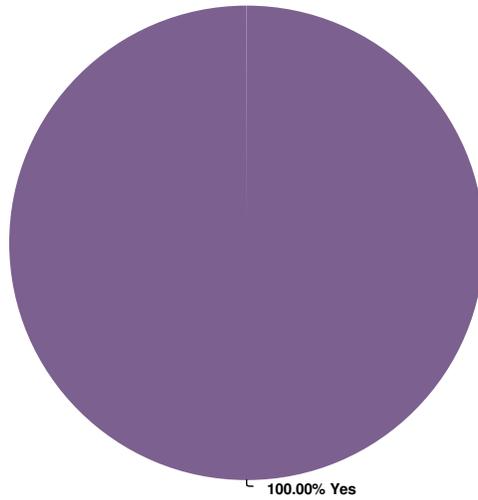
Value	Percent	Count
Never	1.6%	1
At least monthly	3.2%	2
At least every six (6) months	39.7%	25
At least annually	55.6%	35
<b>Total</b>		<b>63</b>

26. How often does the pharmacy require or provide aseptic technique training for technicians?



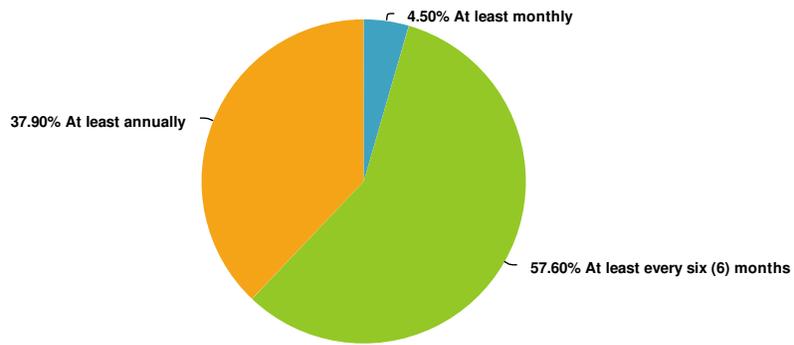
Value	Percent	Count
Never	1.6%	1
At least monthly	3.1%	2
At least every six (6) months	43.8%	28
At least annually	51.6%	33
<b>Total</b>		<b>64</b>

27. Does the pharmacy perform process validations using growth medium to validate aseptic technique?



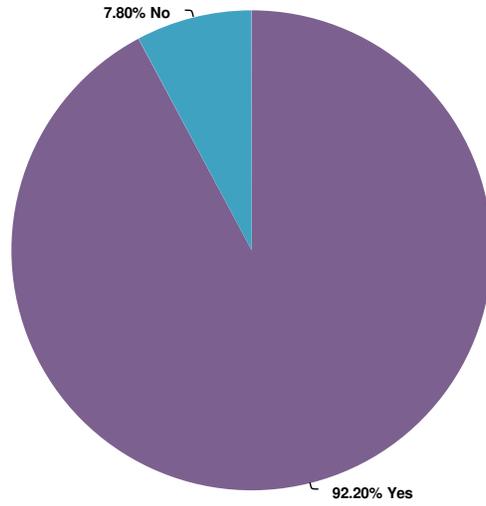
Value	Percent	Count
Yes	100.0%	66
Total		66

28. If yes, how often?



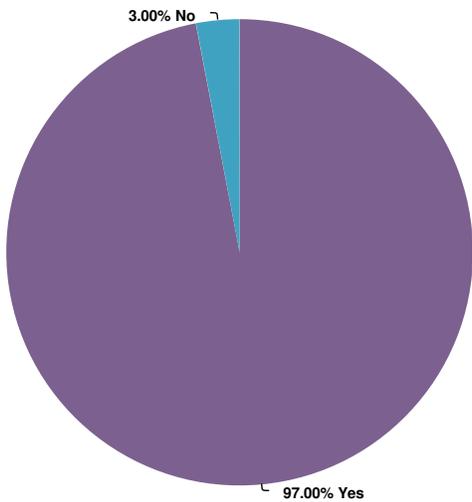
Value	Percent	Count
At least monthly	4.5%	3
At least every six (6) months	57.6%	38
At least annually	37.9%	25
<b>Total</b>		<b>66</b>

29. Is process validation performed for all risk level activities?



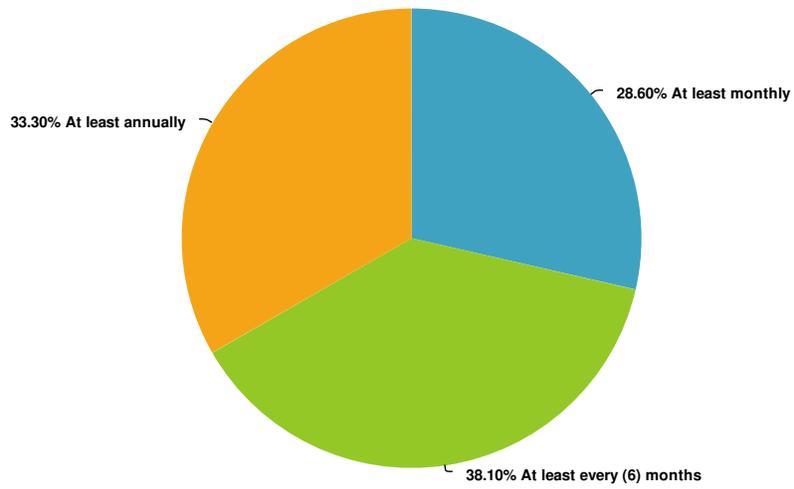
Value	Percent	Count
Yes	92.2%	59
No	7.8%	5
Total		64

30. Does the pharmacy perform glove-fingertip sampling?



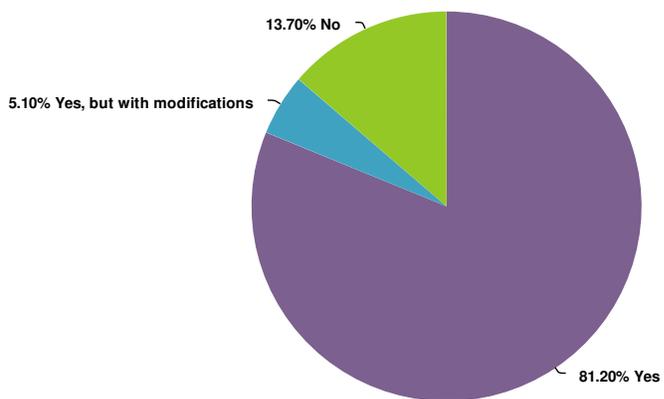
Value	Percent	Count
Yes	97.0%	64
No	3.0%	2
Total		66

31. If yes, how often



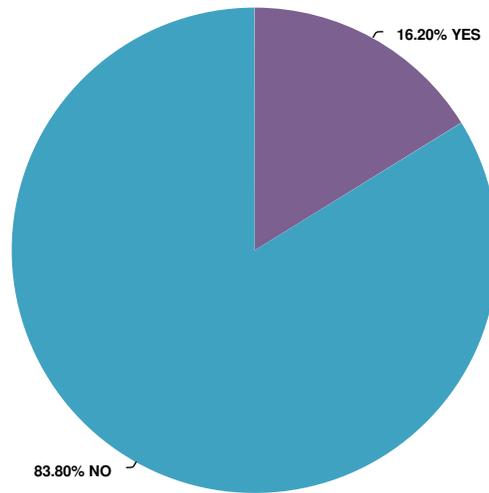
Value	Percent		Count
At least monthly	28.6%		18
At least every (6) months	38.1%		24
At least annually	33.3%		21
<b>Total</b>			<b>63</b>

32. Has your state adopted USP 797?



Value	Percent	Count
Yes	81.2%	95
Yes, but with modifications	5.1%	6
No	13.7%	16
<b>Total</b>		<b>117</b>

### 33.COMMENTS



Value	Percent	Count
YES	16.2%	19
NO	83.8%	98
Total		117

**SECTION E – OPEN**  
**(FOR INFORMATIONAL PURPOSES)**

**#E1 Licensees Presently Under Discipline**

- Pharmacists
- Pharmacy Interns
- Pharmacies
- Drug Distributors
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List

### Licensees Presently Under Disciplinary Order

## Drug Distributor

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
900044/Goetze-Niemer Co., Inc. Goetze-Niemer Co., Inc.	2013-004431	Probation	08/19/2015 02/18/2017
	Probation for eighteen (18) months. Repeat violations of products stored outside of the manufacturer's recommended temperature range. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2010019242/Medisca Inc Medisca Inc	2011-007123	Probation	09/10/2014 09/09/2017
	Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.		
2010034009/Medisca Inc Medisca Inc	2011-007122	Probation	09/10/2014 09/09/2017
	Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.		
900635/Medisca Inc. Medisca Inc.	2011-007093	Probation	09/10/2014 09/09/2017
	Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.		
2012037544/T L Corporation Quick Care Oxygen System	2011-004178	Probation	01/24/2013 01/23/2017
	Restricted license issued on Probation for four (4) years. Operated as a drug distributor without a license. Section 338.055.2(6), RSMo.		

### Licensees Presently Under Disciplinary Order

Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2008027645/Al-Lozi, Ala M			
	2012-007176	Suspension	10/24/2014 11/23/2014
	Suspension for 30 days followed by Probation for five (5) years. Diversion of controlled substances from employer without a valid prescription for herself. Section 338.055.2(5), (13), (15), and (17), RSMo.		
	2012-007176	Probation	11/24/2014 11/23/2019
	Suspension for 30 days followed by Probation for five (5) years. Diversion of controlled substances from employer without a valid prescription for herself. Section 338.055.2(5), (13), (15), and (17), RSMo.		
2005033291/Baehr, Jennifer L			
	2011-000615	Suspension	12/02/2011 12/01/2012
	Suspension for one (1) year followed by Probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use, impaired pharmacist, and pled guilty to Class C felony. Section 338.055.2(1), (2), (5), (6), (13), (15), and (17), RSMo.		
	2011-000615	Probation	12/02/2012 12/01/2017
	Suspension for one (1) year followed by Probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use, impaired pharmacist, and pled guilty to Class C felony. Section 338.055.2(1), (2), (5), (6), (13), (15), and (17), RSMo.		
1999141844/Baker, Jodie Jane			
	2012-007445	Suspension	04/08/2014 04/07/2016
	Two (2) years Suspension followed by three (3) years Probation. Violation of discipline involving failure to submit compliance reports to Board; failure to complete alcohol/drug treatment program and did not submit submit required documentation of such program; failure to call-in daily and did not submit to testing when selected by Board's urinalysis program. Section 338.055.2(5), (6), (13), and (15), RSMo.		
	License expired 10/31/14 suspension tolled for 523 days.		
	2012-007445	Probation	04/08/2016 04/07/2019
	Two (2) years Suspension followed by three (3) years Probation. Violation of discipline involving failure to submit compliance reports to Board; failure to complete alcohol/drug treatment program and did not submit submit required documentation of such program; failure to call-in daily and did not submit to testing when selected by Board's urinalysis program. Section 338.055.2(5), (6), (13), and (15), RSMo.		
	License expired 10/31/14 suspension tolled for 523 days.		
028642/Ballard, Bruce D			
	2014-004079	Probation	10/28/2015 10/27/2017
	Probation for two (2) years. Violation of discipline involving dispensing errors. Section 338.055.2(5), (6), (13), and (15), RSMo.		
045170/Beckett, Abbey C			
	2011-002794	Suspension	03/28/2012 04/26/2012
	Suspended for thirty (30) days followed by Probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from pharmacy for personal use, forged controlled substance prescriptions, failed to timely file loss reports, and entered deferred prosecution agreement regarding charges of Possession of a Controlled Substance, Stealing a Controlled Substance, and Fraudulently Attempting to Obtain a Controlled Substance. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo		
	2011-002794	Probation	04/27/2012 04/26/2017
	Suspended for thirty (30) days followed by Probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from pharmacy for personal use, forged controlled substance prescriptions, failed to timely file loss reports, and entered deferred prosecution agreement regarding charges of Possession of a Controlled Substance, Stealing a Controlled Substance, and Fraudulently Attempting to Obtain a Controlled Substance. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo		
028754/Berding, Dennis J			
	2009-003351	Suspension	01/01/2011 12/31/2011
	Suspension for one (1) year followed by probation for five (5) years. Violation of discipline involving failure to timely take and pass jurisprudence exam, and engaged in the practice of pharmacy while his pharmacist license was suspended. Section 338.055.2(5) and (6), RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
028754/Berding, Dennis J	2009-003351	Probation	01/01/2012 12/31/2016
	Suspension for one (1) year followed by probation for five (5) years. Violation of discipline involving failure to timely take and pass jurisprudence exam, and engaged in the practice of pharmacy while his pharmacist license was suspended. Section 338.055.2(5) and (6), RSMo.		
043330/Berger, Randall M	2008-007505	Suspension	02/25/2011 10/31/2012
	Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.		
	LICENSE EXPIRED 10/31/12, SUSPENSION TOLLED TILL RENEWS--1382 DAYS		
	2008-007505	Suspension	07/29/2014 11/23/2015
	Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.		
	LICENSE EXPIRED 10/31/12, SUSPENSION TOLLED 10/31/12 to 7/28/14, SUSPENSION STARTED AGAIN 7/29/14 WHEN RENEWED. 482 SUSPENSION DAYS REMAIN.		
	2008-007505	Probation	11/24/2015 11/23/2020
	Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.		
2003026181/Broadbent, Carmen K	2014-007296	Probation	03/07/2015 03/06/2018
	Probation for three (3) years. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
027483/Buntin, William R	2011-002696	Suspension	07/01/2012 09/30/2012
	Suspended for three (3) months followed by Probation for five (5) years. While pharmacist-in-charge, violation of discipline involving outdated drugs in pharmacy, controlled substance not included in controlled substance inventory, failure to timely respond to inspection compliance notice, compounding log and product label did not contain active/therapeutic ingredients for a compounded product, expired license displayed, sold pseudoephedrine products without a current Methamphetamine Epidemic Self-Certification, failed to maintain updated electronic record of controlled substance shipments. Section 338.055.2(5), (6), (13), and (15), RSMo.		
	2011-002696	Probation	10/01/2012 09/30/2017
	Suspended for three (3) months followed by Probation for five (5) years. While pharmacist-in-charge, violation of discipline involving outdated drugs in pharmacy, controlled substance not included in controlled substance inventory, failure to timely respond to inspection compliance notice, compounding log and product label did not contain active/therapeutic ingredients for a compounded product, expired license displayed, sold pseudoephedrine products without a current Methamphetamine Epidemic Self-Certification, failed to maintain updated electronic record of controlled substance shipments. Section 338.055.2(5), (6), (13), and (15), RSMo.		
044686/Crader, Jodi L	2010-004854	Suspension	10/13/2011 07/12/2012
	Suspended for nine (9) months followed by probation for five (5) years. Operated a vehicle while under the influence of drugs, practiced pharmacy while impaired, abused controlled and non-controlled drugs by taking the medications more frequently than prescribed, and had same drug filled on same day at two different pharmacies. Section 338.055.2(1), (5), (13), (15), and (17), RSMo		

### Licensees Presently Under Disciplinary Order

Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
044686/Crader, Jodi L	2010-004854	Probation	07/13/2012 07/12/2017
	Suspended for nine (9) months followed by probation for five (5) years. Operated a vehicle while under the influence of drugs, practiced pharmacy while impaired, abused controlled and non-controlled drugs by taking the medications more frequently than prescribed, and had same drug filled on same day at two different pharmacies. Section 338.055.2(1), (5), (13), (15), and (17), RSMo		
042911/Drake, Mary V	2011-006865	Suspension	01/03/2015 01/03/2015
	Sixty (60) days suspension--credit given for suspension served under Illinois disciplinary order, followed by Probation for five (5) years. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.		
	2011-006865	Probation	01/03/2015 01/02/2020
	Sixty (60) days suspension--credit given for suspension served under Illinois disciplinary order, followed by Probation for five (5) years. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2001018151/Floyd, Joseph Lyn	2012-002486	Revoked	02/26/2016 02/25/2023
	Revoked, and cannot reapply for seven (7) years. Misappropriated controlled substances from employers, incorrectly dispensed controlled and non-controlled substances, dispensed improperly labeled prescriptions, and use of controlled substances to the extent it impaired his ability to function as a pharmacist. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.		
2010026492/Gates, Allison C	2014-004938	Probation	07/09/2016 07/08/2021
	Five (5) years probation. Admitted to being under the influence of alcohol while practicing. Section 338.055.2(2), (5), and, (13), RSMo.		
042059/Greaves, Mark A, Sr	2015-007038	Voluntary Surrender	07/27/2016 07/26/2021
	Voluntary surrender of license, and cannot reapply for five (5) years. Admitted to diversion of controlled substances from employer. Pleaded guilty to violating 21 U.S.C.843 (a)(3). Section 338.055.2 (5), (6), (13), (15), and (17) RSMo.		
042363/Gregory, Jeffrey M	2008-001887	Revoked	12/08/2010 12/07/2017
	Pharmacist license revoked and cannot reapply for seven (7) years. Pled guilty to one felony count of Adulteration of a Commercial Product. Section 338.065, RSMo.		
040707/Griggs, Douglas E	2011-000277	Suspension	03/29/2012 09/28/2012
	Suspended for six (6) months followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal use, impaired. Section 338.055.2(5), (6), (13), and (15), RSMo.		
	2011-000277	Probation	09/29/2012 09/28/2017
	Suspended for six (6) months followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal use, impaired. Section 338.055.2(5), (6), (13), and (15), RSMo.		
028136/Grove, Donald W, Jr	2011-005767	Probation	05/07/2014 05/06/2017
	Probation for three (3) years. As pharmacist-in-charge, insufficient and incorrect compounding logs, misbranded by incorrectly labeling compounded drug products, dispensed adulterated drug products made with expired ingredients, failed to verify expiration dates, and failed to properly supervise personnel to assure compliance with laws/regulations. Section 338.055.2(5), (6), (13), and (15), RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
045232/Harris, Craig	2014-006550	Probation	01/22/2016 01/21/2019
	Probation for three (3) years. As pharmacist-in-charge, no annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; pharmacy permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.		
029716/Hinson, Donald M	2008-002070	Suspension	12/22/2008 12/14/2009
	Temporary suspension following expedited hearing. Extended use of methamphetamine, unlawful dispensing of controlled substances, and impaired professional judgment demonstrated by these acts constitutes a clear and present danger to patients. Section 338.055, RSMo.		
	2008-002070	Revoked	12/15/2009 12/14/2016
	Revoked, cannot reapply for seven (7) years. Extended use of methamphetamine, unlawful dispensing of controlled substances, and impaired professional judgment demonstrated by these acts constitutes a clear and present danger to patients. Section 338.055.2 (1), (2), (5), (13), (15), and (17), RSMo.		
043616/Hoehn, Patricia A	2013-000128	Probation	08/11/2016 08/10/2020
	Probation for five (5) years. Pleaded guilty to the Class D Felony of using "False Statements Relating to Health Care Matters" in the United States District Court, Eastern District of Missouri. Section 338.065.1, RSMo.		
040431/Hollaway, Daniel J	2008-002040	Suspension	09/12/2012 09/11/2014
	Suspension for two (2) years followed by Probation for five (5) years. As owner and pharmacist-in-charge, misappropriated controlled substances from pharmacy; dispensed controlled substances to himself without a prescription, without proper labeling and without directions. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
	2008-002040	Probation	09/12/2014 09/11/2019
	Suspension for two (2) years followed by Probation for five (5) years. As owner and pharmacist-in-charge, misappropriated controlled substances from pharmacy; dispensed controlled substances to himself without a prescription, without proper labeling and without directions. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
2004034762/Horsman, Joshua P	2010-007303	Suspension	07/22/2014 08/04/2014
	Suspension for two (2) weeks followed by Probation for five (5) years. Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.		
	2010-007303	Probation	08/05/2014 08/04/2019
	Suspension for two (2) weeks followed by Probation for five (5) years. Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.		
2013038703/Huning, Grant Martin	2015-001117	Voluntary Surrender	07/26/2016 07/25/2023
	Voluntary surrender of license, and cannot reapply for seven (7) years. Admitted to diversion of controlled substances from employer; adulterated drugs. Pleaded guilty to a Class C felony of tampering with consumer products. Section 338.055.2(1), (5), (6), (13), (15), and (17) RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2012013212/Jackson, Hillary A			
	2014-000525	Suspension	01/30/2015 12/08/2015
	Administrative Hearing Commission granted temporary authority to suspend for one (1) year due to misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, consumed controlled substance without a prescription while working as a pharmacist. Section 338.055.4 and .5, RSMo.		
	See Suspension/Probation effective 12/8/15.		
	2014-000525	Suspension	12/08/2015 12/07/2017
	Suspension for two (2) years followed by Probation for five (5) years. Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
	2014-000525	Probation	12/08/2017 12/07/2022
	Suspension for two (2) years followed by Probation for five (5) years. Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
045077/Jones, Michael T			
	2013-006818	Suspension	06/21/2016 06/20/2019
	Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to a felony regarding making false statements to federal officials. Section 338.065, RSMo.		
	2013-006818	Probation	06/21/2019 06/20/2024
	Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to a felony regarding making false statements to federal officials. Section 338.065, RSMo.		
026334/Kammer, M D			
	2009-004608	Probation	01/19/2012 01/18/2017
	Probation for five (5) years. As pharmacist-in-charge, drugs received from non-wholesale, unlicensed drug distributors; failed to complete DEA CII order forms; prescriptions filled for another pharmacy without Class J license; failed to keep complete acquisition, purchase and distribution records; and CII cabinet not properly locked. Section 338.055.2(5), (6), (10), (13), and (15), RSMo.		
040031/Kessler, Timothy E			
	2010-001357	Suspension	06/22/2011 06/21/2013
	Suspension for two (2) years followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal consumption, falsified inventory records to cover up his misappropriation. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.		
	2010-001357	Probation	06/22/2013 06/21/2018
	Suspension for two (2) years followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal consumption, falsified inventory records to cover up his misappropriation. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.		
043358/Kimbel, Craig M			
	2008-000979	Suspension	04/26/2010 04/25/2013
	Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to three felony counts of Fraudulently Attempting to Obtain A Controlled Substance. Section 338.065.1, RSMo.		
	2008-000979	Probation	04/26/2013 04/26/2018
	Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to three felony counts of Fraudulently Attempting to Obtain A Controlled Substance. Section 338.065.1, RSMo.		
041747/Kozlowski, Jean M			
	2012-003316	Probation	10/24/2014 10/23/2016
	Probation for two (2) years. Dispensed a legend drug product without a valid, patient specific prescription. Section 338.055.2(5), (13), and (15), RSMo.		

### Licensees Presently Under Disciplinary Order

Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2005000313/Krieg, Shannon M	2014-003733	Probation	12/08/2015 03/22/2018
	Two (2) additional years of probation. Violation of discipline, tested positive for marijuana, failed to call-in daily to drug testing, and submitted diluted urinalysis samples. Section 338.055.2(5), (6), (13), and (15), RSMo		
2009025376/Law, Amanda L	2013-000992	Probation	05/01/2016 04/30/2021
	Probation for five (5) years effective 5/1/2016. Ingested a controlled substance obtained from employer without a valid prescription; pled guilty to felony possession of a controlled, then withdrew guilty plea following completion of drug court. Section 338.055.2(2), (5), (13), (15), and (17), RSMo.		
2004031557/Lindsey, Mika Lynn	2014-005282	Probation	05/23/2016 05/22/2021
	Probation for five (5) years. Found guilty, or entered a plea of guilty or nolo contendere to selling pseudoephedrine without proper certification. Section 338.055.2 (5), (6), (13), and (15) RSMo.		
2001018155/Lowe, Teresa Ann	2014-004084	Probation	05/17/2016 05/16/2018
	Probation for two (2) years. Dispensing errors, Section 338.055.2 (5) and (13) RSMo.		
027646/Magee, Patrick E	2007-005181	Probation	08/02/2012 08/01/2017
	Probation for five (5) years. Tested positive for controlled substances, did not have valid prescription(s), alcohol addiction. Section 338.055.2(5), (13), (15), and (17), RSMo.		
2007019763/Mawuenyega, Rebecca	2010-001256	Probation	05/08/2014 05/07/2017
	Probation for three (3) years. Dispensing errors, failed to identify controlled substances and amounts returned to the hospital pharmacy and failed to destroy them in a manner that they were beyond reclamation, entered hospital IV room/sterile products area without appropriate garbing, misbranding due to medications dispensed in containers bearing incorrect information,. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2005007845/Maxwell, Rhonda L	2014-007574	Probation	08/11/2016 08/10/2019
	Probation for three (3) years. As Pharmacist-in-Charge, failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor; 2 of which were written and filled for Maxwell. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system. misbranding; and record keeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.		
028380/Middleton, Darryl K	2014-002317	Probation	01/06/2016 01/05/2019
	Probation for three (3) years. As pharmacist-in-charge, created and filled a prescription without prescriber authorization for himself to be used for his pet, misbranding and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
042307/Mitchell, Brian	2012-007516	Revoked	11/11/2015 11/10/2020
	Revoked, cannot reapply for five (5) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.065, RSMo.		

### Licensees Presently Under Disciplinary Order

Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
028332/Morris, Lynn A	2014-007286	Probation	04/17/2015 04/16/2018
	Probation for three (3) years. Allowed employees to obtain non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; dispensed prescriptions without doctor authorization; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
029418/Nippes, Jeffrey K	2012-000064	Revoked	05/31/2013 05/31/2020
	Revoked, cannot reapply for seven (7) years. Impaired pharmacist; misappropriated controlled substances from employer for personal consumption; pled guilty to one count of theft/stealing. Section 338.055.2(1), (2), (5), (13), (15), and (17), RSMo.		
028845/Nyberg, Dwight K, Jr	2012-003950	Probation	01/22/2016 01/21/2021
	Probation for five (5) years. As pharmacist-in-charge, diversion of controlled substances for personal use without a valid, patient specific prescription. Section 338.055.2(5), (13), (15), and (17), RSMo.		
	VOLUNTARY SURRENDER OF LICENSE EFFECTIVE 1/21/16		
2000148445/Ori, Lee Eric	2013-006282	Probation	07/26/2016 07/25/2019
	Three (3) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and record keeping violations. Section 338.055.2 (4), (5), (6), (13), and (15), RSMo.		
2010027151/Ostropolkiy, Artem	2011-005290	Probation	06/14/2014 06/13/2017
	Probation for three (3) years. Dispensed unauthorized refills. Section 338.055.2(5), (13), and (15), RSMo.		
2000148345/Owens, Anthony	2011-002793	Suspension	07/10/2012 08/09/2012
	Suspension for thirty (30) days followed by Probation for five (5) years. Possessed and consumed cocaine. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.		
	2011-002793	Probation	08/10/2012 08/09/2017
	Suspension for thirty (30) days followed by Probation for five (5) years. Possessed and consumed cocaine. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.		
042773/Palans, Andrew G	2014-005634	Probation	08/12/2016 08/11/2019
	Probation for three (3) years. As Pharmacist-in-Charge, dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Section 338.055.2 (5) (6), and (13), RSMo.		
044098/Pollard, William L, Jr	2008-006917	Revoked	10/26/2009 10/25/2016
	Revoked, cannot reapply for seven (7) years. Violation of discipline, tested positive for prescription drugs for which he did not have valid prescriptions, diluted/attempted to dilute urine samples, failed to report to the Board as required, misappropriated controlled substances from employer for personal consumption, created fictitious prescriptions for current patients and then deleted records from the computer system, created and filled controlled substance prescriptions for fictitious patients and then purchased said prescriptions for personal use. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2006035339/Pomaville, Kerri L	2008-003342	Probation	06/02/2012 06/01/2017
	Probation for five (5) years. While pharmacist-in-charge, took prescriptions, including controlled substances, from employer without first paying for them and without following proper release procedures. Section 338.055.2(5), (6), and (13), RSMo.		
2009011857/Radtke, Amanda A	2012-005409	Revoked	02/26/2016 02/25/2023
	Revoked, cannot reapply for seven (7) years. Misappropriated controlled substances from employers; created, forged and dispensed prescriptions that were not authorized and were not dispensed to real patients and either removed them for her own possession or provided them to unknown individuals. Section 338.055.2(5), (6), (13), and (15), RSMo.		
029924/Richardson, Mary R	2013-004480	Revoked	02/28/2014 02/27/2021
	Revoked and cannot reapply for seven (7) years. Violation of discipline regarding failure to comply with Kansas Committee on Impaired Pharmacy Practice program, failure to enroll/activate FirstLab account, failure to submit documentation for a chemical dependency evaluation/program and documentation of support group attendance, and failure to submit compliance reports to the Board. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
2001028180/Ross, Clintin Z	2013-002254	Suspension	11/11/2015 11/10/2016
	Suspension for one (1) year followed by Probation for five (5) years. Pled guilty to two felony counts of stealing a controlled substance, illegally removed controlled substances from employers. Section 338.055.2(5), (13), and (15), and Section 338.065, RSMo.		
	2013-002254	Probation	11/11/2016 11/10/2021
	Suspension for one (1) year followed by Probation for five (5) years. Pled guilty to two counts of stealing a controlled substance, illegally removed controlled substances from employers. Section 338.055.2(5), (13), and (15), and Section 338.065, RSMo.		
041385/Satterfield, Ronald D	2012-001910	Probation	06/26/2013 06/25/2018
	Probation for five (5) years. Dispensed legend and controlled substance prescriptions to himself without valid prescriptions, early refills, and misbranding. Section 338.055.2(5), (13), (15), and (17), RSMo.		
2009021440/Schreiner, Ashley Irene	2011-006494	Probation	08/12/2015 08/11/2017
	Probation for two (2) years. As pharmacist-in-charge, created controlled substance prescriptions not authorized by a physician; dispensed controlled substance prescription to an unknown person without a valid, patient specific prescription; and failed to supervise pharmacy personnel to assure full compliance with state/federal law/regulations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2002022650/Stark, Kristina L	2011-004395	Revoked	03/02/2012 03/02/2019
	Revoked and cannot reapply for seven (7) years. Violation of discipline involving failure to return licenses to Board office, failure to submit 6-month compliance reports, failure to submit to urinalysis testing, failure to complete alcohol/drug treatment program requirements, and failure to obtain mental health evaluation. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.		
2013026251/Steele, Cody Ross	2014-007462	Probation	02/12/2016 02/11/2017
	Probation for one (1) year. Dispensing errors, one of which resulted in patient death. Section 338.055.2(5) and (13), RSMo.		

### Licenses Presently Under Disciplinary Order

## Pharmacist

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2011019651/Taylor, William E	2014-007297	Probation	04/23/2015 04/22/2017
	Probation for two (2) years. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2011032868/Thompson, Timothy Eugene	2014-005340	Revoked	03/07/2015 03/06/2022
	Revoked and cannot reapply for seven (7) years. Violation of discipline, removed controlled substances from employer pharmacy without a valid prescription and for which he did not pay; did not provide employer copy of Settlement Agreement. Section 338.055.2(5), (6), (13), and (15), RSMo.		
042316/Wagenknecht, Mark A	2010-006399	Suspension	03/15/2011 03/14/2013
	Suspension for two (2) years, followed by Probation for five (5) years. Violation of discipline. Chemically dependent, repeatedly failed to call into Board's urinalysis testing program, failed to provide urine samples when requested. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.		
	2010-006399	Probation	03/15/2013 03/14/2018
	Suspension for two (2) years, followed by Probation for five (5) years. Violation of discipline. Chemically dependent, repeatedly failed to call into Board's urinalysis testing program, failed to provide urine samples when requested. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.		
028605/Walker, Michael L	2013-004642	Voluntary Surrender	07/08/2014 07/07/2021
	Voluntary Surrender of license, cannot reapply for seven (7) years. Second violation of discipline; failure to take, maintain adequate records, and provide proof to the Board of continuing education hours; and refused to pay delinquent CE fee.		
044753/Welch, Shannon T	2008-001343	Suspension	01/03/2012 07/02/2012
	Suspension for six (6) months followed by Probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use without a prescription, impaired pharmacist. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.		
	2008-001343	Probation	07/03/2012 07/02/2017
	Suspension for six (6) months followed by Probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use without a prescription, impaired pharmacist. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.		
029907/Williams, James H, Jr	2014-003538	Probation	09/15/2016 09/14/2021
	Probation for five (5) years. Disciplinary action in Kansas relating to diversion of controlled substances for personal use. Section 338.055.2 (1), (5), (13), (15) and (17), RSMo.		
2005007715/Young-Guffey, Wendy S	2010-007974	Revoked	10/13/2011 10/12/2018
	Revoked and cannot reapply for seven (7) years. Violation of discipline involving expired license, failed to submit compliance reports, failed to comply with urinalysis testing program requirements, failed to take/pass jurisprudence exam, and failed to participate in alcohol/drug and mental health treatment programs. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacy

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
2011012258/Care Pharmacy LLC Care Pharmacy LLC	2011-005302	Revoked	07/31/2015 07/30/2022
	Revoked and cannot reapply for seven (7) years. Technician dispensing without a pharmacist on duty; dispensing controlled substances without a written prescription, and prescription error. Section 338.055.2(5) for incompetency, misconduct dishonesty and misrepresentation, (6), (13), and (15), RSMo.		
2011002754/Niemann Foods Inc County Market Pharmacy 375	2015-006030	Probation	05/13/2016 05/12/2018
	Probation for two (2) years. Failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Pharmacists verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor. Employees created prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2015043696/Missouri CVS Pharmacy, LLC CVS/pharmacy #16845	2015-007403	Probation	02/19/2016 02/21/2017
	Restricted permit issued on Probation until 2/21/17. Previous owner disciplined for loss of controlled substances and failure to provide adequate security controls to prevent employee theft of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2000150222/GWL, Inc. Economy Drug	2014-000233	Probation	10/24/2014 10/23/2017
	Probation for three (3) years. Pharmacy permit did not include Class H sterile compounding classification; distributed compounded drugs for other than individual patient by prescription; and failed to perform testing on risk level 3 products dispensed into Missouri. Section 338.055.2(6) and (13), RSMo.		
2014002635/Entirelypets Pharmacy LLC Entirelypets Pharmacy LLC	2013-004667	Probation	01/28/2014 10/21/2017
	Restricted pharmacy permit issued on Probation until October 21, 2017. Disciplinary action in another state regarding practicing without a permit to do so and had dispensed prescription drugs to consumers without a good faith veterinarian examination. Section 338.055.2(8), RSMo.		
003475/Family Pharmacy Inc. Family Pharmacy	2014-007287	Probation	04/17/2015 04/16/2018
	Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2002026762/Lynn A. Morris, RPh. Family Pharmacy	2014-007289	Probation	04/17/2015 04/16/2018
	Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2007028926/Family Pharmacy of Missouri LLC Family Pharmacy #5	2014-007288	Probation	04/17/2015 04/16/2018
	Probation for three (3) years. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		

### Licensees Presently Under Disciplinary Order

## Pharmacy

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
005915/Grove Professional Pharmacy Inc Grove Pharmacy-Home Infusion Division	2013-006265	Probation	08/13/2016 08/12/2018
	Probation for two (2) years. Dispensed compounded products to practitioners for office use and for administration on persons other than or in addition to the prescribed patient. Dispensed drugs under prescriptions which did not contain the name of patients who were prescribed the drugs. Section 338.055.2 (6), (13), and (15), RSMo.		
2014002930/National Prescription Services Inc HRI Pharmacy	2013-003215	Probation	01/29/2014 01/28/2017
	Restricted pharmacy permit issued on Probation for three (3) years. Disciplinary action in other states against pharmacist-in-charge's pharmacist license regarding felony conviction for attempted embezzlement, misdemeanor conviction for attempted theft. Section 338.055.2(2) and (8), RSMo.		
003756/J & D Pharmacy Inc J & D Pharmacy Inc	2011-002314	Probation	05/07/2014 05/06/2017
	Probation for three (3) years. Insufficient and incorrect compounding logs, misbranding by incorrectly labeling compounded drug products, dispensed adulterated drug products made with expired ingredients, and failed to verify expiration dates. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2015001161/John W Hollis Inc John Hollis Pharmacy	2014-003644	Probation	01/14/2015 01/13/2018
	Restricted pharmacy permit issued on probation for three (3) years. Prior disciplinary action against president/owner's Tennessee pharmacist license due to alcohol and drug abuse. Section 338.055.2(8), RSMo.		
2015001480/Lexi's Medicine, Inc. Lexi's Medicine, Inc.	2014-007285	Probation	01/20/2015 01/19/2020
	Restricted pharmacy permit issued on probation for five (5) years. President/pharmacist-in-charge of prior permit pled guilty to knowingly selling pseudoephedrine at retail without possessing a valid self-certification from the Attorney General of the United States. Section 338.055.2(2) and (15), RSMo.		
2008019033/Grand Medical Group, LLC Medicine Shoppe Pharmacy	2013-006051	Probation	07/11/2015 07/10/2018
	Probation for three (3) years. Inspection violations including CII safe unlocked and CIII-Vs not dispersed through inventory, overfilled stock bottles, failure to timely complete controlled substance inventory, failure to provide patient counseling, labeling errors, failure to maintain distribution records, adulteration of drug products, failure to use gloves when handling tablets, and return to stock violations. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2005035753/Arcadia Ego, Inc. Mitchell Pharmacy	2012-006118	Revoked	10/27/2015 10/26/2022
	Revoked, cannot reapply for seven (7) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.065, RSMo.		
2009033432/Precision Pharmacies LLC Precision Pharmacy	2014-001052	Probation	05/07/2015 02/10/2017
	Probation until 2/10/17. Disciplinary action in other states regarding multiple sterile compounding violations, acting as a manufacturer/wholesaler without a license, and various labeling and recordkeeping violations. Section 338.055.2(5), (8), and (13), RSMo.		
004254/Rider Drug Inc. Rider Drug Inc.	2014-004022	Probation	01/22/2016 01/21/2019
	Probation for three (3) years. No annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.		

## Licensees Presently Under Disciplinary Order

## Pharmacy

Lic Num/Licensee DBA	Complaint	Action Taken	Action From/Through
006018/Semo Drugs of Kennett, Inc. Semo Drugs Of Kennett	2012-006772	Probation	01/06/2016 01/05/2019
	Probation for three (3) years. Technician theft of controlled substances, failure to maintain adequate security to deter theft of controlled substances. Section 338.055.2(6), RSMo.		
2001019642/Rostie Enterprises, LLC The Medicine Shoppe	2005-006704	Revoked	01/07/2013 01/06/2020
	Revoked and cannot reapply for seven (7) years. Pharmacist-in-charge/owner participated in scheme whereby excessive, suspicious, unsigned controlled substance prescriptions faxed from an agent of out-of-state physicians were dispensed for cash. Section 338.055.2(5), (6), (13), and (15), as well as 4 CSR 220-2.010(1)(N).		
2002009522/Sung (Sam) Y. Bae The Medicine Shoppe Pharmacy	2012-001101	Probation	03/18/2014 03/17/2017
	Probation for three (3) years. Dispensed controlled and non-controlled prescriptions for office stock, did not obtain patient-specific prescriptions for the dispensings, prescriptions received were not valid due to insufficient information, improper labeling, failure to properly document controlled substance transfers and controlled substance destruction, transferred controlled substances to facility not DEA registered, shared CSOS password with employees, controlled substance losses, failure to implement effective security controls. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2000148820/Sung Y. Bae The Medicine Shoppe Pharmacy	2012-004219	Probation	03/18/2014 03/17/2017
	Probation for three (3) years. Failure to properly document controlled substance transfers and controlled substance destruction, improper transfer of Schedule II controlled substances, unauthorized sharing of CSOS key with employees, reuse of medications from cassettes, opus cassette violations, electronic data processing system errors. Section 338.055.2(5), (6), (13), and (15), RSMo.		
2015039678/Village Fertility Pharmacy Inc. Village Fertility Pharmacy Inc.	2013-001836	Probation	11/05/2015 11/04/2018
	Restricted permit issued on Probation for three (3) years. Shipped into Missouri prior to licensure and disciplinary action in other states. Section 338.055.2(4), (5), (6), and (8), RSMo.		
2000157695/Walgreen Co Walgreens #05278	2014-000543	Probation	03/17/2016 03/16/2019
	Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.		
2005014836/WALGREEN CO. Walgreens #09301	2014-004530	Probation	05/17/2016 05/16/2019
	Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.		
003121/L & P Corp Wharf Pharmacy	2014-006377	Probation	08/12/2016 08/11/2019
	Probation for three (3) years. Dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Inaccurate records, failure to keep records in a uniform fashion for at least 5 years. Section 338.055.2 (5) (6), and (13), RSMo.		

**Licensees Presently Under Disciplinary Order**

Pharmacy Intern

Lic Num/Licensee  
DBA

Complaint

Action Taken

Action From/Through

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2015028229/Goff, Ryan T

2015-006355

Probation

07/12/2016 07/11/2018

Probation for two (2) years. Theft (non-drug). Section 338.055.2 (5) and (13), RSMo.

# MISSOURI BOARD OF PHARMACY

## Pharmacy Technician Employment Disqualification List

These individuals are not eligible for employment as pharmacy technicians

Revised 8/30/2016

\*\*\*\*\*Licensees should also check the Pharmacy Conditional Registration List and the HB 600 (tax suspension) list to verify authorization to work.\*\*\*\*\*

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Adams	Alicia	Marie		Kansas City	MO	64151	Disqualified	12/1/2012	11/30/2017
Adams	Cherish	Amanda	2008030853	Fenton	MO	63026	Disqualified	5/15/2013	5/14/2018
Aguilar	Nathan	W		Springfield	MO	65802	Disqualified	6/15/2014	6/14/2019
Aguilera	Juan			Chicago	IL	60623	Disqualified	2/15/2016	2/14/2021
Akin	Timothy	W		O Fallon	MO	63366	Disqualified	9/15/2014	9/14/2019
Algya	Heather	N	2013007406	Galena	MO	65656	Disqualified	9/15/2014	9/14/2019
Allen	Erica	C	2009033760	Hazelwood	MO	63042	Disqualified	8/5/2016	8/4/2021
Allen	Robert	K		Kansas City	MO	64117	Disqualified	6/1/2012	5/31/2017
Almaguer	Zoila	F	2015010731	Kansas City	MO	64108	Disqualified	2/25/2016	2/24/2019
Apela	Talimalo	Lenora	2011032278	Florissant	MO	63034	Disqualified	12/1/2012	11/30/2017
Arehart	Marlee	R	2014040588	Carl Junction	MO	64834	Disqualified	8/20/2016	8/19/2021
Avery	Justin	W	2009036704	Harrisonville	MO	64701	Disqualified	6/1/2012	5/31/2017
Baker	Regina	B	2014038377	Kansas City	MO	64110	Disqualified	11/18/2015	11/17/2020
Ballard	Alvin	Aaron	2001015471	Senath	MO	63876	Disqualified	3/1/2013	2/28/2018
Barnhart	Katherine	L	2000149513	O Fallon	MO	63368	Disqualified	12/1/2012	11/30/2017

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Baughman	Michael	C	2013020103	Clinton	MO	64735	Disqualified	5/13/2016	5/12/2021
Becker	Jodi	A	2014041799	Imperial	MO	63052	Disqualified	5/22/2015	5/22/2020
Beers	Abigail		2013032537	St. Robert	MO	65584	Disqualified	11/15/2014	11/14/2019
Benad	Robert	P	2014009441	Columbia	MO	65203	Disqualified	9/10/2015	9/9/2020
Bennett	Chrystina	Y	2013010536	Mansfield	MO	65704	Disqualified	9/10/2015	9/9/2020
Billings	Jillian	E	2013035508	Keytesville	MO	65261	Disqualified	9/15/2014	9/15/2019
Bilyeu	Vicky	Ann	2002004816	Walnut Shade	MO	65771	Disqualified	12/1/2012	11/30/2017
Black	Liana	E	2015010820	Grandview	MO	64030	Disqualified	8/15/2016	8/14/2018
Bland	Cory	W		Saint Charles	MO	63303	Disqualified	4/24/2015	4/23/2018
Blankenship	Stephanie	Christine	1999141642	Saint Louis	MO	63116	Disqualified	11/1/2011	10/31/2016
Blystone	William			Springfield	MO	65802	Disqualified	11/15/2014	11/14/2019
Bohrer	Shannon	Michael	2005037729	Saint Louis	MO	63129	Disqualified	12/1/2012	11/30/2017
Bolden	Chante'	Michelle	2012019125	Maryland Height	MO	63146	Disqualified	11/30/2015	11/29/2020
Borgman	Kevin	R	2012019316	Springfield	MO	65804	Disqualified	9/1/2013	8/31/2018
Bradley	De'Vion	O		Saint Louis	MO	63116	Disqualified	12/1/2012	11/30/2017
Brenner	Linda	A	2012005355	Grandview	MO	64030	Disqualified	6/1/2014	5/31/2019
Brown	Dalton	R		Salem	MO	65560	Disqualified	9/1/2013	8/31/2018
Brown	Patricia	Alice	2006009178	Saint Charles	MO	63303	Disqualified	12/1/2012	11/30/2017
Brown	Talisha	Shanea	2013044294	Grandview	MO	64030	Disqualified	6/18/2015	6/17/2020

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Bruton	Tina	Marie	2007025183	Jasper	MO	64755	Disqualified	2/22/2016	2/21/2018
Buchner	Benjamin	L	2013009901	Billings	MO	65610	Disqualified	2/15/2014	2/14/2019
Buehrlen	Kalyn	R		Jefferson City	MO	65101	Disqualified	6/1/2014	5/31/2019
Buffkins	Courtney	M	2010000621	Saint Louis	MO	63133	Disqualified	3/1/2013	2/28/2018
Burns	Sarah	M	2014009467	Kirbyville	MO	65679	Disqualified	11/20/2015	11/19/2020
Burton	Melinda	Sue	2001029159	Webb City	MO	64870	Disqualified	9/10/2015	9/9/2020
Burts	Kristina	Marie		O Fallon	MO	63366	Disqualified	3/1/2013	2/28/2018
Bush	Kashmere	A	2015042423	Hazelwood	MO	63135	Disqualified	8/5/2016	8/4/2021
Byers	Jared	O'Neil	2012011899	Buena Vista	VA	24416	Disqualified	9/1/2012	8/31/2017
Cain	Kelly	D	2011011746	Potosi	MO	63664	Disqualified	3/1/2013	2/28/2018
Canada	Damon	J	2014036022	Raytown	MO	64133	Disqualified	12/9/2015	12/8/2020
Cardwell	Steven	S		Saint Joseph	MO	645010	Disqualified	2/19/2016	2/18/2021
Carlson	Sylvia	D		Four Seasons	MO	65049	Disqualified	2/15/2014	2/14/2018
Carmichael	Sarah	L		Kansas City	MO	64155	Disqualified	10/15/2015	10/14/2020
Carr	Tammy	J	2012001518	Osage Beach	MO	65065	Disqualified	6/1/2014	5/31/2019
Carroll	Amber	Nicole	2012039851	Kansas City	MO	64110	Disqualified	2/15/2014	2/14/2019
Carter	Kieaira	Danielle	2012013602	Saint Louis	MO	63134	Disqualified	8/19/2016	8/18/2021
Champion	Hope		2011037525	Park Hills	MO	63601	Disqualified	3/1/2013	2/28/2018
Choate	Lee	D		Trenton	MO	64683	Disqualified	3/15/2012	3/14/2017

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Cipponeri	Nancy	M	2000147124	Hazelwood	MO	63042	Disqualified	5/15/2013	5/14/2018
Clooney	Matthew	Richard	2007020875	Saint Peters	MO	63376	Disqualified	5/15/2011	5/14/2016
Cole	Jasmine	T	2014041816	Florissant	MO	63033	Disqualified	2/15/2016	2/14/2021
Conn	Deziray	Adonnica		Kansas City	MO	64117	Disqualified	10/1/2012	9/30/2017
Coppage	LaToya	N	2007036636	Kansas City	MO	64138	Disqualified	6/25/2015	6/24/2020
Cramer	Amber	June	2012026470	Moberly	MO	65270	Disqualified	8/15/2014	8/14/2017
Crane	Jordan		2011000480	Palmyra	MO	63461	Disqualified	10/1/2015	9/30/2020
Cross	Michael	A		Mexico	MO	65265	Disqualified	9/15/2014	9/14/2019
Cunningham	Lakelia	E.	2007013476	Shiloh	IL	62221	Disqualified	5/22/2015	5/21/2020
Curry	Niccole	Brianna	2010037766	Kansas City	MO	64126	Disqualified	2/15/2014	2/14/2017
Dang	Kevin	Le	2012022774	Kansas City	MO	64124	Disqualified	11/1/2013	10/31/2018
Daniels	Rhonda			Fisk	MO	63940	Disqualified	3/20/2015	3/19/2020
Darity	Victoria	L	2014025678	Kansas City	MO	64119	Disqualified	9/9/2015	9/8/2020
Davis	Lorenzo	Antonio	2010014498	Saint Louis	MO	63136	Disqualified	11/1/2011	10/31/2016
Dawson	Tanisha	Nicole	2012032692	Saint Ann	MO	63074	Disqualified	5/6/2015	5/5/2020
Denning	Joshua	R		Saint Peters	MO	63376	Disqualified	11/1/2013	10/31/2018
Dixon	Daryle			St. Louis	MO	63116	Disqualified	2/15/2015	2/14/2020
Dugger	Donna	Marie	2010030608	Saint Louis	MO	63123	Disqualified	12/15/2011	12/14/2016
Easley	Darryl	M		Saint Louis	MO	63137	Disqualified	4/24/2015	4/23/2020

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Eberhart	Marcus	L		Hazelwood	MO	63042	Disqualified	5/6/2016	5/5/2021
Edwards	Gina	M		Saint Louis	MO	63114	Disqualified	9/15/2014	9/14/2019
Edwards	Rebekah	Kathryn	2007021018	Moscow Mills	MO	63362	Disqualified	5/15/2011	5/14/2016
Ehrenreich	Henrietta	F	2008008075	Saint Louis	MO	63126	Disqualified	6/15/2014	6/14/2019
English	Brandy	Lynn	2009004469	Fulton	MO	65251	Disqualified	9/1/2013	8/31/2018
Eskridge	Ralph	L.		Kansas City	MO	64131	Disqualified	4/15/2014	4/14/2019
Fajardo	Emmanuel		2006021185	Fort Leonard Wo	MO	65473	Disqualified	5/22/2015	5/21/2020
Finnell	Roxanne	R	2014033570	Salem	MO	65560	Disqualified	2/22/2016	2/21/2021
Foster	Tawona	D		Imperial	MO	63052	Disqualified	11/15/2014	11/14/2019
Fox	Janet	Lynn	2005001272	Saint Louis	MO	63123	Disqualified	6/18/2015	6/17/2020
Freeman	Ryan		2011009662	Plattsburg	MO	64477	Disqualified	3/1/2013	2/28/2018
Fuller	Angela	E	2011010621	Shawnee Mission	KS	66226	Disqualified	6/1/2012	5/31/2017
Gadberry	Katrina	G	2014038357	Oran	MO	63771	Disqualified	12/15/2015	12/14/2020
Gaines	Heather		2010029371	Saint Louis	MO	63126	Disqualified	2/15/2012	2/14/2017
Gaines	Shelbi	Lynn	2009033726	Saint Louis	MO	63121	Disqualified	8/19/2016	8/18/2021
Gates	Jonathan	Paul	2009033729	Saint Louis	MO	63116	Disqualified	11/30/2015	11/29/2020
Gloyd	David	C		Saint Louis	MO	63146	Disqualified	11/15/2014	11/14/2019
Goldman	Erin	Elizabeth	2012042016	Wood River	IL	62095	Disqualified	2/15/2014	2/14/2019
Gooden	Bruce	Eric	2009031022	Saint Louis	MO	63137	Disqualified	9/15/2014	9/14/2019

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	DATE ELIGIBLE FOR REHIRE
Green	Devin		2013043149	St. Louis	MO	63103	Disqualified	2/15/2015	2/14/2020
Habibovic	Ines		2012004906	Saint Louis	MO	63123	Disqualified	9/15/2014	9/14/2019
Hamilton	Kenneth		2010041611	Mounds	IL	62964	Disqualified	11/1/2011	10/31/2016
Hansen	Robert	L		St. Charles	MO	63301	Disqualified	6/1/2012	5/31/2017
Harden	Juanita	Marie	2010037805	Saint Louis	MO	63121	Disqualified	3/1/2013	2/28/2018
Hargrove	Taisa	Shanae		Saint Louis	MO	63113	Disqualified	12/1/2012	11/30/2017
Harrelson	Angela	R	2010021239	Clinton	MO	64735	Disqualified	12/1/2012	11/30/2017
Haseker	Christopher	Lee	2011013573	Saint Louis	MO	63121	Disqualified	2/15/2012	2/14/2017
Hawkins	Kiauna	C	2014020488	Saint Louis	MO	63134	Disqualified	8/5/2016	8/4/2021
Haynes	Jaime	Renay	2010033870	Campbell	MO	63933	Disqualified	9/1/2011	8/31/2016
Herbolsheimer	Christopher	Allen	2012009575	West Plains	MO	65775	Disqualified	9/1/2013	8/31/2018
Herron	Charles			Kansas City	MO	64131	Disqualified	11/1/2011	10/31/2016
Hoffmann	Nina	Renee	2013011667	Saint Charles	MO	63301	Disqualified	6/18/2015	6/17/2020
Holliday	Kortney	A	2013045071	Farmington	MO	63640	Disqualified	9/9/2015	9/8/2020
Hostler	Kali	Joe Ann	2006010913	Caruthersville	MO	63830	Disqualified	12/15/2011	12/14/2016
Houston	Jamie	Lyn	2009016249	Maryland Height	MO	63043	Disqualified	12/15/2011	12/14/2016
Hoyle	Valerie	Ann	2015006286	Richmond	MO	64085	Disqualified	2/29/2016	2/28/2021
Hubert	Dorthea	L	2014044448	Saint Louis	MO	63138	Disqualified	9/10/2015	9/9/2020
Hubert	James	I	2014003873	Saint Louis	MO	63146	Disqualified	11/24/2015	11/23/2020

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Hunt	David	A	2004032855	Poplar Blff	MO	63901	Disqualified	9/1/2011	8/31/2016
Hunt	Natasha	Dale		Battlefield	MO	65619	Disqualified	7/15/2015	7/14/2020
Jackson	Briana	Aonea	2012042124	Saint Louis	MO	63130	Disqualified	5/13/2016	5/12/2021
Jackson	Timorrow	Michelle	2010039840	Overland	MO	63114	Disqualified	8/20/2016	8/19/2021
Jacobs	Meagen	E		Belleville	IL	62220	Disqualified	9/1/2013	8/31/2018
Jamie	Marcum	D		Kansas City	MO	64116	Disqualified	5/13/2016	5/12/2021
Jamison	Katherine	Elizabeth	2015026644	Willow Springs	MO	65793	Disqualified	2/19/2016	2/18/2021
Javier	Federico	D		Saint Louis	MO	63121	Disqualified	2/15/2016	2/14/2021
Jenkins	Tamika	Ryanette		Grandview	MO	64030	Disqualified	12/1/2012	11/30/2017
Johnson	Jeffrey	Charles	1999142470	Columbia	MO	65202	Disqualified	5/15/2013	5/14/2018
Johnson	Lora	Beth		Oran	MO	63771	Disqualified	9/15/2013	9/14/2018
Johnson	Marcus	Lamont		Saint Louis	MO	63123	Disqualified	10/1/2012	9/30/2017
Jones	Alexander			Saint Louis	MO	63136	Disqualified	3/14/2016	3/13/2021
Jones	DeMarco			Saint Louis	MO	63138	Disqualified	3/1/2013	2/28/2018
Jones	Kyle	L	2013005171	O Fallon	MO	633668	Disqualified	12/15/2015	12/14/2020
Jones	LaRon			Saint Louis	MO	63118	Disqualified	4/24/2015	4/23/2020
Jones	Lora	L	2014005711	Lonedell	MO	63060	Disqualified	2/15/2015	2/14/2020
Jordan	Brenesha	T		Saint Louis	MO	63139	Disqualified	1/15/2015	1/14/2020
Kaiser	Jean	Quinn	2009018915	Sikeston	MO	63801	Disqualified	9/15/2014	9/14/2019

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Keesee	Angela	Marie	2002020249	Mayview	MO	64071	Disqualified	2/15/2015	2/14/2020
Kienzle	Jonathan	E	2013020482	Saint Louis	MO	63129	Disqualified	2/15/2014	2/14/2019
Killian	Christina	Hope		Sainte Genevieve	MO	63670	Disqualified	3/1/2013	2/28/2018
Kirkpatrick	Carol	Paige	2008001201	Charleston	MO	63834	Disqualified	12/1/2012	11/30/2017
Knapp	Glenita	Jean	2000158478	Sedalia	MO	65301	Disqualified	2/29/2016	2/28/2021
Kruse	Melvin	Terrill		Blue Springs	MO	64015	Disqualified	4/15/2012	4/14/2017
Kunderer	Amanda	Lou		Saint Charles	MO	63304	Disqualified	5/15/2013	5/14/2018
Kyle	Mackenzie	A	2015001633	Joplin	MO	64801	Disqualified	8/20/2016	8/19/2021
LaFrance	Sheli	D		House Springs	MO	63051	Disqualified	12/15/2014	12/14/2017
Landry	Kysha	Dawnell	2010035058	Nixa	MO	65714	Disqualified	2/15/2015	2/14/2020
Layman	Judith	N		Saint Louis	MO	63114	Disqualified	5/15/2013	5/14/2018
Leach	Beverly			Saint Louis	MO	63134	Disqualified	1/15/2015	1/14/2020
LeGard	Jeanette	Marie	2009012610	Saint Louis	MO	63136	Disqualified	2/19/2016	2/18/2018
Lemmon	Jasmine	K		Kansas City	MO	64118	Disqualified	7/11/2016	7/10/2021
Lewis	Gail	L	2014001076	Alton	IL	62002	Disqualified	12/9/2015	12/8/2020
Ligon	Frank		2011010766	Independence	MO	64055	Disqualified	9/15/2014	9/14/2019
Liscombe	Andrea	D	2011027974	Saint Charles	MO	63303	Disqualified	11/25/2015	11/24/2020
Lott	Denise	Marcia	1999142606	Saint Louis	MO	63116	Disqualified	3/1/2013	2/28/2018
Lowe	Mary	R		Scott City	MO	63780	Disqualified	9/25/2015	9/24/2018

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Lucas	Janice	Marie	2006035149	Wentzville	MO	63385	Disqualified	9/10/2015	9/9/2020
Lupo	Stephanie	Christine	2007002057	Saint Louis	MO	63125	Disqualified	8/5/2016	8/4/2021
Maddock	Susan	Rose	1999143069	Hillsboro	MO	63050	Disqualified	5/13/2016	5/12/2021
Madison	Kenyatta	M		St. Louis	MO	63115	Disqualified	11/15/2014	11/14/2019
Manry	Tanya		2011011289	Stafford	MO	65757	Disqualified	11/1/2011	10/31/2016
Manzella	Salvatore	J	2013012027	Saint Louis	MO	63129	Disqualified	11/20/2015	11/19/2020
Marshall	Malik	D	2015007135	Saint Louis	MO	63121	Disqualified	11/30/2015	11/29/2020
Massimiano	Deborah	R	2012006394	Rockaway Beach	MO	65740	Disqualified	12/1/2012	11/30/2017
McCrorey	Stephanie	Gayle		Sainte Genevieve	MO	63670	Disqualified	9/25/2015	9/24/2020
McCutcheon	Whitney	Kay	2012011256	Marquand	MO	63655	Disqualified	6/1/2014	5/31/2019
McDowell	Brenda	Fay	1999142430	Republic	MO	65738	Disqualified	9/15/2014	9/14/2019
McManis	Hollie	Ruthanne	2010009333	Branson	MO	65656	Disqualified	12/15/2011	12/14/2016
McNabb	Brandy	Suzanne	2005039389	Kennett	MO	63857	Disqualified	12/15/2015	12/14/2020
Merriweather	Sherry	L		East Saint Louis	IL	62203	Disqualified	4/15/2014	4/14/2019
Middlebrooks	William	James		St. Louis	MO	63033	Disqualified	10/1/2013	9/30/2018
Miller	Emily	Joyce	2012040319	Mexico	MO	65265	Disqualified	2/29/2016	2/28/2021
Milliman	Kerie	S		Kansas City	MO	64188	Disqualified	10/1/2013	9/30/2018
Mitchell	Harold	C.	2010015476	Saint Louis	MO	63112	Disqualified	8/19/2016	8/18/2021
Mittler	Stephani	A	2011013575	saint Ann	MO	63074	Disqualified	9/1/2011	8/31/2016

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Mosby	Sopheha	E		Holts Summit	MO	65043	Disqualified	11/15/2014	11/14/2019
Mueller	Erica	J	2011019482	Saint Louis	MO	63123	Disqualified	9/10/2015	9/9/2020
Muya	Dadiri	H	2013045077	Saint Louis	MO	63116	Disqualified	8/19/2016	8/21/2021
Neal	Tashara	Miranda	2012010915	Saint Louis	MO	63132	Disqualified	12/1/2012	11/30/2017
Nelson	Laura	Michelle	2008032615	Independence	MO	64054	Disqualified	9/1/2013	8/31/2018
Nevels	Ashley	N		Lexington	MO	64067	Disqualified	8/1/2012	7/31/2017
Niemerg	Joel	M	2014041070	Saint Louis	MO	63118	Disqualified	11/30/2015	11/29/2020
Nieves	Rachel	C	2015037908	Springfield	MO	65803	Disqualified	5/13/2016	5/12/2021
Nunley	Corbin	B		Saint Louis	MO	63110	Disqualified	2/15/2012	2/14/2017
Oldham	Tiffany			Dexter	MO	63841	Disqualified	6/18/2015	6/17/2020
Oppenheim	Alexander	Michael	2010015080	Jefferson City	MO	65109	Disqualified	11/16/2015	11/15/2020
Orr	Paulette	D	2012002777	Columbia	MO	65202	Disqualified	12/15/2012	12/14/2017
Palans	Austin	M		Lake Saint Louis	MO	63367	Disqualified	2/22/2016	2/21/2021
Palazzolo	Samantha	C	2012000197	Imperial	MO	63052	Disqualified	9/15/2014	9/14/2019
Parker	Denise			Saint Louis	MO	63116	Disqualified	12/15/2012	12/14/2017
Paulus	Alex	M		O'Fallon	MO	63366	Disqualified	6/1/2012	5/31/2017
Perry	Ronald	O		St. Joseph	MO	64501	Disqualified	12/9/2015	12/8/2020
Powell	Katie	Ann	2014018870	Columbia	MO	65202	Disqualified	5/13/2016	5/12/2021
Powell	Shanta			St. Louis	MO	63146	Disqualified	8/15/2014	8/14/2019

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Rasa	Christy	Ann	500579	Corder	MO	64021	Disqualified	6/30/2016	6/29/2021
Ray	Andrew	Joseph	2012022635	Springfield	MO	65807	Disqualified	3/1/2013	2/28/2018
Reilly	Kristin	Lynne		Belton	MO	64012	Disqualified	12/9/2015	12/10/2020
Rhodes	Octavia	R	2011019702	Saint Louis	MO	63137	Disqualified	12/1/2012	11/30/2017
Rhodes	Tinisha		2007004851	Kansas City	MO	64109	Disqualified	6/8/2015	6/8/2020
Richard	Amy	M	2014020631	Kansas City	KS	66101	Disqualified	9/9/2015	9/8/2020
Richardson	Ryan	G		Maryland Height	MO	63043	Disqualified	3/22/2016	3/21/2021
Rickerson	Rhonda	L	2014030927	Cabool	MO	65689	Disqualified	2/22/2016	2/21/2021
Riddle	Sarah	Ashley	2007002089	Baxter Springs	KS	66713	Disqualified	6/1/2012	5/31/2017
Ridgeway	Stacie	Nicole	1999139962	Dixon	MO	65459	Disqualified	2/15/2012	2/14/2017
Ries	Mota		2011035768	Lake Saint Louis	MO	63367	Disqualified	12/1/2012	11/30/2017
Riess	Anna	Catherine	2010014630	Saint Louis	MO	63129	Disqualified	6/15/2015	6/14/2020
Riner	Cynthia	Louise	2010007051	Kansas City	MO	64158	Disqualified	2/15/2015	2/14/2020
Rittenberry	Tiffany	N	2011005404	Caruthersville	MO	63830	Disqualified	6/18/2015	6/17/2020
Roberson	Bobby	G		Independence	MO	64055	Disqualified	9/15/2014	9/14/2019
Roberts	Tiffany	Marie	2008005022	Kansas City	MO	64116	Disqualified	9/1/2011	8/31/2016
Robinson	Anjail	Nicole	2008025098	Saint Louis	MO	63137	Disqualified	11/15/2014	11/14/2019
Robinson	Tearra	T		Kansas City	MO	64124	Disqualified	4/24/2015	4/23/2020
Ross	Kyrstin	M	2015026675	Butler	MO	64730	Disqualified	2/5/2016	2/4/2021

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Ross	Lakeishreial			Saint Louis	MO	63137	Disqualified	2/15/2015	2/14/2020
Rosson	Heather	Ann	2001032939	Independence	MO	64056	Disqualified	3/1/2013	2/28/2018
Ruth	Aimie	K		O Fallon	MO	63366	Disqualified	3/22/2016	3/21/2021
Sample	Kristen	L	2011030156	Springfield	MO	65803	Disqualified	2/15/2014	2/14/2019
Samuel	Rebecca			Riverside	MO	64150	Disqualified	12/15/2012	12/14/2017
Schaefer	Matthew	Arnold	2012011259	Saint Louis	MO	63139	Disqualified	5/15/2013	5/14/2018
Schul	Alison	Gayle	2008025493	Crestwood	MO	63126	Disqualified	12/1/2012	11/30/2017
Sestak	Toni	E	2009037025	Jefferson City	MO	65110	Disqualified	11/20/2015	11/19/2020
Shannon	Charles	E		Saint Louis	MO	63112	Disqualified	3/7/2016	3/6/2021
Shaw	Joyce	Ann	2005025143	Saint Ann	MO	63074	Disqualified	8/5/2016	8/4/2021
Shears	Jaime	D		Rockaway Beach	MO	65740	Disqualified	8/20/2016	8/19/2019
Sherman	Hayley	Marie		Jefferson City	MO	65109	Disqualified	5/15/2013	5/14/2018
Simon	John	William	2010035107	Savannah	MO	64485	Disqualified	6/1/2014	5/31/2019
Slape	Tommy	Joe	2010028235	Independence	MO	64052	Disqualified	12/15/2011	12/14/2016
Smith	Asia	C		Kansas City	MO	64130	Disqualified	3/15/2015	3/14/2020
Smith	Ebony	N	2012039962	Saint Louis	MO	63136	Disqualified	8/15/2014	8/14/2019
Smith	Kendra	LaTrice	2003029949	Saint Louis	MO	63115	Disqualified	3/1/2013	2/28/2018
Sowell	DeJuan	Cornell	2013012940	Florissant	MO	63031	Disqualified	11/15/2014	11/14/2019
Stinson	Sarah	A	2012004070	Bonne Terre	MO	63628	Disqualified	10/1/2013	9/30/2018

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Stone	Jeffrey	L	2013011341	Saint Louis	MO	63112	Disqualified	2/15/2014	2/14/2019
Subido	Angelo		2013030408	Raytown	MO	64138	Disqualified	8/20/2016	8/19/2017
Sutherland	Troy			University City	MO	63130	Disqualified	10/1/2015	9/30/2020
Szachta	Kathryn	Jane	2007003361	Bridgeton	MO	63044	Disqualified	8/15/2014	8/14/2019
Tackitt	Billy	G		Springfield	MO	65807	Disqualified	8/15/2012	8/14/2017
Tedrick	Robert	N	2014043743	Saint Charles	MO	63303	Disqualified	9/9/2015	9/8/2020
Terry	Yolanda	Maria	2000160010	Camdenton	MO	65020	Disqualified	3/15/2014	3/14/2019
Thomas	Bonnie	Elizabeth	2007016756	Ozark	MO	65721	Disqualified	12/1/2012	11/30/2017
Thomas	Jasmine		2011037538	Saint Louis	MO	63137	Disqualified	12/1/2012	11/30/2017
Thomas	Katherine	Rebecca	2010004877	Excelsior Springs	MO	64024	Disqualified	12/1/2012	11/30/2017
Thornton	Brian		2010038400	Ballwin	MO	63011	Disqualified	11/1/2013	10/31/2018
Thornton-Starr	Ashley	L.		Columbia	MO	65202	Disqualified	2/15/2014	2/14/2019
Townsend	Trevor	J	2013028295	Harrisonville	MO	64701	Disqualified	8/15/2014	8/14/2019
Triplett	Ashley	N	2014005471	Jefferson City	MO	65109	Disqualified	11/15/2014	11/14/2019
Turner	Ashley	Michele	2011008652	Fredericktown	MO	63645	Disqualified	2/15/2014	2/14/2019
Turner	June	R	2015042138	Saint Louis	MO	63137	Disqualified	5/13/2016	5/12/2021
Turner	Kelly	C	2014013689	Fenton	MO	63026	Disqualified	5/13/2016	5/12/2021
Turner	Mary	Alice		Sullivan	MO	63080	Disqualified	10/1/2013	9/30/2018
Vaughn	Caleb	Randell		Florissant	MO	63033	Disqualified	8/15/2012	8/14/2017

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Vines	Tiana	Nichelle		Hazelwood	MO	63042	Disqualified	5/15/2011	5/14/2016
Von Holt	John			Lees Summit	MO	64063	Disqualified	9/15/2014	9/14/2019
Walker	Mark	A		Kansas City	MO	64132	Disqualified	10/1/2013	9/30/2018
Walker	Michael			Springfield	MO	65804	Disqualified	3/1/2013	2/28/2018
Walker	Stephanie	Renee	2006010278	Bernie	MO	63822	Disqualified	11/1/2011	10/31/2016
Walsh	Dylan	C	2014025475	Glen Carbon	IL	62034	Disqualified	5/22/2015	5/21/2020
Warfel	Laura	E	2010009436	Florissant	MO	63031	Disqualified	3/1/2013	2/28/2018
Weilmuenster	Erin	Elizabeth	2012040645	Florissant	MO	63033	Disqualified	12/15/2015	12/14/2020
Welch	Brian	Allen		Kirksville	MO	63501	Disqualified	11/15/2011	11/14/2016
Welch	Randi	Nicole	2008028492	University City	MO	63130	Disqualified	3/1/2013	2/28/2018
Werner	Misty	Nicole	2009031253	Peculiar	MO	64078	Disqualified	6/1/2012	5/31/2017
West	Brenda	B		Elwood	KS	66024	Disqualified	2/5/2016	2/4/2021
White	Nicholas	Edward	2009037146	Lees Summit	MO	64086	Disqualified	2/15/2015	2/14/2020
White	Pamela	R		Kansas City	MO	64106	Disqualified	11/15/2011	11/14/2016
White	Shonnel	Romone	2008004162	Raymore	MO	64083	Disqualified	11/1/2011	10/31/2016
Wideman	Brian			Saint Louis	MO	63114	Disqualified	11/1/2011	10/31/2016
Williams	Dominic	C	2012006084	University City	MO	63130	Disqualified	12/1/2012	11/30/2017
Williams	Jason	C		Saint Louis	MO	63121	Disqualified	5/22/2015	5/21/2020
Williams	Rickita	L		Saint Louis	MO	63133	Disqualified	7/11/2016	7/10/2021

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Williams	Sara	K	2011015135	Lawson	MO	64062	Disqualified	11/1/2013	10/31/2018
Willis	Miley	Amanda	2010035134	Neosho	MO	64850	Disqualified	6/15/2015	6/14/2020
Wilmesherr	Lindsay	Diane	2005027050	O Fallon	MO	63366	Disqualified	6/18/2015	6/17/2020
Winkler	Kayla	Dawn	2012022021	Kansas City	MO	64151	Disqualified	3/1/2013	2/28/2018
Winters	Gary	Lee	2006030208	Ballwin	MO	63011	Disqualified	12/1/2012	11/30/2017
Woods-Gonzale	Kevin	Daniel		Hazelwood	MO	63042	Disqualified	11/15/2014	11/14/2019
Wright	Marissa	R		Saint Louis	MO	63133	Disqualified	11/1/2013	10/31/2018
Wright	Patricia	M		Kansas City	MO	64109	Disqualified	11/1/2011	10/31/2016
Young	Gina		2011000211	Independence	MO	64050	Disqualified	9/15/2014	9/14/2019
Ziegler	Kelly	Marie	1999143383	Saint Clair	MO	63077	Disqualified	6/15/2015	6/14/2020
Zulpo	Matt	J		Saint Louis	MO	63125	Disqualified	5/15/2013	5/14/2018

# MISSOURI BOARD OF PHARMACY

## Pharmacy Technician Conditional Registration List

These individuals are eligible for employment as pharmacy technicians under conditions printed on his/her registration

Revised 6/2/2016

\*\*\*\*\*Licensees should also check the Pharmacy Technician Employment Disqualification List and the HB 600 (tax suspension) list to verify authorization to work.\*\*\*\*\*

LAST NAME	FIRST NAME	MIDDLE NAME	REGISTRATION NUMBER	CITY	STATE	ZIP CODE	ACTION TAKEN	EFFECTIVE DATE	END DATE
Ackerson	Jasmine	S	2016003248	Saint Louis	MO	63138	Conditional Employment	2/2/2016	2/1/2019
Bagwell	Teresa	L	2011029020	Rogersville	MO	65742	Conditional Employment	6/30/2015	6/29/2017
Ballard	Mary	E	2014003335	O Fallon	MO	63366	Conditional Employment	11/13/2015	11/12/2018
Barstead	Aaron	James	2005029992	Springfield	MO	65803	Conditional Employment	6/30/2015	6/29/2017
Benson	Barbara	Ann	2000145606	Villa Ridge	MO	63089	Conditional Employment	11/13/2015	11/12/2016
Bingham	Brian	Ward	1999139521	Springfield	MO	65804	Conditional Employment	6/30/2015	6/29/2017
Bolinger	Beverly	A	2015044899	Dearborn	MO	64439	Conditional Employment	12/31/2015	12/30/2018
Brown	Daniel	H	2016002922	Arnold	MO	63010	Conditional Employment	1/29/2016	1/28/2019
Bryant	Sean	Thomas	2008024449	Springfield	MO	65807	Conditional Employment	6/30/2015	6/29/2017
Burnam	Amanda	J	2015002878	Belton	MO	64012	Conditional Employment	1/30/2015	1/29/2017
Bush	Tiera	S	2016011645	Kansas City	MO	64134	Conditional Employment	4/26/2016	4/25/2019
Cain	Brian	Joseph	2010029248	Kansas City	MO	64157	Conditional Employment	6/1/2014	
Cobb	Angela	J	2015032439	St. Louis	MO	63118	Conditional Employment	9/10/2015	9/9/2019
Cojocaru	Ioana	M	2006027621	Saint Louis	MO	63116	Conditional Employment	6/15/2015	6/14/2017
Coleman	Erica	Rochelle	2015032438	Saint Louis	MO	63104	Conditional Employment	9/10/2015	9/9/2018
Cressley	Jessica	B	2011041318	Tipton	MO	65081	Conditional Employment	5/6/2016	5/5/2019
Culpepper	Marcia	R	2016003836	Saint Louis	MO	63137	Conditional Employment	2/5/2016	2/4/2019

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Cummings	Chelsie	D	2011032280	Bruner	MO	65620	Conditional Employment	6/30/2015	6/29/2017
Davis	Adonna	L	2013040345	Saint Louis	MO	63118	Conditional Employment	11/1/2013	10/31/2016
Deatherage	Amber	Dawn	2008030878	Springfield	MO	65810	Conditional Employment	6/30/2015	6/29/2017
Duley	Michael	B	2013012309	Saint Louis	MO	63123	Conditional Employment	9/15/2014	9/14/2016
Fabah	Satta	C	2014042451	Kansas City	MO	64117	Conditional Employment	12/9/2014	12/8/2019
Flannigan	Jody	Lynn	2006007797	Nixa	MO	65714	Conditional Employment	6/30/2015	6/29/2017
Galbraith	Kathryn	D	2015018638	Kansas City	MO	64153	Conditional Employment	6/15/2015	6/14/2018
Gross	Tanika	Marie	2010027578	Columbia	MO	65202	Conditional Employment	11/13/2015	11/12/2017
Gurlekce	Gulbahor		2016007243	Ballwin	MO	63021	Conditional Employment	3/4/2016	3/3/2018
Hagedorn	Nicole	Lynnette	2003022869	Freeman	MO	64746	Conditional Employment	11/15/2014	
Hayward	Laura	M	2015032440	California	MO	65018	Conditional Employment	9/10/2015	9/9/2018
Hill	Kayla	R	2011034720	Raymore	MO	64083	Conditional Employment	11/15/2014	11/14/2016
Hoerrmann	Jeanette	E	2013036620	Kirksville	MO	63501	Conditional Employment	10/1/2013	9/30/2016
Hubbard	Stacy		2011003177	Forsyth	MO	65653	Conditional Employment	6/30/2015	6/29/2017
Jackson	Brandon	B	2013045723	East Saint Louis	IL	62205	Conditional Employment	2/15/2015	2/14/2017
Johnston	Ronald	Lee	2013032971	Excelsior Springs	MO	64024	Conditional Employment	9/1/2013	8/31/2016
Jones	Billie	J	2007002013	Bruner	MO	65620	Conditional Employment	6/30/2015	6/29/2017
Joplin	Joel	K	2016007118	Blue Springs	MO	64015	Conditional Employment	3/3/2016	3/2/2019
Kammer	Mindy	Lynn	2001002546	Creve Coeur	MO	63141	Conditional Employment	12/15/2012	12/14/2017
Kittleman	Shannon	Michelle	2008026972	Nixa	MO	65714	Conditional Employment	6/30/2015	6/29/2017
Lee	Janie	A	2012033200	Saint Louis	MO	63107	Conditional Employment	11/13/2015	11/12/2018
Manlove	Bianca	L	2015006577	Kansas City	MO	64132	Conditional Employment	3/2/2015	3/1/2017

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Martin	Rex	A	2016003019	Platte City	MO	64079	Conditional Employment	2/1/2016	1/31/2019
Maybee	Katie	Ann	2014018870	Edwards	MO	65326	Conditional Employment	6/15/2014	6/14/2016
McCollum	Holly	Darlene	2002022954	Ozark	MO	65721	Conditional Employment	7/15/2015	7/14/2020
McDonald	Rachael	J	2014033911	Cedar Hill	MO	63016	Conditional Employment	9/15/2014	9/14/2017
McDowell	Jessica	Christine	2015002783	Blue Springs	MO	64015	Conditional Employment	1/30/2015	1/29/2018
McMenamy	Angela	M	2016008970	O'Fallon	MO	63366	Conditional Employment	3/18/2016	3/17/2019
Merritt	Katrece	S	2014019514	Saint Louis	MO	63137	Conditional Employment	6/15/2014	
Miles	Jessica	R	2011032291	Ava	MO	65608	Conditional Employment	6/30/2015	6/29/2017
Miller	Alex	C	2014029177	St. Louis	MO	63126	Conditional Employment	8/15/2014	
Nolan	Amanda		2015038637	St. Joseph	MO	64507	Conditional Employment	10/27/2015	10/26/2018
Novak	Joyce	Renee	1999139916	Springfield	MO	65804	Conditional Employment	6/30/2015	6/29/2017
Ochampaugh	Derek	M	2015038628	High Ridge	MO	63049	Conditional Employment	10/27/2015	10/26/2018
O'Leary	Mark	W	2016002570	St. Louis	MO	63122	Conditional Employment	1/27/2016	1/26/2018
Parhomski	Christina	L	2015038817	Florissant	MO	63033	Conditional Employment	10/28/2015	10/27/2018
Parker	Heather	Ann	2010025258	Sedalia	MO	65301	Conditional Employment	5/31/2016	5/30/2019
Parman	Wendy	R	2016003020	Grant City	MO	64456	Conditional Employment	2/1/2016	1/31/2019
Peine	Aundria	Lynn	2005022340	Niangua	MO	65713	Conditional Employment	6/30/2015	6/29/2017
Perkins	Jackie		2011005216	Sparta	MO	65753	Conditional Employment	6/30/2015	6/29/2017
Pratt	Jennifer	E	2002029170	Saint Louis	MO	63129	Conditional Employment	6/18/2015	6/17/2016
Reece	Cassy	R	2016003837	Pittsburg	KS	66762	Conditional Employment	2/5/2016	2/4/2019
Rieffer	Edmond	Max	2012034185	Saint Peters	MO	63376	Conditional Employment	11/1/2013	10/31/2018
Rifenburg	Kelli	Renee	2004017535	Springfield	MO	65802	Conditional Employment	6/30/2015	6/29/2017

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Roberts	Billie	Jo	2001002907	Ava	MO	65608	Conditional Employment	6/30/2015	6/29/2017
Rogers	Sammy	Lee	2004004874	Rogersville	MO	65742	Conditional Employment	6/30/2015	6/29/2017
Salge	Jacob	M	2012007572	Saint Peters	MO	63376	Conditional Employment	6/18/2015	
Sanders	Melissa	Kay	1999143056	Nixa	MO	65714	Conditional Employment	6/30/2015	6/29/2017
Scheele	Kelli	B	2016005984	Kansas City	MO	64119	Conditional Employment	2/25/2016	2/24/2019
Shlafshteyn	Irina		2014029176	St. Louis	MO	63141	Conditional Employment	8/15/2014	8/14/2016
Smith	Briana	L	2013032972	Columbia	MO	65201	Conditional Employment	9/1/2013	
Soto	Carmen	E	2013040349	Bolivar	MO	65613	Conditional Employment	11/1/2013	10/31/2016
Spiva	Pamela	Sue	2000145439	Joplin	MO	64801	Conditional Employment	6/30/2015	6/29/2017
Stanley	Amie	A	2013036585	Warrensburg	MO	64093	Conditional Employment	10/1/2013	9/30/2018
Stark	Tiffany	K	2015044513	Kansas City	MO	64154	Conditional Employment	12/24/2015	12/23/2018
Stewart	Brittany	R	2014028859	Springfield	MO	65804	Conditional Employment	6/30/2015	6/29/2017
Thudium	Billy	E	2016007104	Kirksville	MO	63501	Conditional Employment	3/3/2016	3/2/2019
Uhrmacher	Anthony	J	2014043318	Shawnee	KS	66216	Conditional Employment	12/1/2014	11/30/2019
Valerio	Olivia	J	2015002793	Kansas City	MO	64132	Conditional Employment	1/30/2015	1/29/2018
Vaughan	Hayden	Skip	2006006433	Springfield	MO	65807	Conditional Employment	6/30/2015	6/29/2017
Vietor	Jacqueline	Jean	2005029963	O Fallon	MO	63366	Conditional Employment	6/15/2014	
Washington	Christine		2015041648	St. Louis	MO	63116	Conditional Employment	11/24/2015	11/23/2018
Wendlandt	Courtney	Renee	2002021648	Springfield	MO	65803	Conditional Employment	6/30/2015	6/29/2017
Wesolowski	Stephen	G	2016002571	Devils Elbow	MO	65457	Conditional Employment	1/27/2016	1/26/2021
Wilbon	Shantassa	L	2015011202	Saint Joseph	MO	64503	Conditional Employment	4/13/2015	4/12/2017
Williams	Jerrica	Janay	2009004283	Saint Louis	MO	63121	Conditional Employment	2/15/2015	2/14/2017

#E2 **Board Licensee Statistics**

*(As of October 14, 2016)*

- Drug Distributor Registrant- 99
- Drug Distributor – 1,391
- Pharmacist – 10,653
- Pharmacy – 2,678
- Pharmacy Intern – 2,164
- Pharmacy Technician – 20,633
- Temporary Drug Distributor – 3
- DDR, DDT, DDS combined – 1,493

**#E3 NABP MODEL PHARMACY ACT REVISION**

<https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/>

**#E4 NABP Boards of Pharmacy Member Manual**

<https://nabp.pharmacy/wp-content/uploads/2016/09/Board-Member-Manual.pdf>