



PHARMACY SELF-ASSESSMENT FORM

MISSOURI DIVISION OF
PROFESSIONAL REGISTRATION
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<http://pr.mo.gov/pharmacists.asp>

Missouri Pharmacy Self-Assessment

The *Pharmacy Self-Assessment* tool is provided by the Board of Pharmacy to assist pharmacies in assessing their compliance with Missouri pharmacy requirements. Compliance violations are preventable! Regular assessment can help detect, prevent and resolve compliance issues prior to an inspection.

WHO CAN BENEFIT FROM THIS ASSESSMENT

- ✓ Pharmacist-in-Charge
- ✓ Pharmacy Permitholders
- ✓ Pharmacy Owners
- ✓ Pharmacy Supervisors
- ✓ Risk, Compliance or Quality Assurance Staff

HOW TO USE THIS ASSESSMENT

To maximize value, the Self-Assessment should be completed when you have sufficient time to adequately review the pharmacy's compliance activities. *Do not assume you are in compliance!* Physically review the pharmacy's records and policies and procedures to determine compliance with each assessment standard listed. Skipping this process could lead to missed areas of non-compliance. Assessment standards marked "no" likely indicate a compliance violation/concern and should be immediately corrected. *Note: The Self-Assessment includes the most frequently identified compliance violations and does not constitute an exhaustive list of all compliance criteria. Your inspector will review additional compliance requirements during an inspection.*

WHEN TO USE THIS ASSESSMENT

Compliance monitoring and education should be an on-going activity. Licensees are encouraged to use this tool as often as necessary. At a minimum, the Board recommends an annual assessment. The Board also recommends an assessment if the pharmacy experiences a change in:

- ✓ Pharmacist-in-charge
- ✓ Pharmacy Ownership
- ✓ Risk, Compliance or Quality Assurance Managers
- ✓ Significant staff changes

CONTINUING EDUCATION CREDIT

The Board has approved two (2) hours of pharmacy continuing education (CE) credit for Missouri licensed pharmacists serving as a pharmacy manager, owner, supervisor, corporate officer or the pharmacist-in-charge. CE is available for each calendar year licensees completes the Self-Assessment. To be eligible for CE, the attached Certification Form must be returned to the Board before December 31st of the applicable calendar year. Self-Assessments completed after the biennial continuing education deadline will not be eligible for credit for the preceding renewal period.

AFTER THE ASSESSMENT

Review your results carefully. Self-Assessment standards marked "no" may signal areas of non-compliance. ***Review the law and take corrective action immediately.*** Discuss results with pharmacy staff and identify ways to remain compliant. Remember, compliance is a team effort!





Respond to all applicable Assessment Standards. Mark "yes" if the pharmacy is in compliance. Standards marked "no" may indicate areas of non-compliance.

Licensing				
Standard	Response			Cite
	YES	NO	N/A	
1. The pharmacy's permit is current and posted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.020(5)
2. The pharmacy permit bears the name of the current pharmacist-in-charge.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.010(1)(M)
3. The classifications listed on the pharmacy's permit are correct and accurate. • A classification change form must be filed with the Board if a function has been added/deleted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.020(10)
4. The pharmacy has a Class-C: Long-Term Care permit if the pharmacy is dispensing to patients in a long-term care facility (e.g., a nursing home, retirement facility, mental care facility or any other facility that provides extended care to resident patients).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.020(9)(C)
5. The pharmacy has a Class-D: Non-Sterile Compounding permit if the pharmacy is engaged in non-sterile compounding in batch quantities using bulk ingredients.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.020(9)(D)
6. The pharmacy has a Class-H: Sterile Compounding permit if the pharmacy is engaged in sterile compounding. A Class-H permit is required to compound bladder irrigation products.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.020(9)(H)
7. The pharmacy has a Class-J: Shared Services permit if pharmacy services are provided to, or received from, another pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.650
8. The pharmacy has a Class-M: Specialty (Bleeding Disorder) permit if the pharmacy is providing blood-clotting products to patients with bleeding disorders. ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-6.100
9. Storage sites used to store pharmaceuticals or confidential pharmacy records at a different address than the pharmacy are registered with the Board.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.010(1)(I)(J)

Support Staff/Pharmacy Supervision				
	YES	NO	N/A	
10. All pharmacist licenses, intern pharmacist licenses and technician registrations are current and posted in the pharmacy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.010; § 338.013.4
11. All posted pharmacist licenses have a 2" x 2" photo displayed/attached.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.010(1)(K)
12. For technicians working on a pending technician application, a complete copy of the technician application submitted to the Board is kept in the pharmacy. To be complete, the application must be notarized, signed and include the correct fee and a fingerprinting receipt.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	§ 338.013.3
13. The pharmacy has a written list of all technicians and their duties.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.090(2)(BB)
14. The required technician list is current and up-to-date.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.090(2)(BB)
15. All technicians and intern pharmacists are supervised by a pharmacist.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 CSR 2220-2.700(1)

¹The pharmacy permit classes referenced represent the most common licensing violations noted on inspection. Other permit classifications exist that are not listed above; See § 338.220 and 20 CSR 2220-2.020 for a complete list of all required pharmacy permit classes.



16. Technicians and intern pharmacists only enter prescription data or take verbal prescription orders when a pharmacist is present.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.700(1)
17. Technicians and intern pharmacists only compound or prepare prescriptions when a pharmacist is present.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.700(1)
18. Technicians and intern pharmacists only sell or dispense prescriptions/medication to patients when a pharmacist is present (<i>even if the Rx has been previously checked by a pharmacist</i>).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.700(1)
19. The "no pharmacist on duty" sign is posted when there is no pharmacist on duty.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(A)

Pharmacy Conditions/Medication Storage				
20. The pharmacy is maintained in a clean, orderly and sanitary manner.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)
21. Trash/waste is appropriately disposed of.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)
22. The pharmacy has a functioning hot & cold water supply and sewage disposal.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)3.
23. Pharmacy equipment is clean and sanitary, including, the sink and any reconstitution device(s).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)
24. Dispensing/compounding equipment is in good working condition.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(C)
25. Medication is stored separately from employee medications.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(G)
26. Animals are not permitted in the pharmacy area, except as otherwise authorized by the Americans with Disabilities Act (ADA).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)3.
27. The pharmacy regularly checks for outdated, distressed, misbranded, and adulterated drugs/devices.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.090(2)(V)
28. All required reference materials are current and available in the pharmacy (manually or electronically).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(C)
29. Pharmacy staff know how and where to access reference materials maintained electronically, including relief or "floating" staff.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(C)
30. Medications are stored within the manufacturer or USP recommended temperatures.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(F)
31. Temperature sensitive medications are stored in a thermostatically controlled area with a thermometer or temperature measuring device.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(F)
32. Temperature control devices are working and properly functioning. <i>Physically check temperature measurement device(s).</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(2)(F)
33. Bulk compounding ingredients are stored in a clean, dry area and in properly labeled containers.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(6)(A)
34. Pharmacy staff use gloves when handling individual tablets/capsules, including, when bubble packing medication.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(F)
35. Patient information is kept confidential and only disclosed as authorized by law.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.100
36. Stock bottles are not overfilled. (Check "yes" if this statement is correct). • <i>This is misbranding!</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 196.015



37. Prescriptions returned to stock are maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container. • <i>Except as allowed for long-term care return/reuse, return to stock is only allowed if the medication was not dispensed to the patient and maintained in accordance with USP or manufacturer's recommendations. Medication may <u>not</u> be poured back into the original stock container.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-3.040(3)
38. <i>Physically check a sample of the pharmacy's inventory.</i> Outdated, distressed, misbranded and adulterated drugs are physically separated from the active inventory and stored in a separate area that is clearly identified.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(6)

Controlled Substances				
39. The pharmacy has DEA & BNDD registrations for each schedule of controlled substances possessed/dispensed and all registrations are current.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 195.030.2, RSMo; 21 CFR 1301.11
Inventory Requirements				
40. An annual controlled substance inventory was taken for all controlled substances (including Schedule-V OTC pseudoephedrine products).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.042
41. The annual inventory for Schedule-II controlled substances is documented separately from the annual inventory for Schedule III-V controlled substances.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.042
42. The date & time the annual inventory was completed is documented on the inventory (e.g., beginning/close of business).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1304.11(a)
43. If the pharmacist-in-charge has changed, a controlled substance inventory was completed at the time of the PIC change.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.090(2)(T)
Security				
44. The pharmacy has adequate security to prevent unauthorized access to controlled substances and to deter theft.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.031
45. Schedule-II controlled substances are stored in a locked/substantially constructed cabinet.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.034
46. The Schedule-II controlled substance cabinet remains locked except when accessing drugs (<i>cabinet keys should not be kept in the lock readily available to pharmacy staff</i>).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.034
Drug Purchases/Transfer				
47. Medication is transferred either by invoice (schedule III-V) or via CSOS/a DEA 222 form (Schedule II).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.330, § 338.333/ 21 CFR 1305.3
48. All Schedule-III to Schedule-V invoices are dated when received.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.048(4)
49. Invoices for Schedule III-V controlled substances include the address and DEA number for both parties.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.330, § 338.333/ 21 CFR 1305.3
50. DEA Power of Attorney forms are current and have been completed for all pharmacy staff authorized to execute DEA-222 forms or CSOS orders.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1305.5
51. CSOS usernames/passwords are not shared or used by other people.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1305.21
52. <i>Review a sample set of DEA 222 forms or CSOS orders from each vendor.</i> All DEA 222 forms have been properly completed and all CSOS orders have been electronically checked into the CSOS system (including distributions to other pharmacies/reverse distributors).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR § 1305.13, § 1305.22



53. Records of drugs transferred by invoice/DEA-222 are maintained for two (2) years.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CSR 1304.04
Schedule V- OTC Pseudoephedrine Products				
54. If selling over-the-counter pseudoephedrine products, the pharmacy's DEA self-certification of compliance for the Combat Methamphetamine Act has been renewed annually.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 USC § 830(e)(1)(B)
55. All OTC sales of pseudoephedrine products are reported to Missouri's approved database (NPLEx).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.074
56. All NPLEx users have their own database password.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.074(3)(M)
57. NPLEx passwords are not shared/used by other persons.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	19 CSR 30-1.074(3)(M)

General Dispensing				
58. Medication is only dispensed pursuant to a patient-specific prescription or, for Class-B Hospital pharmacies, pursuant to a patient-specific medication order.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.095; § 338.165
59. Prescriptions are not used to dispense medication to a prescriber for office stock or for office use. <i>(Mark "yes" if this is correct).</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.095
60. Child-resistant containers are used as required by the Federal Poison and Prevention Packaging Act.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	16 CFR 1700.14
61. A prescription is required to flavor any over-the-counter medication.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(10)
62. All prescriptions are verified by a licensed pharmacist prior to dispensing.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(B)
63. A pharmacist verifies all compounded or reconstituted products/preparations.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(1)(B)
64. The name of the pharmacist responsible for reviewing data accuracy for each original prescription is documented in the pharmacy's prescription record system.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.017(1)(J)
65. If different from the pharmacist reviewing data accuracy, the identity of the pharmacist responsible for verifying the final product prior to dispensing is documented in the pharmacy's prescription record system <i>(required for all prescriptions original and refill).</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.017(1)(J)
66. Faxed prescriptions are only received from a prescriber's office or agent.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.085
67. Any changes/alterations made to the prescription are documented in the pharmacy's records.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.018(1)(H)
68. Drugs that have been rated inequivalent by the FDA are not substituted (B-rated).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.056
69. The maximum expiration date on repackaged medication is twelve (12) months from the date of repackaging or the manufacturer's expiration date, whichever is earlier. <i>This includes drugs in automated devices.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.130(1)(D)
70. Medication is transferred to other practitioners/entities either by invoice (non-controlled and schedule III-V) or via CSOS/a DEA 222 form (Schedule II).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.330, § 338.333/ 21 CFR 1305.3
PATIENT COUNSELING				
71. The pharmacy collects and maintains appropriate patient information to facilitate counseling (i.e.- clinical information, disease states, allergies)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.190(1)
72. Patients are offered an opportunity to consult with a pharmacist each time a prescription is dispensed (new and refill).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.190

73. Patient counseling is only provided by a licensed pharmacist or a licensed intern pharmacist under the pharmacist's supervision.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.190(1)
PRESCRIPTION TRANSFERS				
74. Prescription refills are transferred to another pharmacy within one (1) business day of a transfer request, unless otherwise prohibited by law.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.120(3)
75. Prescriptions transferred out of the pharmacy are voided in the pharmacy's records to prevent further dispensing.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.120(2)
76. Controlled substance prescription refills are only transferred between licensed pharmacists.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.120(1)



Licenses should manually review a sufficient sample of prescription records to verify compliance with the following requirements. Appropriate sample size will vary depending on pharmacy volume. At a minimum, the Board recommends reviewing 10% of the pharmacy's average weekly prescription volume.

Prescription Review				
77. All prescriptions have been assigned a consecutive number or a unique readily retrievable identifier.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.059
78. Written and faxed prescriptions from Missouri prescribers are in the required two-line format.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.056
79. All reviewed prescriptions contain: a. The prescribing date b. The name of the patient(s) or, for animals, the species and owner's name. c. The prescriber's name (verbal prescriptions) or a written or electronic signature (written, faxed or electronic prescriptions) d. Name, strength and dosage of the medication, device or poison e. Directions for use f. Number of refills, if applicable g. Quantity (in weight, volume or # of units) h. An indication of whether generic substitution is authorized	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.018(1)
80. The correct drug, strength and quantity was dispensed on each prescription.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010
81. Generic/biosimilar substitution was only made when specifically authorized by the prescriber.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.056
82. No more than the allowed and prescribed number of refills were dispensed.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010
83. All reviewed prescription labels contain: a. The date the prescription was filled b. A prescription number or other unique identifier c. The prescriber's name d. The correct directions for use e. The pharmacy's name and address f. The exact name and dose of medication dispensed	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.059
CONTROLLED SUBSTANCES: In addition to the above requirements, the Board recommends reviewing a minimum of 25 controlled substance prescriptions in each schedule to verify compliance with the following:				
84. All reviewed controlled substance prescriptions also include: a. The prescriber's address b. The patient's address c. The prescriber's DEA number d. Dosage form	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.018(1)



85. Controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or physician assistant (PA) for Missouri patients include the name, telephone # and address of <u>both</u> the APRN/PA and the supervising/collaborating physician.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 334.735.4, 20 CSR 2200-4.200(3)(G).7.
86. All controlled substance prescriptions are manually signed by the prescriber except for DEA compliant electronic prescriptions.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR § 1306.8
87. All faxed controlled substance prescriptions are manually signed (<i>stamped/electronic signatures are not allowed</i>)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1306.05
88. No Schedule-II prescriptions were refilled. (<i>Mark "yes" if this answer is correct</i>)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1306.12(a)
89. Except as otherwise allowed under state/federal law for long-term care patients and patients with a documented terminal illness, the remaining portion of any partially filled Schedule II prescriptions was dispensed within 72-hours or the prescriber was notified that the remaining portion was not filled.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	21 CFR 1306.13
90. If more than a 30-day supply of a Schedule-II controlled substance was dispensed, the specific medical reason for dispensing is documented on the prescription or on a form attached to the prescription. (<i>Per BNDD, diagnosis alone is not a sufficient medical reason</i>).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 195.080.2
91. Labels for controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or physician assistant (PA) for Missouri patients include the name of the prescriber <u>and</u> the supervising/collaborating physician.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 195.100.5

Non-Sterile Compounding				
92. The pharmacy has a Class-D pharmacy permit if the pharmacy performs non-sterile compounding in <u>batch</u> quantities using <u>bulk active</u> ingredients.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(9)(D)
93. The pharmacy has compounding policies and procedures.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(7)(A)
94. The pharmacy has established quality control policies and procedures to ensure products have the proper identity, strength, quality and purity.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(7)(A)
95. The pharmacy maintains a drug monitoring system to evaluate the quality of compounding services.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(B)
96. The required drug monitoring system evaluates/tracks reported infection rates, adverse drug reactions, recalls and prescriber/client complaints.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(B)
97. A recall is initiated when a compounded product is deemed to be misbranded or adulterated.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(C)
98. The Board is notified in writing within three (3) days of any recall related to a misbranded/adulterated compounded product.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(C)
99. In the event of a recall of a misbranded/adulterated <u>non-sterile</u> compounded product, the prescriber is notified of the nature of the recall, the problems identified and any recommended actions to ensure public health or safety.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(C)
100. The pharmacy does not compound commercially available products or products that are essential copies of commercially available products. <i>Mark "yes" if this answer is correct. If "no" is marked, see question # 101.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(9)

101. If a commercially available product is compounded, the pharmacy has documented that the commercially available product is unavailable or documented the <u>specific medical need</u> for compounding the product in the pharmacy's records.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(9)
102. The pharmacy doesn't make specific claims about compounded products without supporting analytical data (i.e., designating a product as slow release/extended release, poison ivy prevention/relief or "bio-identical hormone replacement"). <i>Mark "yes" if this answer is correct.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(12)
Sanitation/Dispensing				
103. Compounding areas are clean, sanitary and trash is properly disposed of.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(5)(A)
104. Equipment surfaces are not reactive, additive or absorptive in a manner that will alter the safety, identity, strength or quality of a compound.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(6)(E)
105. No expired ingredients or batch compounded products are in the compounding area. <i>(Mark "yes" if this answer is correct)</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.090(2)(V)
106. All compounded prescriptions returned to stock have an in-house lot number and a beyond-use date designated on the container label and in the compound log. <i>These are considered batched.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 20 CSR 2220-2.400(7)(A), (D)
107. All bulk active ingredients meet compendial standards (USP, NF, etc) or a certificate of analysis for the bulk substance is on file (i.e.- camphor blocks).	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(8)(A)2
108. Compounding records are maintained for 2-years from the compounding date.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(5)(A)
109. The actual name of each active or therapeutic ingredient is listed on the prescription container. • <i>General designations are non-compliant (i.e.- "Magic Mouthwash").</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(7)(F)
 Review the pharmacy's compounding log for the previous 3-6 months and assess the following:				
110. The compounding log includes: a. The compounding method** b. Compounding date c. Identity of the compounding pharmacist d. A list of all drug products/ingredients and their amounts by weight or volume e. The source, lot number and beyond-use date for each drug product/ingredient f. In-house lot number and beyond-use date for bulk compounded products g. The prescription number/unique identifier, and h. A description of the compounding process and the order of drug products/ingredient addition, if necessary for proper compounding.** <i>** This information may be separately stored in the pharmacy's records if immediately retrievable.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.400(7)(A)
111. No expired drugs were used in compounding. <i>Mark "yes" if this statement is correct.</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.090(2)(V)



STERILE COMPOUNDING (ALL RISK LEVELS):			
The Board filed an emergency and amended rule in 2016 to substantially revise Missouri's sterile compounding requirements. A Sterile Compounding Implementation Guide is available on the Board's website that explains the major changes. The Board anticipates publishing a separate sterile compounding self-assessment form in the future. In the interim, licensees should review 20 CSR 2220-2.200 and the Implementation Guide to ensure compliance with Missouri law.			

Immunizations by Protocol

112. Immunizing pharmacists have filed an annual Notification of Intent to immunize by protocol with the Board.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(2)
113. All immunizing intern pharmacists have filed a Notification of Intent to immunize by protocol with the Board.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(2)
114. Immunizations are only administered by protocol to patients 12-years of age or older.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(1)(A)
115. The pharmacy only administers influenza, pneumonia, meningitis, shingles, hepatitis A, hepatitis B, diphtheria, tetanus and pertussis vaccines by protocol.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	\$ 338.010.1
116. Patients are asked to remain in the pharmacy for a "safe amount of time" after being immunized to observe any adverse reactions.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(2)
<i>Review the current immunization protocol for compliance with the following:</i>				
117. All immunizing pharmacists have signed <u>and</u> dated the immunization protocol.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(5)
118. All immunization protocols contain:	YES	NO	N/A	20 CSR 2220-6.050(5)
a. The name and signature of all participating pharmacist(s) and physician(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. The time period of the protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. A list of vaccines that can be administered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. A list of the patient/patient groups the pharmacist is authorized to immunize	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. The authorized routes and anatomic sites of administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Emergency response procedures, including, adverse reactions, anaphylactic reactions and accidental needle sticks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. The length of time pharmacists are required to observe a patient for adverse reactions after an injection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. Provisions for disposing of used/contaminated supplies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. The street address of all locations where the pharmacist is authorized to immunize	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. Procedures for record-keeping and immunization notifications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k. Provisions for terminating the protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

 *Review a representative sample of the pharmacy's immunization records to evaluate compliance with the following:*

119. Immunization records are maintained for at least two (2) years.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(6)(D)
120. Immunization records are stored separately from the pharmacy's prescription files.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(6)(D)(1)
121. Immunization records include the patient's primary care provider (if provided) and the correct dose, route and anatomic site of administration. <i>(This is a common violation)</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(6)(D)
122. A prescription was created under the protocol physician's name within 72-hours of immunization or a prescription was obtained from the authorizing physician within the required 72-hours.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(6)(C)



123. The protocol physician was notified of an immunization within 72-hours of administration.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(7)(A)
124. The patient's primary care provider (PCP) was notified within fourteen (14) days of administration.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(7)(B)
125. The protocol physician and the patient's PCP were notified of an adverse event/reaction within twenty-four (24) hours.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(7)(C)
126. The dates required notifications were made are documented in the pharmacy's records.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.050(7)(E)

Medication Administration by Medical Prescription Order



Review a sample of the pharmacy's administration records to evaluate compliance with the following:

127. All administering pharmacists have filed a Notification of Intent by prescription order with the Board. <i>(This is different from a Notification of Intent to immunize by protocol).</i>	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.040(3)
128. All administration prescription orders contain the: a. Date of the original order b. Prescriber's name c. Patient's name d. Name of drug and dose to be administered e. Route of administration f. A statement that the drug is to be administered by a pharmacist. g. If applicable, the date or schedule of any subsequent administrations	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.040(5)
129. The prescriber was notified of administration within 72-hours.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.040(7)(A)
130. For vaccines administered by prescription order, the patient's primary care provider (PCP) was notified within fourteen (14) days of administration.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	§ 338.010.13
131. The prescriber was notified of any adverse events/reactions within twenty-four (24) hours.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.040(7)(B)
132. The pharmacy's policies and procedures for administration by medical prescription order are reviewed annually.	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.040(4)(C)

Policies and Procedures

133. The pharmacy has written policy and procedures for the following pharmacy services/activities <i>(if applicable)</i> :				
a. Automated dispensing and storage systems	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.900(1)(B)
b. Administration by Medical Prescription Order	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.055(4)
c. Class-I (consultant pharmacy in residence) services	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.010(10)(B)
d. Class-J services	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.650(1)(C)
e. Class-M Specialty (Bleeding Disorder)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-6.100(4)
f. Electronic Record-Keeping System	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.083(4)
g. Long-term care	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.140(2)



h. Nuclear services	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.500(2)(E)
i. Prescription delivery (including mail order)	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.013(1)
j. Renal dialysis services	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.600(2)(E)
k. Sterile Products	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.200(2)
l. Technician responsibility/supervision	YES <input type="checkbox"/>	NO <input type="checkbox"/>	N/A <input type="checkbox"/>	20 CSR 2220-2.090(2)(CC)



You have completed the Pharmacy Self-Assessment form. Review your results closely and share with pharmacy staff. Remember, compliance is a team effort! Maintain a copy of the Self-Assessment in your records for future reference. Do not send the Self-Assessment form to the Board.

Assessment Completed By	Date



**MISSOURI BOARD OF PHARMACY
SELF-ASSESSMENT CONTINUING EDUCATION
CERTIFICATION FORM**

The Board has approved two (2) hours of continuing education credit for pharmacy managers, owners, supervisors or pharmacist-in-charge for each calendar year the licensee completes the Self-Assessment. To be eligible for CE, this Certification Form must be returned to the Board before December 31st of the applicable calendar year. Self-Assessments completed after the biennial continuing education deadline will not be eligible for credit for the preceding renewal period.

NAME OF LICENSEE COMPLETING SELF ASSESSMENT	MO PHARMACIST LICENSE #	Position/Title	Date
LICENSEE ADDRESS (ADDRESS OF PERSON REQUESTING CE)	CITY, STATE	ZIP	
PHARMACY ADDRESS (ADDRESS OF PHARMACY REVIEWED)	CITY, STATE	ZIP	
PHARMACY PERMIT NUMBER	DATE SELF-ASSESSMENT COMPLETED		
<p>I, the undersigned person, do hereby attest that I have completed the Self-Assessment for the pharmacy identified above and request continuing education (CE) credit.</p>			
_____		_____	
Licensee Signature		Print Name	

****Your CE certificate will be mailed to the licensee address listed above****

Mail this certification to:
Missouri Board of Pharmacy
Attn: Compliance Coordinator
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, Missouri 65109