

MISSOURI BOARD OF PHARMACY 2016 NON-RESIDENT PHARMACY SURVEY



Dear Missouri Pharmacy Permit Holder:

Pursuant to Chapter 338 of the Revised Statutes of Missouri and rule 20 CSR 2220-2.025, the Missouri Board of Pharmacy is conducting a survey of Missouri licensed non-resident pharmacies that currently hold a Class-H Sterile Compounding pharmacy permit. The purpose of this survey is to assess sterile compounding activity in this state.

The survey should be completed by the facility's pharmacist-in-charge and returned to the Board office on or before **June 15, 2016**. Completed surveys and the requested documentation should be mailed to:

Missouri Board of Pharmacy
3605 Missouri Boulevard
Jefferson City, Missouri 65102

Alternatively, a fillable PDF survey is available on the Board's website at <http://pr.mo.gov/pharmacists.asp>. The fillable PDF may be completed and mailed to the Board office at the address above along with any requested documentation.

PHARMACY NAME			PHARMACY PERMIT NO.
PHARMACY ADDRESS	CITY	STATE	ZIP CODE
EMAIL ADDRESS		PHARMACY TELEPHONE NUMBER	
PHARMACY TELEPHONE NUMBER		E-MAIL ADDRESS	
PHARMACIST-IN-CHARGE		PHARMACIST-IN-CHARGE LICENSE NUMBER	

1. Does the pharmacy compound sterile preparations for Missouri patients?

- Yes
 No
 Not currently, but we choose to maintain the pharmacy's Class-H permit.

*Skip to question #30 if the pharmacy does **not** distribute or dispense compounded sterile products in Missouri.*

2. If yes, what percentage of the pharmacy's business is related to sterile compounding for Missouri patients?

- Less than 10%
 11% to 25%
 26% to 50%
 51% to 75%
 Greater than 75%

3. What type(s) of sterile products does the pharmacy compound for Missouri patients? Check all that apply.

- Risk Level 1
 Risk Level 2
 Risk Level 3

4. Does the pharmacy compound **RISK LEVEL 3** products for Missouri patients?

- Yes
 No

5. If yes, what percentage of the pharmacy's business is related to compounding **RISK LEVEL 3** products for Missouri patients?

- Less than 10%
 11% to 25%
 26% to 50%
 51% to 75%
 Greater than 75%

6. What type(s) of **RISK LEVEL 3** products does the pharmacy compound for Missouri patients? Check all that apply.

- Not Applicable
 Implantable pellets
 Injectables
 Irrigation solutions
 Ophthalmic preparations
 Inhalation preparations
 Other: _____ (attach additional sheets if necessary)

7. Does the pharmacy hold a Missouri Class-J Shared Services pharmacy permit? (If yes, provide a list of all Missouri pharmacies that the pharmacy operates with under a Class J shared services agreement).

- Yes
 No

8. 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)?

- Yes
 No

9. If "yes", what would be the pharmacy's largest single batch in a typical week:

- 24 or less doses in a single batch
 25-49 doses in a single batch
 50-99 doses in a single batch
 100-999 doses in a single batch
 1,000 or greater doses in a single batch

10. What drug(s) do you compound in a batch process for Missouri patients? (Please provide a listing of each drug)

11. What risk level are your batch preparations?

- Risk Level 1
 Risk Level 2
 Risk Level 3

12. What percentage of your sterile compounded preparations prepared in a batch are high risk preparations (this would include non-sterile to sterile preparations)?

- Less than 10%
 11% to 25%
 26% to 50%
 51% to 75%
 Greater than 75%

13. Is a patient specific prescription required prior to distributing or dispensing a sterile compound into Missouri?

- Yes
 No

14. Are you registered with the FDA (U.S. Food and Drug Administration) as a 503(B) outsourcing facility?

- Yes
 No

15. If you are a registered 503(B) outsourcing facility, are you shipping or do you intend to ship non-patient specific compounds into Missouri?

- Yes
 No

Please note that a Missouri drug distributor license is required for 503(B) entities shipping non-patient specific compounds into Missouri*

16. When was the pharmacy last inspected by your state regulatory authority? (Please provide a copy of your last state inspection)

- Less than six (6) months
- Within the last year
- Within the last eighteen (18) months
- Within the last two (2) years
- More than two (2) years ago

17. Was the inspector for your last state regulatory inspection an inspector from the state regulatory board of pharmacy or a contracted vendor?

- An inspector of my state regulatory board for pharmacy
- A contracted vendor
- Unknown

18. 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)?

- Yes (Please provide a copy of the inspection report/findings)
- No

19. Has the pharmacy been inspected by the Food and Drug Administration (FDA)?

- Yes
- No

20. If so, when was the pharmacy inspected by the FDA (month/date/year)?

- Date: _____
- Not applicable

21. Did the FDA issue a Form 483 as a result of the inspection?

- Yes (Please provide a copy of the Form 483)
- No

22. Has your pharmacy's sterile compounding activities been inspected by a third-party vendor (e.g., VPP-NABP)? If so, on what date?

- Yes (Provide a copy of the inspection report)
- No

23. How often does the pharmacy require or provide aseptic technique training for pharmacists?

- Never
- At least monthly
- At least every six (6) months
- At least annually
- At least every two (2) years

24. How often does the pharmacy require or provide aseptic technique training for technicians?

- Never
- At least monthly
- At least every six (6) months
- At least annually
- At least every two (2) years

25. Does the pharmacy perform process validation using growth medium to validate aseptic technique?

- Yes
- No

26. If yes, how often?

- Never
- At least monthly
- At least every six (6) months
- At least annually
- At least every two (2) years

27) Is process validation performed for all risk level activities?

- Yes
- No

28) Does the pharmacy perform glove-fingertip sampling?

- Yes
- No

29) If yes, how often?

- Never
- At least monthly
- At least every six (6) months
- At least annually
- At least every two (2) years

30) Has your state adopted USP 797?

- Yes
- Yes, but with modifications
- No

DOCUMENT REQUEST

Please provide the following documents:

- A list of all sterile compounding preparations dispensed into Missouri between January 1, 2015 and December 31, 2015. (The list should include the following for each preparation: the type of preparation, risk level, # of dosage units dispensed, prescription # and if the product was prepared from a batch)
- A list of all sterile preparations that the pharmacy routinely compounds in a batch process for Missouri patients.
- Copies of the most recent pharmacy inspection report from any state board of pharmacy or state regulatory board or agency for the practice of pharmacy. (This includes the pharmacy's home state inspection report and any other state/regulatory board of pharmacy).
- If the pharmacy was inspected by the FDA and a Form 483 was issued, provide a copy of the Form 483.
- If the pharmacy's sterile compounding activities have been inspected by a third party vendor (e.g., VPP-NABP), provide the most recent inspection report.
- A list of all Missouri pharmacies that the pharmacy operates with under a Class J-shared services agreement.

Your survey response and the **requested documentation** should be returned by mail to—

Missouri Board of Pharmacy
3605 Missouri Boulevard
Jefferson City, Missouri 65102

Surveys should be returned before **June 15, 2016**. A PDF fillable version of the survey is available online at <http://pr.mo.gov/pharmacists.asp>.