



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Response to 2015 Pew Questionnaire on pharmacy compounding policy

START Please enter the name of the state for which you are completing this survey and date entered:

STATE NAME: **The Commonwealth of Massachusetts**

DATE: **February 24, 2016**

Q1 Does your state track (select all that apply):

- The number of pharmacies in the state that perform compounding?
- The number of pharmacies in the state that perform sterile compounding?
- * The number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients into the state?
- None of the above.
- Don't know

* **pending**: Pharmacy Reform Legislation Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice created additional pharmacy licenses categories, including non-resident pharmacies shipping into the Commonwealth. The Board is currently promulgating regulations. Once approved, non-resident pharmacies will be required to be licensed by the Board of Pharmacy if they dispense or ship into the Commonwealth of Massachusetts.

If your state does track the number of pharmacies in the state that perform compounding:

Q2a How many in-state pharmacies perform compounding? Please provide total count.

There are **29** pharmacies in the Commonwealth of Massachusetts that have filed a sterile compounding attestation. Massachusetts requires all pharmacies licensed by the Board to provide non-sterile compounded medications, unless a waiver has been granted.

If your state does track the number of pharmacies in the state that perform sterile compounding:

Q2b How many in-state pharmacies perform sterile compounding? Please provide total count.

There are **29** pharmacies in the Commonwealth of Massachusetts that have filed a sterile compounding attestation.

If your state does track the number of out-of-state pharmacies that ship or dispense compounded drugs to providers or patients into the state:

Q2c How many out-of-state pharmacies currently ship or dispense compounded drugs to providers or patients inside of the state? Please provide total count.

The Board does not have this information at this time. The Board is currently promulgating regulations. Once approved, non-resident pharmacies will be required to be licensed by the Board of Pharmacy if they dispense or ship into the Commonwealth of Massachusetts.

Q3 Does the state mandate USP Chapter 797 on Sterile Compounding or equivalent for pharmacies that perform sterile compounding?

- Yes
- Yes, but not in its entirety
- No, but will under pending policy change
- No
- Don't know

If you answered "Yes" or "Yes, but not in its entirety" then please answer the following question:

Q3a Please provide name of legislation or regulation that mandates USP Chapter 797 on Sterile Compounding or equivalent for pharmacies that perform sterile compounding.

RESPONSE: M.G.L. c 112, § 39G and 247 CMR 9.01(3)

Q4 How is compounding defined by the state for the purpose of meeting USP 797 standards? (Please select all that apply):

- Constrained to 2 or more ingredients
- Repacking
- Reconstituting or dilution or pooling
- Other (please describe): In Massachusetts, compounding is defined as the preparation, mixing, assembling, packaging or labeling of 1 or more active ingredients with 1 or more other substances by or under the supervision of a licensed pharmacist within a licensed pharmacy to create a final drug preparation that is formulated:

(1) for use on or for a patient as a result of a practitioner's prescription order, based on the relationship between the practitioner, patient and pharmacist in the course of routine professional practice to meet the unique medical need of an individual patient by producing a significant difference between the compounded drug preparation and a comparable commercially available drug that is justified by a documented medical need as determined by the prescribing practitioner including, but not limited to, the removal of a dye for medical reasons, a change in strength, a change in dosage, form or delivery mechanism; provided, that a price difference shall not be a significant difference to justify compounding;

(2) in anticipation of prescription orders based on routine, regularly-observed prescribing patterns which can be verified by accountability documentation; or

(3) for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing.

Except as provided in clause (1), "compounding" shall not include the preparation of commercially available, federal Food and Drug Administration approved drugs or drug preparations.

- Don't know

Q5 For pharmacists that perform sterile compounding, does the state set specific minimum expectations for regular training on sterile compounding, beyond USP requirements (such as a minimum number of hours of continuing education devoted to sterile compounding)?

- Yes
- No
- Don't know

If Yes. Is Selected for Q5, please answer the following question

Q5a If yes, what are the additional training requirements for pharmacists that perform sterile compounding?

Respondent comment: Pharmacists engaged in or overseeing sterile and / or non-sterile complex compounding shall obtain 5 hours (sterile) and / or 3 hours (non-sterile complex) of continuing education credit per year. See M.G.L c. 112, § 24A

Q6 Are sterile-compounding-related violations tracked separately by the state?

- Yes
- No
- Don't know

If Yes Is Selected for Q6, please answer the following question

Q6a How many of the following sterile compounding-related violations occurred in 2014? Select and respond to all that apply.

- Total number of sterile-compounding violations: _____
- ...violations that resulted in disciplinary action: _____
- ...violations that resulted in a mandatory recall: _____
- ...violations that resulted in a cease and desist order: _____
- Don't know

Q7 Does the state require pharmacies that perform sterile-compounding to report serious adverse events to the state and/or Med Watch (the FDA Safety Information and Adverse Event Reporting Program)?

- Yes, to the state and to MedWatch
- State only
- MedWatch only
- Not required to report serious adverse events to state or MedWatch
- Don't know

Q8 Does the state list disciplinary actions related to pharmacy violations on a public website?

- Yes
- No
- Don't know

If Yes Is Selected for Q8, please answer the following question:

Q8a Does the state separately list disciplinary actions for compounding-related violations?

- Yes
- No
- Don't know

Q9 Does the state have the authority to share information about inspections, investigations, and enforcement concerns related to drug compounding with other regulators and officials, both federal and state? Select all that apply:

- The state has no authority to share information with any other regulators and officials
- Information is available on public website through announcements and/or reports
- Has the authority to share with in-state regulators and officials
- Has the authority to share with regulators and officials in other states
- Has the authority to share with federal regulators and officials
- Don't know

Q10 Are pharmacies that perform sterile-compounding required to report voluntary recalls to the state and/or FDA?

- Yes, to the state and FDA
- State only
- FDA only
- Neither
- Don't know

Q11 Does the state have the authority to mandate a recall?

- Yes
- No
- Don't know

Q12 Does the state have the authority to issue cease and desist orders?

- Yes
- No
- Don't know

Q13 Does the state have the authority to request reports from pharmacies that perform sterile compounding on the number of sterile products they prepare?

- Yes Massachusetts requires sterile compounding pharmacies to file this information twice per year.
- No
- Don't know

Q14 Does the state allow pharmacies to compound without patient-specific prescriptions, such as to provide a doctor with a stock of medicines to use in the office?

- Yes
- Yes, but with specific limits (please describe these limits):
- No. Dispensing stock supplies to physicians for “office use” is prohibited in Massachusetts; however pharmacies may compound in anticipation of a patient specific prescription. The compounded preparation cannot be dispensed until the prescription is received. The pharmacy must be able to support the anticipatory compounding volume with prescription data.
- Pending policy change: state will prohibit compounding without patient-specific prescriptions
- Pending policy change: state will limit compounding without patient-specific prescriptions
- Pending policy change: state will allow compounding without patient-specific prescriptions
- Don't know

If “Yes” OR “Yes, but with specific limits (please describe these limits):” OR “No.” Is Selected, please answer the following question:

Q14a Please provide name of legislation or regulation that addresses compounding without patient-specific prescriptions.

RESPONSE: M.G.L. c. 112, § 39F

Q15 How does the state license or register facilities that register with FDA under the new federal outsourcing facility; (OF) category of drug compounders?

(The Drug Quality and Security Act of 2013 created a new section of federal law that allows a facility that compounds sterile drugs to register with the FDA as an “outsourcing facility.” Outsourcing facilities do not have to compound pursuant to patient prescriptions, but they must comply with Good Manufacturing Practices and submit to risk-based FDA inspections, among other requirements)

- State law or regulation has a specific outsourcing facility licensure or registration category
- State is currently developing a specific outsourcing facility licensure or registration category
- State licenses or registers outsourcing facilities as manufacturers
- State licenses or registers outsourcing facilities as wholesalers
- State licenses or registers outsourcing facilities as pharmacies
- State does not license or register outsourcing facilities
- Other: _____
- Don't know

If “State law or regulation has a specific outsourcing facility licensure or registration category” is selected, please answer the following question:

Q15a Please provide name of legislation or regulation that establishes the specific outsourcing facility licensure or registration category

RESPONSE: M.G.L. c 112 section 36E and 247 CMR 21

Q16 How does the state address facilities that perform sterile compounding without patient-specific prescriptions that are not registered with FDA? Select all that apply:

- Require those facilities to register with the FDA as outsourcing facilities
- Inform FDA of such facilities
- Take disciplinary action (if facility was a pharmacy dispensing without a patient - specific prescription)
- None of the above
- Don't know

Q17 Is there a separate license or other requirement (e.g. permit) for pharmacies that perform sterile compounding?

- Yes *
- No
- Don't know

* **pending:** Pharmacy Reform Legislation Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice created additional pharmacy licenses categories that include a separate license for sterile compounding pharmacies.

Q18 Does the state independently license out-of-state pharmacies that ship or dispense products to providers or patients inside of the state?

- Yes *
- No
- Don't know

* **pending:** Pharmacy Reform Legislation Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice created additional pharmacy licenses categories including non-resident pharmacies shipping into the Commonwealth.

Q19 How many inspectors (full-time equivalents, FTEs) does the state employ that conduct pharmacy inspections?

- Provide number: 12

Q20 Describe the minimum training requirements for inspectors that assess pharmacies that perform sterile compounding. Select all that apply:

- Entry-to-practice degree in pharmacy (e.g. BPharm, PharmD)
- Licensed pharmacist
- Training on applicable USP standards.
- Prior experience in pharmacy
- Prior experience in compounding pharmacy
- Prior experience in sterile technique/compounding
- No minimum training is mandated for inspectors.
- Other (please describe): _____
- Don't know

Q21 What specific circumstances trigger the state to conduct inspections for in-state pharmacies that perform sterile compounding. Select all that apply:

- Initial licensure
- Licensure renewal
- When pharmacy remodels or moves location
- When a complaint or incident occurs
- Other: _____
- None of the above
- Don't know

Q22 How frequently does the state conduct routine inspections for in-state pharmacies that perform sterile compounding?

- At least every 6 months
- At least every 1 year
- At least every 2 years
- At least every 3 years
- At least every 5 years
- No specific frequency
- Don't know

Q23 Does the state prioritize inspections of in-state pharmacies that perform high-risk sterile compounding?

("High-risk" as per USP 797 standards - for example preparation of sterile product with non-sterile ingredients)

- Yes
- No
- Don't know

Answer If "Yes" Is Selected, please answer the following question:

Q23a How frequently does the state conduct routine inspections for in-state pharmacies that perform high-risk sterile compounding?

("High-risk" as per USP 797 standards - for example preparation of sterile product with non-sterile ingredients)

- At least every 6 months
- At least every 1 year
- At least every 2 years
- At least every 3 years
- At least every 5 years
- No specific frequency
- Don't know

Q24 Does the state board of pharmacy inspect hospital pharmacies that perform sterile compounding?

- Yes *
- No
- Sometimes
- Don't know

* **pending**: Pharmacy Reform Legislation Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice created additional pharmacy licenses categories including institutional sterile compounding pharmacies.

Q25 Are inspections of pharmacies that perform sterile-compounding announced?

- Yes
- No. Inspections are traditionally unannounced; however, new pharmacy or inspections for Board approved renovations / relocations may be coordinated with the pharmacy (as such are scheduled rather than unannounced)
- Sometimes
- Don't know

Q26 How long do inspections of pharmacies that perform sterile compounding usually last?

- Less than 4 hours
- 4-8 hours (with multiple investigators conducting the inspections in teams of 2-3)
- 1-3 days
- Other: _____
- Don't know

Q27 What factors are evaluated during a sterile compounding inspection? Select all that apply:

- Hand-hygiene
- Garbing
- Aseptic technique
- Training
- Facility design and construction
- Cleaning
- Environmental monitoring
- Equipment certification and calibration
- Sterilization procedures and verification
- Control of components and materials
- Standard operating procedures
- Documentation
- Other (please describe): _____
- Don't know.

Q28 Is direct observation of sterile compounding activity required during inspections of pharmacies that perform sterile compounding, even if it must be simulated?

- Yes
- No
- Don't know

Q29 Does the state have the ability to take and test samples of sterile compounded drugs for inspections or investigations?

- Yes
- No
- Don't know

Q30 How does the state follow-up with pharmacies to ensure that violations are addressed? Select all that apply:

- State conducts on-site inspection to verify that issues are addressed
- State requires written response from pharmacy describing how issues are addressed
- Other (please describe): Documentation through reports related to sterile compounding operations, such as environmental monitoring, etc.
- No follow-up is performed after violations are identified
- Don't know

Q31 Do state inspectors ever conduct or coordinate inspections with the Food & Drug Administration (FDA)?

- Yes
- No
- Don't know

Q32 How does the state verify that out-of-state pharmacies that perform sterile compounding comply with their applicable regulations? Select all that apply:

- Compliance is not verified
- Inspection performed by home-state operated agency or group
- Inspection performed by National Association of Board of Pharmacies' (NABP) Verified Pharmacy Program *
- Inspection performed by other third party approved in advance by the state
- Inspection performed by a third party not approved in advance by the state
- Review of inspection report by another state, conducted in the past ____ years (please provide): _____
- Pharmacy must provide self-evaluation or attestation of compliance
- Other (please describe): _____
- Don't know

* **pending:** Pharmacy Reform Legislation Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice created additional pharmacy licenses categories including non-resident. The non-resident pharmacies will be held to the same standards as in-state pharmacies. The Board has solicited the services of NABP to perform the non-resident inspections.

Q33 Must inspection reports by third parties or other states demonstrate compliance with USP standards?

- Yes, as well as compliance with Massachusetts regulations.
- No
- Don't know
- Not applicable

Q34 Do third-party inspectors provide all information on compliance and any compliance-failures that are observed?

- Yes *
- No
- Don't know
- Not applicable

*** pending promulgation of regulations**

Q35 What specific circumstances trigger the state to assess compliance for out-of-state pharmacies that perform sterile compounding. Select all that apply:

- At initial licensure
- Licensure renewal
- When facility remodels or moves location
- When a complaint or incident occurs
- Other: _____
- None of the above
- Don't know

*** pending promulgation of regulations**

Q36 How frequently does the state assess compliance for out-of-state pharmacies that perform sterile compounding?

- At least every 6 months
- At least every 1 year *
- At least every 2 years
- At least every 3 years
- At least every 5 years
- No specific frequency
- Don't know

*** pending promulgation of regulations**

Q37 How does the state provide oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards?

- Oversight provided by the state board of medicine
- Oversight provided by the state board of pharmacy
- No oversight system to ensure compliance
- Other (please describe): _____
- Don't know.

Q38 Does the state have a mechanism to track which in-state physician offices or clinics perform sterile compounding? (Please exclude any entity registered as a pharmacy)

- Yes
- No

X Don't know (Board of Pharmacy does not have jurisdiction over physician practices in Massachusetts)

Q39 Are physician offices or clinics that perform sterile compounding held to the same quality standards as pharmacies that perform sterile compounding, such as USP Chapter 797?

- Yes
- No

X Don't know (Board of Pharmacy does not have jurisdiction over physician practices in Massachusetts; however, clinics licensed as institutions that contain an institutional pharmacy will be required to register with the Board once regulations are promulgated)

Q40 Does the state board of medicine or other state regulatory body have the ability to track adverse events associated with sterile compounded products made in a physician office or clinic?

- Yes
- No
- X Don't know**

FINISH