

## Bureau of Health Care Services

# Compounding Pharmacy Law FAQ

### (PA 280 of 2014)

**1. When does this new law come into effect?**

This new law is in effect beginning September 30, 2014.

**2. Will I need to be licensed to conduct business in Michigan?**

Yes, the law requires that all pharmacies, manufacturers and wholesale distributors must have a Michigan license to do business in this state, whether or not they are located in this state.

**3. Will there be new licensing requirements if we're involved in compounding of pharmaceuticals?**

Yes. An applicant for a new pharmacy license for a pharmacy that will provide compounding services for sterile pharmaceuticals must provide verification of current accreditation or verification that the pharmacy is in the process of obtaining verification through the Pharmacy Compounding Accreditation Board (PCAB) of the Accreditation Commission for Health Care (ACHC). Information about PCAB accreditation can be found at [www.achc.org](http://www.achc.org). If the pharmacy is in the accreditation process, the applicant must demonstrate compliance with USP standards. [Section 17748a(1)]:

By September 30, 2015, a pharmacy that was licensed on September 30, 2014 and provides compounding services for sterile pharmaceuticals must be accredited by the PCAB, in the process of obtaining PCAB accreditation or be in compliance with USP standards.[ Section 17748a(2)]

The law requires verification of current accreditation or compliance with USP standards at the time a license renewal application is submitted by a pharmacy that provides compounding services for sterile pharmaceuticals. [Section 17748a(3)]

**4. Does the new law contain any prohibitions as it pertains to the compounding of pharmaceuticals?**

Yes, the law states that a pharmacist shall not offer excess compounded pharmaceuticals to other pharmacies for resale. A compounding pharmacy shall not

distribute samples or complimentary starter doses of a compounded pharmaceutical to a health professional. [Section 333.17748a(7)]

The law states that a person is prohibited from compounding and manufacturing drug products or allowing the compounding and manufacturing of drug products at the same location [Section 333.17748a(10)].

The law prohibits the compounding of sterile or nonsterile pharmaceuticals without a prescription but does allow under certain conditions [Section 333.17748b(1)].

The law states that the department shall not authorize a pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals without a prescription if the pharmacist or pharmacy is under investigation, is in the process of being disciplined, or is in a disciplinary status. [Section 333.17748b(4)].

The law prohibits a prescriber or health agency or facility from re-dispensing or selling a compounded product to a patient, a prescriber, or a health facility or agency [Section 333.17748b(8)].

**5. Does this new law allow for the compounding of certain drugs in limited quantities?**

Yes, Section 333.17748b(1) states the following:

Except as otherwise provided in this subsection, a pharmacist or pharmacy shall not compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients without a prescription, unless the pharmaceutical compounded by the pharmacist or pharmacy complies with the most recent guidance on pharmacy compounding of human drug products under 21 USC 353a. Upon application by a pharmacist or compounding pharmacy, the department may authorize the pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients in limited quantities without a prescription. This subsection does not apply to the compounding of topical nonsterile pharmaceuticals. The department shall prescribe the form of the application for use under this subsection.

**6. Will I be subject to more inspections if I'm involved in the compounding of pharmaceuticals?**

An inspection may be conducted at the time an application is submitted but much would depend on information contained in the application and whether the information would raise questions that would warrant an inspection. The new law does state, in part, that the department may, without prior notice to the pharmacist or the pharmacy, physically inspect the facility where the compounding of nonsterile or sterile pharmaceuticals occurs. [Section 333.17748b(3)]

**7. When will the Compound Pharmacy applications be available?**

Applications are available to download. Please visit our website link: [http://www.michigan.gov/lara/0,4601,7-154-35299\\_63294\\_27529\\_27548---,00.html](http://www.michigan.gov/lara/0,4601,7-154-35299_63294_27529_27548---,00.html) Check the listing under the heading “*Licensing Applications and Forms.*”

**8. How does a PIC tied to an Out-of-State Pharmacy become licensed in Michigan?**

Complete the Michigan Pharmacist by Endorsement Application. You may download this application by clicking on the following link: [https://www.michigan.gov/documents/lara/Pharmacist\\_Endorsement\\_455794\\_7.pdf?20140922103557](https://www.michigan.gov/documents/lara/Pharmacist_Endorsement_455794_7.pdf?20140922103557).

**9. Once I receive my Compound Pharmacy license, will my license appear on a list as authorized to compound pharmaceuticals?**

The new law requires that the Department post, on its internet website, a list of those pharmacies and pharmacists authorized to compound pharmaceuticals. The listing will be made available as soon as licenses are issued.

**10. Under what circumstances will I need to designate a Pharmacist-In-Charge (PIC) and is the PIC required to be licensed in Michigan?**

The new law requires that a pharmacy, manufacturer or wholesale distributor designate a PIC.

If the entity is a **pharmacy** located in, and doing business in Michigan, a PIC is required and the PIC must be licensed in Michigan.

If the **pharmacy** is **not located in Michigan** and is doing business in Michigan, the PIC must be licensed in Michigan.

If the entity is a **manufacturer or a wholesale distributor** a PIC is currently required.

- The PIC may be licensed in Michigan or if the entity is located in another state, the PIC may be licensed in the other state. *Effective March 30, 2015, a wholesaler distributor can have either a PIC or a “facility manager.”*
- An out-of-state **wholesale distributor** will be allowed to have one PIC responsible for multiple facilities even if the locations are distant.
- As a Michigan licensed manufacturer or wholesale distributor, all **supplier, distributor, or durable distributor** entities are currently required to designate a PIC. The PIC may be licensed in Michigan or if the entity is located in another state, the PIC may be licensed in the other state. *Effective March 30, 2015, a manufacturer or wholesale distributor will have an exemption from this requirement with respect to a device saleable on prescription only but not with respect to any drug saleable on prescription only.*

## 11. As a wholesale distributor why would I be required to have a PIC?

The definition of a “wholesale distributor” as articulated in the Public Health Code states the following and if your services fall under this definition then you must comply with this new requirement:

"Wholesale distributor" means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barter, or otherwise disposes of, to other persons for resale, compounding, or dispensing, a drug or device saleable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device. [Section 333.17706(1)]

*Effective March 30, 2015, a wholesale distributor can have either a PIC or a “facility manager.” In addition, a manufacturer or wholesale distributor will have an exemption from this requirement with respect to a device saleable on prescription only but not with respect to any drug saleable on prescription only.*

## 12. As a durable medical equipment provider why would I be required to have a PIC?

The definition of a “wholesale distributor” or “manufacturer” as articulated in the Public Health Code states the following and if your services fall under either of these definitions then you must comply with the new PIC requirement:

"Wholesale distributor" means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barter, or otherwise disposes of, to other persons

for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device.

“Manufacturer” means a person who prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and who supplies, distributes, sells, offers for sale, barter, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing.[Section 333.17706(1)]

*Effective March 30, 2015, manufacturer or wholesale distributor licensees are exempt from designating a PIC or Facility Manager with respect to a device saleable on prescription only but not with respect to any drug saleable on prescription only.*

**13. Am I required to have a PIC if I am a durable medical equipment provider providing ONLY MEDICAL OXYGEN?**

No. A PIC is not required for a manufacturer/wholesale distributor who only provides medical oxygen. MCL 333.17770(e) provides for an exemption.

**14. Does the new law define a Pharmacist-in-Charge?**

Yes. “Pharmacist in charge” or “PIC” means the pharmacist who is designated by a pharmacy, manufacturer, or wholesale distributor as its pharmacist in charge under Section 17748(2).”

**15. Does the new law define the responsibilities of a PIC?**

Yes. Section 333.17748(5) states: “A pharmacist in charge shall supervise the practice of pharmacy for the pharmacy in which he or she has been designated the PIC. The duties of the PIC include, but are not limited to, the following:

(a) Supervision of all activities of pharmacy employees as they relate to the practice of pharmacy including the purchasing, storage, compounding, repackaging, dispensing, and distribution of drugs and devices to ensure that those activities are performed in compliance with this part and the rules promulgated under this part.

(b) Enforcement and oversight of policies and procedures applicable to the employees of the pharmacy for the procurement, storage, compounding, and

dispensing of drugs and the communication of information to the patient in relation to drug therapy.

(c) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance of security provisions to be used when the pharmacy is closed.

(d) Establishment and supervision of the record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs and devices.

(e) Establishment of policies and procedures for individuals who are delegated responsibilities for any of the tasks described in this subsection by the PIC.”

## **16. Does the new law contain new reporting requirements?**

Yes, the law mandates that a pharmacy, manufacturer, or wholesale distributor shall report to the department a change in ownership, management, location, or designated PIC not later than 30 days after the change occurs [Section 333.17748(4)].

The law mandates compliance with FDA requirements applicable to compounding services for sterile pharmaceuticals by an outsourcing facility [Section 333.17748a(4)].

The law requires that a pharmacy shall notify the department of a complaint filed by another state in which the pharmacy is licensed for violations of that state's pharmacy laws, an investigation by federal authorities regarding violations of federal law, or an investigation by any agency into violations of accreditation standards regarding compounding activities within 30 days of knowledge of the complaint or investigation. [Section 333.17748a(5)].

The law requires that a pharmacy or pharmacist authorized to compound pharmaceuticals under this section that becomes aware of an adverse event attributed to the integrity of the product of a compounded pharmaceutical shall report the adverse event to the department not later than 10 calendar days after becoming aware of the adverse event. For purposes of this subsection, an adverse event does not include an isolated allergic reaction to a substance included in the compound if the allergic reaction is treated and relieved with standard protocol. [Section 333.17748b(6)].

## **17. Are Manufacturer/Wholesale Distributor PICs required to work an average of 8 hours per week at each location?**

No. The 8 hour per week requirement applies to Pharmacies only and not to Manufacturer/Wholesale Distributor PICs.

**18. Are Veterinarians required to have a Pharmacist in Charge or a Facility Manager?**

No. MCL 333.17748 requires only pharmacies, manufacturers and wholesale distributors to have a “pharmacist in charge.” Effective March 30, 2015, a wholesale distributor can have either a “pharmacist in charge” or a “facility manager.” In addition, a manufacturer or wholesale distributor will have an exemption from this requirement with respect to a device saleable on prescription only but not with respect to any drug saleable on prescription only.

**19. Does the new compounding law apply to Veterinarians?**

The law (MCL 333.17702) defines compounding as the preparation, mixing, assembling, packaging, and labeling of a drug or device by a Pharmacist under the following circumstances:

- (a) Upon the receipt of a prescription for a specific patient.
- (b) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice;
- (c) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.
- (d) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

Compounding does not include any of the following:

- (a) Except as provided in MCL 333.17748c, the compounding of a drug product that is essentially a copy of a commercially available product.
- (b) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.
- (c) The compounding of allergenic extracts or biologic products.

**20. Who can I contact for more information?**

For pharmacy-related issues, please contact the Pharmacy Services Unit at (517) 373-1737 during regular office hours.

For questions regarding licensing and filing your application, please contact us at (517) 335-0918 or visit our website at: [http://www.michigan.gov/lara/0,4601,7-154-35299\\_63294\\_27529\\_27548---,00.html](http://www.michigan.gov/lara/0,4601,7-154-35299_63294_27529_27548---,00.html).