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Oversight of Pharmacies: Accreditation & Inspections – Michigan Update

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Bureau of Professional Licensing

- Established in July 2015
- 11 Occupational Licensing/Regulation Boards
- 24 Health Professional Licensing/Regulation Boards
- Boards are advisory and determine sanctions
- License and regulate over 745,000 individuals
- 4 Divisions: Licensing, Investigations & Inspections, Legal Affairs, and Special Programs
- License and Regulate Pharmacies, Pharmacists, and Pharmacy Technicians, Manufacturer/Wholesaler

Quality & Accreditation

Enacted PA 280 of 2014 (September 30, 2014):

- New pharmacy applicants, MCL 333.17748a(1):
  - Pharmacy that provides compounding services for sterile pharmaceuticals shall submit verification of current accreditation through a national accrediting organization approved by the board or verify the pharmacy is in the accreditation process.
  - Department shall not issue a license to a pharmacy described in this subsection that is not accredited unless the applicant demonstrates compliance with USP standards in a manner determined by the board.

Quality & Accreditation

- Existing pharmacies, MCL 333.17748a (2):
  - By **September 30, 2016**, a pharmacy that is licensed on September 30, 2014 and that provides compounding services for sterile pharmaceuticals **must be accredited by a national accrediting organization approved by the board**;
  - Be verified by the board as in the accreditation process;
  - Be in compliance with USP standards as determined by the board.
  - NOTE: Michigan has a 2 year renewal cycle for pharmacies.

Quality & Accreditation

- Board of Pharmacy approved of the following third-party accreditation for USP 797 compliance:
  - NABP
  - PCAB
  - Joint Commission – Medication Compounding Certification Program
- Third-party USP accreditation is required for all sterile compounders.
- R 338.477g, a pharmacy may petition the board of a different accreditation organization.

Quality & Accreditation

In accordance with the accreditation process set by statute, MCL 333.17748a(2):

- August 2016, Board set deadline of **June 30, 2017** for pharmacies currently in the accreditation process to be completed.

Current draft Rules:

- www.Michigan.gov/ORR
  - Latest Rules Activity
  - Pending Rule Changes
  - Licensing and Regulatory Affairs – 2014-147 LR

Quality & Accreditation:

Other provisions of PA 280 of 2014 include:

- Verification of USP accreditation for sterile compounders when licenses are renewed.
- Outsourcing facilities must comply with FDA requirements.
- Any complaint in another state, investigation by federal or accreditation authorities must be reported to the department within 30 days.
- Detailed compounding records must be retained for 5 years.
- Samples (complimentary starter doses) for compounded drugs are prohibited.
- The department may promulgate additional rules pertaining to compounding.

Inspections

- Pre-licensure inspections
- Rely on NABP-VPP to verify inspections/status of out-state pharmacies
- Inspections/accreditation reviewed every two years (renewal cycle) for sterile compounding pharmacies
- Restructured organizationally:
  - 2 Pharmacist Specialists focus on complex/complaint inspections
  - 4 Regulation Officers (Inspectors) conduct retail inspections

Inspections & NABP Partnership

Michigan is developing a partnership with NABP to assist in protecting the public:

- Conducted survey of over 2779 MI Pharmacies
- Patient Specific:
  - 843 performing non-sterile
  - 203 performing sterile
- Non-Patient Specific:
  - 80 performing non-sterile
  - 55 performing sterile

Inspections & NABP Partnership

- Survey was follow-up to 2012 Michigan Survey
- Inspect sterile compounding pharmacies
- Train Pharmacy Specialists and Inspectors
- Looking to see if there are other ways to use NABP as a resource and build on partnership and collaboration to achieve state's mission and objectives

Questions?

THANK YOU!