Oversight of Pharmacies: Accreditation & Inspections – Michigan Update

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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
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!