



# NABP

National Association of Boards of Pharmacy

Second Committee Meeting to Assess the Available Scientific Data Regarding the Safety and Effectiveness of Ingredients Used in Compounded Topical Pain Creams

NASEM

Washington, DC

## **Federal and State Regulations of Compounding**

May 20, 2019

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# NABP

- The National Association of Boards of Pharmacy (NABP) was Founded in 1904
- Not for Profit Organization whose members include all 50 States and Territories
- Support Member Boards of Pharmacy to Protect Public Health through its pharmacist license transfer and pharmacist competence assessment programs, as well as through its accreditation programs

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# US State Boards of Pharmacy

50 individual state boards are responsible for enforcing state Pharmacy Practice Acts by regulating the practice of pharmacy within their state to ensure protection of the public

- 43 states established Boards of Pharmacy in the 1800s. The first was in 1870
- Pharmacy Practice Acts are State Statutes (laws) which are created by State Legislation. The Boards create regulations (rules).
- Boards of Pharmacy reside within different State Agencies including Departments of Health and Occupational Licensing.
- Some Boards of Pharmacy are independent of other agencies.



# US State Boards of Pharmacy

- License pharmacists, pharmacies, technicians (individuals cannot practice pharmacy or sell prescription medication without being licensed by the state board)
- Perform regular onsite practice compliance reviews and inspections
- Regulate retail practice and hospital practice
- In some states, boards will also license prescription drug wholesalers (80%), manufacturers, and sterile compounding outsourcing facilities



# US State Board of Pharmacy Stats

## Board of Pharmacy Member Composition

- Average number of pharmacist members = 6
- Average number of public members = 2
- Average term length = 4 years
- Average term limit = 2 terms (8 have no term limits)

## Board Staffing

- Executive director and associate executive director
- Compliance officers/Inspectors - Average number = 6
  - High = 49 (CA)
  - Low = 1
  - States with > 10: CT (10), FL (18), GA (10), MA (13), NC (13), TX (21), VA (11), WA (12)
- Legal/General counsel
- Various administrative support staff



# Pharmacist Educational Requirements

- US state boards of pharmacy recognize pharmacy degree programs accredited by the Accreditation Council for Pharmacy Education (ACPE)
- 135 accredited pharmacy degree programs in the US.
- 1,740 supervised internship hours required before fully licensed by the state board
- After initial licensure, each pharmacist must participate in continuing education programming as part of a life-long learning requirement



# Board of Pharmacy Oversight

- Dependent on Resources available to the State
- “Practice of the profession of pharmacy” includes interpretation of orders, **compounding**, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug through Pharmacist Care Services
- Some state Boards regulate drugs from Manufacturer to the Patient



# Boards of Pharmacy Oversight

Board of pharmacy responsibilities include, but are not limited to:

- Regulation of Drug Laws modeled after the Federal Food, Drug, and Cosmetic Act (FDA law)
- Requirements for Licensure of pharmacists and pharmacies
- Establishment of pharmacist practice standards
- Establishment of standards for pharmacies, including physical facility, technical equipment, environment, supplies, personnel, and procedures for the procurement, storage, compounding, dispensing of drugs
- The Regulation of Compounding has historically fallen under the authority of the State Boards of Pharmacy





# Boards of Pharmacy Oversight

## Routine Inspections by Boards of Pharmacy: Focus on Compounding

- Enhanced significantly since 2012 (NECC) with devoting of increased resources including more inspections and more training
- States adopt United States Pharmacopeia (USP) Standards in part or entirety
- Compounding training is routinely provided to the States through NABP at no charge, and by the USP, and Educational organizations such as Critical Point at reduced costs or no charge.
- The knowledge and experience of State Boards in the area of compounding is continually improving



# Boards of Pharmacy Oversight

NABP developed, at the request of its members, an inspection program (VPP) to assist states with routine inspections of compounding pharmacies and train state inspectors.

- To date over 1200 pharmacies have been inspected by NABP according to a uniform “Blueprint” inspection developed by the States
- These inspections occur in all 50 states
- Evaluate compounding against USP Standards
- Findings reported to the pharmacy and to the State Board

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# National Standards and Board of Pharmacy Regulations

The definition of “drug” adopted by States is most often a variation of the federal definition and includes:

- A substance recognized by an official pharmacopoeia or formulary
- A substance (other than food) intended to affect the structure or any function of the body.
- This definition includes Active Pharmaceutical Ingredients (APIs or Bulk Drugs)
- The official compendium recognized by Food and Drug Administration (FDA) and many State Boards of Pharmacy is the USP-NF.



# National Standards and Board of Pharmacy Regulations

The state Boards of Pharmacy primarily adopt the following USP chapters.

- USP Chapter <795> for Pharmaceutical Compounding of Non-Sterile compounded drugs
- USP Chapter <797> for Sterile Compounded Drugs

USP Chapter <800> for Hazardous Drugs is in varying stages of being incorporated into State regulations



# Board of Pharmacy Compounding Oversight Compounded vs. Non-compounded Pain Medications

- The approval of drugs is a very important and detailed process that is recognized by the states as a major function of the FDA in protecting the health of the public. The Boards of Pharmacy support this process of safety and efficacy by:
  - Ensuring the receipt of legal drugs (approved) from legal channels (sources) by compliance with the Drug Quality and Security Act - Title II, known as the Drug Supply Chain Security Act (DSCSA) which is being implemented to trace drugs using each bottle's serial number
  - Properly storing and handling medication
  - Insure the accurate dispensing of a drug is pursuant to a legitimate prescription



# Board of Pharmacy Compounding Oversight Compounded vs. Non-compounded Pain Medications

- Compounded drugs are not FDA Approved Drugs
  - Since the NECC tragedy, states have focused on the safety of compounded drugs from a quality perspective, especially drugs intended to be sterile.
  - States focus on the controls in place for the compounding processes including physical layouts, proper environmental conditions, product testing, and personnel.
  - Safety and efficacy issues related to ingredients is continually evolving with the states relying on the development of lists (by FDA) of drugs that can and cannot be compounded.
  - Inspectors sometimes see justifications for certain compounded drugs in the form of journal articles and studies



# Compounded Topical Pain Product Findings

- Multiple active ingredients with no supporting literature to support safety or efficacy
- No justification by prescribers for the use of particular combinations of ingredients
- The use of pre-printed prescriptions provided by the compounding pharmacy with the ingredients and percentage, quantity, instructions, and indication.
- The inability of pharmacies to determine if API is manufactured in an FDA registered facility. Receive Certificate of Analysis from Repackager.



# Common Indications for Pain Creams

## Common Categories of Pain on Pre-Printed Rxs

- Myofascial
- Neuropathic with Inflammation
- Neuropathies
  - Peripheral
  - General
- Joints and Musculoskeletal Pain
  - Plantar Fasciitis
  - Tendonitis
  - Osteoarthritis





# Common Pre-Printed Rx Combinations

- Amitriptyline + Clonidine + Gabapentin + Lidocaine + Diclofenac
- Baclofen + Diclofenac + Lidocaine
- Diclofenac + Lidocaine
- Baclofen + Bupivacaine + Cyclobenzaprine + Gabapentin + Orphenadrine + Pentoxifylline
- Bupivacaine + Diclofenac + Doxepin + Gabapentin + Orphenadrine + Pentoxifylline



# Common Pre-Printed Rx Combinations

- Bupivacaine + Doxepin + Gabapentin + Nifedipine + Pentoxifylline + Topiramate
- Diclofenac + Baclofen + Bupivacaine + Gabapentin + Ibuprofen + Pentoxifylline
- Lidocaine + Diclofenac + Baclofen + Gabapentin
- Lidocaine + Capsaicin + Baclofen + Gabapentin
- Ketoprofen + Amitriptyline + Gabapentin + Lidocaine

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Thank you

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