

Protecting
Advocating
Serving

Perspectives on Physician Compounding

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September 21, 2016

Federation of
STATE
MEDICAL
BOARDS

About FSMB



- FSMB offices in Euless, TX, and Washington, DC
- Established in 1912
- Represents 70 state medical and osteopathic boards
- Nonprofit 501(c)6 organization with approximately 185 staff

FSMB Vision and Mission 2015-2020

Vision

The FSMB is an innovative leader, helping state medical boards shape the future of medical regulation by protecting the public and promoting quality health care.

Mission

The FSMB serves as the voice for state medical boards, supporting them through education, assessment, research, and advocacy while providing services and initiatives that promote patient safety, quality health care, and regulatory best practices.

A Trusted Agent

- Interacts with professional organizations (e.g. AMA, AOA, ACCME), the Administration, Congress and State legislators
- Tri-Regulator-- Informal relationship with National Association of Boards of Pharmacy (NABP) and National Council of State Boards of Nursing (NCSBN)
- Collaborates with international regulators through the International Association of Medical Regulatory Authorities (IAMRA)
 - FSMB serves as IAMRA Secretariat

State Medical and Osteopathic Boards

- Protect the public through the regulation of medical practice
 - Statutory Authority – Medical Practice Act –
 - M.D., D.O., P.A., and other health care professionals
 - Regulate more than 917,000 actively licensed physicians and ~80% of physician assistants
 - Licensure
 - Assure competence and set qualifications
 - Evaluate education, training, examinations
 - General undifferentiated practice of medicine
 - Discipline
 - Set standards for competence and professional conduct
 - Receive and investigate complaints
 - Receive and investigate reports (e.g. malpractice, hospitals, law enforcement, state PDMP)
 - Complaint disposition and/or adjudication
 - Range of disciplinary actions

State Medical Boards and Compounding

- Each board unique in its structure, governmental oversight and composition
- Variety of regulations on compounding
- Variety of formal and informal relationships with Boards of Pharmacies
- No medical board issues a special compounding license
- Some states require a state controlled substance license to prescribe (state "DEA registration")

Factors for Licensees and Boards

- Mutual acknowledgement for the need for safe compounding in the office setting
- Confusion as to definitions and concepts:
 - diluting and reconstituting vs. compounding
 - immediate use
 - high risk medications
 - biologics
- Limited evidence on safety
- Impact of regulatory changes on the physician/patient relationship...and access to care
- Joint Commission accreditation standards apply in certain settings

How can FSMB help?

- Serve as an honest broker between parties
- Encourage formal, structured coordination and communication between Medical and Pharmacy boards—and Health Departments
- Produce guidance documents to interpret FDA and USP standards and to inform writing of regulations
- Develop and distribute educational programs to inform physicians and medical boards

What do we still need?

- Final USP standards for 795, 797 and 800
- Conduits to the regulatory entities for help with definitions and interpretations
- Clear understanding of each agency's authority and regulatory scope
- Formalized communication strategy between federal and state regulators
- A registry to track both complaints and outcomes

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Questions?