Update on Compounding Legislative Activities at the State Level

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Disclosures

• David A. Kosar “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.”

The American College of Apothecaries is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Objectives

At the conclusion of this educational session, the pharmacist and technician attendee will be able to:

• List three main areas where state legislators & regulators are changing compounding pharmacy law.
• Compare different state approaches to “office use” dispensing, preparation of “commercially available” products, and “anticipatory compounding.
• Describe three resources for information on state Board of Pharmacy meetings and proposed regulatory actions.
• Discuss short- and long-term impacts of increased inspection activities by Boards of Pharmacy.
States Biennial Sessions 2013-14

- 50 states & DC convened
- 32 adjourned as of 5/31
- 4 more adjourning by 6/6; 5 by 6/30
- 19 remain in session
- 8 meet year round
- 21 carryover 2013 bills to 2014
- 4 have limited carryover of 2013 bills
State Legislative Overview

- 32 bills introduced as of 5/28/13
- 16 bills passed by legislatures*
- 4 bills passed one chamber**
- 8 bills signed by governors*
- 3 bills died
- 8 bills still in committees**
State Legislative Overview

- **Signed into law**
  - GA HB 209
  - ID HB 17 & HB 239
  - MD HB 986
  - MO SB 306
  - TN SB 582
  - VA HB 2312
  - WA HB 1568 & HB 1800
  - WV HB 2577

- **Passed one chamber**
  - LA HB 674
  - MD SB 896
  - NH HB 313

- **Dead/Killed**
  - LA HB 356
  - MS SB 2735
  - TN HB 317

- **Sent to governors**
  - OK SB 522
  - TN SB 582
  - WA HB 1800
State Regulatory Overview

- Regulations proposed in: AZ, CA, DE, FL (4), GA, ID, IA, LA, MA, MS (3), NJ (2), NM, OK, OR (2), TX, WI (2)
- 24 proposed rules as of 5/28/13
- 10 adopted and in effect*
- 1 emergency rule adopted*
- 1 abandoned
- 13 still moving through the process
State Regulatory Overview

• Regulations Adopted
  – California (compounding self-assessment form) – effective 4/1/13
  – Florida (definition—office use) – effective 3/21/13
  – Iowa (compounding practices) – effective 3/13/13
  – Massachusetts (sterile compounding) – effective 2/1/13
  – Mississippi (compounding guidelines) – effective 1/1/13
  – Mississippi (definition, office use ban) – effective 4/11 & 5/16/13
  – Oklahoma (removes sterile from nonsterile rules) – approved 5/1/13
  – Oregon (emergency out-of-state licensure) – effective 4/1/13

• Regulations Abandoned
  – Florida (notification of compounding inspections status)
Legislative, Regulatory Trends

• Compounding definition changes/clarifications
• Licensure requirements
• Pharmacy/facility inspections
• Standards (sterile/nonsterile compounding)
• Commercially available product
• Office use
• Anticipatory compounding
• Accreditation
Compounding Definition Changes/Clarifications

- 9 bills (GA, NH, ID, LA, ME, TN, VA, WV)
- 5 regulations (CA, DE, FL, IA, MS)
Licensure Requirements

• In-state and/or out-of-state (CA, FL, ID, LA, ME, MA, OK, OR)

• Special sterile compounding permits/licenses (FL, MA, MD, MS. MS must register with FDA)

• Manufacturer/wholesaler permits (MD, MN)
  – MD – mfr & whlsr licenses for sterile compounding. HB 986 to governor.
  – MN manufacturer license if not patient specific Rx.
  – State & federal PDMA wholesaler requirements applicable.
  – Good Manufacturing Practices may also be applicable.
Pharmacy/Facility Inspections

- Out-of-state inspection requirements (CA, FL, LA, ME, MD, MA, MO, SC, TX, VA)
- Proposed requirements include:
  - Compounding self-assessment form (CA)
  - In-state BOP does the inspection (SC, TX. Pharmacy pays fee.)
  - Random testing of Rx inventory (MA, MO. MO BOP pays cost.)
  - Submit inspection reports for license (MD, VA)
  - Notify BOP if compounding sterile or nonsterile (VA)
  - Reciprocity with other states (ME)
  - Out-of-state if not patient specific Rx (OR)
Standards (sterile/nonsterile)

• Good Manufacturer Practices (MD, MN, MS)
  – MS (reg) – Batches larger than 10 nonpatient specific

• Good Compounding Practices (MS regs in effect, OK for out-of-state, SC)

• USP 797/795
  – Legislation: MD (HB 986 sent to governor)
  – Regulation: FL, MA (adopted), MS, NJ, WI
Compounding Commercially Available Product

- MA SB 1053 prohibits Rx and OTC
  - Exception: If documented by prescriber that it is medically needed
    - Prescription is required for the exception

- NH HB 313 prohibits
  - Exception: Commercial manufacturer shortage
Office Use

• Legislation
  – NH HB 313 allows with a valid order
  – WA HB 1800 reauthorizes for practitioners and ambulatory centers

• Regulation
  – FL requiring written agreement
  – GA removing office use
  – LA requiring a prescription
  – MS not allowing
Anticipatory Compounding

- MN HB 1208
  - Short-term anticipated pharmacy need
  - Short-term bulk anticipated practitioner’s need
  - Added anticipatory compounding definition
Compounding Pharmacists Accreditation

• Accrediting boards listed in legislation/regulation:
  – Pharmacy Compounding Accreditation Board (PCAB)
  – Accreditation Council for Pharmacy Education (ACPE)
• NJ (3 bills) requiring PCAB
• MA adopted regulation requiring ACPE
• MN for out-of-state compounding pharmacists
Miscellaneous

• Nursing Homes & Hospitals
  – ME LD 1315 prohibits out-of-state purchases

• Compounding Limitations
  – ME LD 1315: State to publish list of drugs that cannot be compounded without BOP or Board of Medicine prior approval
Resources for Compounding Issue

- IACP staff & website (www.iacprx.org)
- National Alliance of State Pharmacy Associations (staff) (www.naspa.us)
- State Pharmacy Associations (staff, newsletters)
- National Association of Boards of Pharmacy (website, e-newsletter) (www.nabp.net)
- State Boards of Pharmacy (staff, websites, newsletters)