

NCSL Fall Forum State Update on Compounding



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National Association of Boards of Pharmacy (NABP)

- 501(c)(3) Charitable and Educational Organization
 - since 1904
- Members are the state boards of pharmacy for 50 states, District of Columbia, and US territories
 - Boards regulate the practice of pharmacy-laws/regulations
 - Boards license pharmacists, pharmacy technicians, pharmacies, other facilities that handle prescription drugs (varies state to state)
 - Disciplinary actions for violations of law/regulation
- Mission to assist our members in public protection
 - License transfer program, examinations, and accreditations

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Examinations	Accreditations	Assessments	Licensure
			
			
			
		Member Services	Consumer Protection
		PPAD HIPDB NABPLAW	 

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Overview

- Identified needs of Boards of Pharmacy following the NECC tragedy
- State specific activities, legislative/regulatory and other to strengthen
- Moving forward with consensus and uniformity-VPP™

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Post NECC-Focus on Boards of Pharmacy

- Which pharmacies are engaged in sterile compounding?
- What is your standard for compounding/sterile compounding?
- How frequently do you inspect your pharmacies?
- What training do your inspectors have to inspect sterile compounding?
- How many cases/disciplinary actions have you taken related to compounding? Resident and nonresident pharmacies?
- How did you report those actions to other regulatory bodies?

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Some Identified State Needs

- Identify and make searchable information on which pharmacies were engaged in compounding, particularly sterile
- Strengthen standards for pharmacy compounding, move toward USP standards
- Clear delineation between compounding & manufacturing-between FDA and state responsibility
- Resources for and focus on inspections
- Training
- Nonresident pharmacies
- Recall ability and communication/reporting

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State Responses-NABP Action Plan

- Surveys/separate licenses to readily identify (legislation where needed)
- Training through Clinical IQ/CriticalPoint-sterile compounding
- Inspections-resident and nonresident
 - Contract for inspection services-IA, NJ
- Legislation/regulations to clarify/strengthen existing laws

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State Legislative Activity

- Legislation was introduced in at least 29 states
 - AL, CA, CO, DE, GA, HI, ID, IL, KY, LA, ME, MD, MA, MN, MS, MO, NV, NH, NJ, NY, OK, PA, RI, SC, TN, TX, VA, WA, WV with about half already having passed something
- Focus-strengthen state board of pharmacy authority and oversight of traditional-while waiting for federal response
 - Nonresident pharmacy requirements-recent inspection
 - Identification/special licensure for sterile
 - Recall and reporting requirements/information sharing
 - Faster ability to enact suspension/disciplinary
 - Move toward USP standards

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Moving forward from the Action Plan

- Continue offering training opportunities
- Continue to work toward improved reporting/communications
- Work toward adoption of national standards-USP the floor for compounding
- Verified Pharmacy Program™ (VPP™)
 - Similar to license transfer system for pharmacies operating in multiple states
 - Ensure “qualified” inspection for nonresident pharmacies
 - Advantages for both states and pharmacies

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State Legislation Recommendations

- Adequate funding for state boards of pharmacy, e.g. robust inspection programs and training of inspectors
- Requirement for compliance with USP standards for all compounding as a uniform “floor”
- Identification of sterile compounding pharmacies
- Requirement for current, qualified inspection of nonresident pharmacies as a condition of licensure
 - Require or recognize VPP or
 - Allow the board to approve a third-party to conduct inspections when the resident state inspection is not available or doesn’t meet criteria

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Conforming to New Federal Law

- May need to review current state law for any conflicts with the new federal law
 - Office use provision may be in question
 - Any recognition/conflict of “do not compound” lists created by FDA in rule
 - Whether to also license/how to license new “outsourcing facility” category by the state

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