

**The National Association of State Controlled Substances Authorities**  
**State Regulatory Developments**  
**NOVEMBER 2008**

**COLORADO**

**Pharmacists/Pharmacy Standards** - Proposed rule of the Department of Regulatory Agencies, State Board of Pharmacy, would amend regulations under 3 CCR 719-1, Rules 6, 11, and 22, to clarify the requirements for pharmacists to conduct pharmaceutical care, drug therapy management, and practice by protocol. The proposal also would describe the requirements to electronically maintain receipts of noncontrolled prescription drugs and clarify the procedures for handling of initial decisions. A hearing is scheduled for Jan. 15, 2009, in Denver.

**Pharmacies/Pharmacists Standards** - Final rule of the Department of Regulatory Agencies, State Board of Pharmacy, amends regulations under 3 CCR 719-1 regarding pharmacy standards. The rule clarifies that all prescription drugs and controlled substances must be obtained from a board-registered entity, changes how initial interpretations and final evaluations of orders are conducted and recorded by pharmacists and pharmacy outlets, recodifies provisions regarding compounding, and clarifies the requirements applicable to in-state prescription drug outlets versus nonresident outlets. The rule also removes redundant language regarding facility requirements for the compounding of sterile products, clarifies pharmacists manager responsibilities, and clarifies requirements for labeling of products packaged and distributed by a prescription drug outlet owned and operated by a hospital or health maintenance organization. In addition, the rule clarifies which pharmacists are nuclear pharmacists and revises registration, minimum equipment, security, and recordkeeping requirements for nuclear pharmacies. Finally, the rule revises inspection requirements for certain types of "other" outlets that dispense large quantities of prescriptions, clarifies when "other" outlets must become prescription drug outlets to their size or amount dispensed, and allows county health departments to collect and redistribute medication during emergencies. The rule is effective Nov. 30, 2008. Contact: Wendy Anderson; DRA, State Board of Pharmacy; (303-894-7754) 11/10/2008

**LOUISIANA**

**Controlled Dangerous Substances** - Final rule of the Department of Health and Hospitals, Board of Pharmacy, revises regulations relating to controlled dangerous substances in one chapter. The rule also addresses pharmacists' financial interest in other health care providers when referring patients. The rule is effective Oct. 20, 2008. Contact: Malcolm Broussard; DHH, Board of Pharmacy; (225-925-6496).

**MAINE**

**Certified Midwives** - Proposed rule of the Department of Professional and Financial Regulation, Board of Pharmacy, would amend regulations under Chapter 1 and adopt regulations under a new MAC Chapter 33 regarding access to certain medications by certified midwives. The proposal would allow midwives to purchase a limited number of uncontrolled drugs and substances to administer to birthing mothers and newborns and allow pharmacists to sell noncontrolled drugs and substances to certified midwives. The proposal also would require pharmacists to conduct identity verification of such midwives, address recordkeeping requirements for both parties relating to the purchase of injectable oxytocin or injectable vitamin K, and require midwives to keep administration records of all uncontrolled drugs and specified substances. In addition, the proposal would specify certain information that midwives must report to the department and to the board. A hearing is scheduled for Nov. 18, 2008, in Gardiner. Comments are due Dec. 12, 2008. Contact: Geraldine Betts; DPFR, Office of Licensing and Registration; (207-624-8625) 10/29/2008

**NEW YORK**

**Controlled Substances Data Submissions for Nursing Homes** - Notice of the Department of Health announces the readoption of a May 14, 2008, emergency rule that amended regulations under 10 NYCRR 80.2 through .134 (nonconsecutive) regarding controlled substances data submissions to prevent diversion of prescription controlled substances. The rule requires pharmacies to submit

information regarding the method of payment and whether the dispensed prescription was a refill or an original. The rule also requires distributors and manufacturers of controlled substances to submit controlled substance sales data. In addition, the rule provides practitioners with increased flexibility when treating chronic pain from conditions other than diseases and increases the time that hospice patients may wait to fill their controlled substance prescriptions. The readoption is effective Oct. 27, 2008, and expires Jan. 24, 2009. Contact: Katherine Ceroalo; DOH, Office of Regulatory Affairs; (518-473-7488)

## NORTH CAROLINA

**Health Professionals** - Proposed rule of the Medical Board would amend regulations to merge the Impaired Physician Program and the Impaired Physician Assistant Program into a single entity, the Physicians Health Program. The proposal also would allow all licensees of the Medical Board, including perfusionists and anesthesiology assistants, to participate. The proposed effective date of the action is April 1, 2009. A hearing is scheduled for Jan. 16, 2009, in Raleigh. Comments are due Jan. 16, 2009. Contact: Medical Board; (919-326-1100)

## VIRGINIA

**Nurse Practitioners/Prescriptive Authority** - Proposed rule of the Department of Professional and Occupational Regulation, Joint Boards of Nursing and Medicine, would amend regulations regarding licensure and prescriptive authority for nurse practitioners. The proposal, which is being issued for fast-track processing, would clarify and update requirements to reflect the collaborative nature of the practice arrangement between licensed nurse practitioners (LPN) and supervising physicians. The proposal also would clarify the evidence of educational qualification in a specialty category, include Category 1 continuing medical education in the approved courses for continuing competency requirements, and allow continuing education hours as evidence of competency for the reinstatement of a lapsed license. In addition, the proposal would require the maintenance of a written protocol to specify the LPN's scope of practice and the submittal of a current practice agreement whenever there are significant changes in prescriptive authority. The proposed effective date is Dec. 25, 2008. Comments are due Dec. 10, 2008. Contact: Jay Douglas; Board of Nursing; (804-367-4515)

## WISCONSIN

**Wholesale Prescription Drug Distributors** - Final rule of the Pharmacy Examining Board amends regulations to update requirements for wholesale prescription drug distributors. The rule revises definitions and addresses requirements for maintaining and updating a list of manufacturer's authorized distributors of record, new qualifications for distributor licensing, inspections, identification and qualification of designated representatives, bonding and additional recordkeeping requirements, and implementation of an electronic track and trace "pedigree" system. The rule is effective Dec. 1, 2008. Contact: Pamela Haack; Department of Regulation and Licensing, Office of Legal Counsel; (608-266-0495)