

The National Association of State Controlled Substances Authorities
State Regulatory Developments
FEBRUARY 2009

COLORADO

Prescription Drug Wholesalers - Final rule of the Department of Regulatory Agencies, State Board of Pharmacy, amends regulations regarding pharmaceutical wholesaler recordkeeping. The rule allows pedigrees to detail distributions of prescription drugs from either the drug manufacturer or first authorized distributor of record through the acquisition and sale by a wholesaler until final sale to a pharmacy or other person dispensing or administering the prescription drug. The rule is effective Jan. 31, 2009. Contact: Wendy Anderson; DRA, State Board of Pharmacy; (303-894-7754)

DISTRICT OF COLUMBIA

Pharmaceutical Detailers - Proposed rule of the Department of Health would adopt regulations regarding pharmaceutical detailers. The proposal would clarify which individuals are subject to licensure requirements, provide a time line for the Board of Pharmacy to make decisions on licensure applications, and clarify practices to comply with the FDA. The proposal also would specify the types of documents and information that must be maintained by pharmaceutical detailers and address actions when health professionals request no further sales calls. In addition, the proposal would establish a supervised practice authorization that will allow applicants with licensure pending to practice under supervision for a period of 60 days. Comments are due March 15, 2009. Contact: Kenneth Campbell; DOH, Office of the General Counsel; (202-442-5977).

MASSACHUSETTS

Oral and Electronic Prescriptions - Final rule of the Board of Registration in Pharmacy amends regulations regarding orally and electronically transmitted prescriptions and electronic data transmission systems. The rule requires pharmacies to obtain positive customer identification before dispensing Schedule II drugs and include a waiver provision for the identification under specified circumstances. The rule is effective retroactive to

Sept. 16, 2008. Contact: James Coffey; Board of Registration in Pharmacy; (617-973-0950)

MAINE

Certified Midwives - Final rule of the Department of Professional and Financial Regulation, Board of Pharmacy, amends regulations regarding access to certain medications by certified midwives. The rule allows midwives to purchase a limited number of uncontrolled drugs and substances to administer to birthing mothers and newborns and allows pharmacists to sell noncontrolled drugs and substances to certified midwives. The rule also requires pharmacists to conduct identity verification of such midwives, addresses recordkeeping requirements for both parties relating to the purchase of injectable oxytocin or injectable vitamin K, and requires midwives to keep administration records of all uncontrolled drugs and specified substances. In addition, the rule specifies certain information that midwives must report to the department and to the board. The rule is effective Feb. 9, 2009 Contact: Geraldine Betts; DPFR, Office of Licensing and Registration; (207-624-8625)

OKLAHOMA

Pharmaceutical Manufacturers/Pedigree Requirement - Emergency rule of the State Board of Pharmacy amends regulations regarding pharmaceutical manufacturers, packagers, and wholesalers. The rule updates recordkeeping procedures to delay the "pedigree requirement" to Jan. 1, 2011. The rule is effective Dec. 11, 2008, and expires Feb. 14, 2009, unless superseded by another rule or disapproved by the legislature. Contact: Bryan Potter; SBP; (405-521-3815)

RHODE ISLAND

Central Fill Operations - Notice of the Department of Health, Board of Pharmacy, announces a hearing on and an extension of the comment period for a Jan. 14, 2009, proposed rule that would amend regulations regarding standards for pharmacists, pharmacies and manufacturers, wholesalers, and distributors. The proposal would revise definitions and revise provisions concerning

central fill operations to address call center operations that function as a shared order processing facility but are not licensed as a pharmacy. The hearing is scheduled for March 17, 2009, in Providence. Comments now are due March 31, 2009. Contact: David Gifford; DOH; (401-222-2231)

SOUTH CAROLINA

Central Fill Pharmacies - Notice of the Department of Labor, Licensing, and Regulation, Board of Pharmacy, announces the drafting of a proposal that would adopt a new Regulation to clarify requirements for central fill pharmacies. Comments are requested, but a date is not specified. Contact: Lee Ann Bundrick; DLLR, Board of Pharmacy; (803-896-4707).

SOUTH DAKOTA

Retail Telepharmacies/Remote Pharmacies - Final rule of the Department of Health, Board of Pharmacy, adopts regulations to establish criteria to allow the use of board-registered technicians to operate a retail telepharmacy when connected to a licensed state central pharmacy using advanced technology, automation, and design. The rule sets forth requirements concerning licensure for remote pharmacies, audiovisual links, signage, toll-free telephone numbers, staffing, pharmacist-to-technician ratios, prescriptions, quality assurance, and the use of automated mechanical dispensing devices. The rule is effective Feb. 2, 2009. Contact: DOH, Board of Pharmacy; (605-362-2737)