

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

COLORADO

Prescription Drug Wholesalers - Final rule of the Department of Regulatory Agencies, State Board of Pharmacy, amends regulations under 3 CCR 719-1, Rule 15.09.11, 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)

FLORIDA

Drugs, Devices, and Cosmetics - Proposed rule of the Department of Health, Division of Family Health Services, would amend regulations regarding records and recordkeeping requirements for drugs, devices, and cosmetics. The proposal would clarify the pedigree requirements for normal distribution chain direct purchase pedigrees, alternative pedigrees, returns, and emergency distributions. Comments are due Jan. 30, 2009. Contact: Rebecca Poston; DOH, Drugs, Devices, and Cosmetics Programs; (850-245-4292)

IDAHO

Pharmacy Standards - Notice of the Board of Pharmacy announces a pending rule that amends regulations to implement changes to the Wholesale Drug Distribution Act and clarifies the definition and requirements and responsibilities for "pharmacist-in-charge." The rule also includes pharmacy technicians among pharmacy employees whose employment changes are reportable and replaces the term "licensed" for "registered" in reference to pharmacists. In addition, the rule changes the name and designation code for one of the organizations offering accredited continuing education programs, requires that certain data concerning Schedule V substances be reported to the board, requires that payment of the annual preceptor site registration fee coincide with license and registration annual renewal, and changes the expiration date for the

registration of a student pharmacist extern. Finally, the rule revises financial disclosure requirements and deletes the requirement for a security bond or equivalent security and the requirement for a separate fund for security deposits. The rule is effective upon adjournment by the state legislature unless it is approved, rejected, amended, or modified by the legislature. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)

Rebuttal Presumption of Violation - Notice of the Board of Pharmacy announces a pending rule that amends regulations regarding rebuttal presumption of violation. The rule limits the evidentiary presumption of a violation warranting discipline to a rebuttal presumption in proceedings to suspend or revoke the controlled substance registration for a registrant for a violation where there is evidence of an amount of a controlled substance unaccounted for by any record. The rule is effective upon adjournment by the state legislature unless it is approved, rejected, amended, or modified by the legislature. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356). Remote Dispensing Pilot Project

Notice of the Board of Pharmacy announces a pending - rule that amends regulations and adopts regulations regarding the practice of pharmacy. The rule implements the Remote Dispensing Pilot Project to allow for the dispensing of prescriptions through remote dispensing machines. The rule also addresses provisions concerning registration, operating memorandum, responsibilities of the pharmacist-in-charge, and drug delivery and control. The rule is effective upon adjournment by the state legislature unless it is approved, rejected, amended, or modified by the legislature. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)

Schedule II Prescriptions - Notice of the Board of Pharmacy announces that amends regulations to specify that no Schedule II prescription order will be filled more than 90 days after the date the order was written. The rule also clarifies the phrase "prescription drug order." The rule currently is in effect as a temporary rule. The pending rule, which was adopted with changes, is effective upon adjournment by the state legislature unless it is

approved, rejected, amended, or modified by the legislature. Contact: Mark Johnston; Board of Pharmacy; (208-334-2536)

KANSAS

Unused Medications - Final rule of the Board of Pharmacy adopts regulations under a new Article to set forth procedures concerning the transfer, acceptance, and recall of unused medications. The rule is effective Jan. 2, 2009. Contact: Debra Billingsley; Board of Pharmacy; (785-296-4056)

NEVADA

Ephedrine, Pseudoephedrine, and Phenylpropanolamine - Notice announces the intention of the State Board of Pharmacy to amend regulations under to clarify that dangerous drugs that contain ephedrine, pseudoephedrine, or phenylpropanolamine are not controlled substances. A comment due date is not specified. Contact: SBP; (775-850-1440)

OHIO

Pharmacy Professionals/Pharmacies - Final rule of the State Board of Pharmacy amends regulations under to revise continuing education requirements for pharmacy interns, update notification and labeling procedures for controlled substances, and clarify language. The rule is effective Jan. 1, 2009. Contact: Mark Keeley; SBP; (614-466-4143)

TENNESSEE

Telepharmacy - Public necessity rule of the Department of Commerce and Insurance, Board of Pharmacy, adopts regulations under a new Chapter regarding the implementation of a pilot program for the dispensing of prescription medications from federally qualified health centers through the use of telepharmacy. The rule defines terms and sets forth requirements concerning licensing and renewal, fees, civil penalties, pharmacist and pharmacy technician responsibilities, and recordkeeping and inspections. The rule is effective Nov. 25, 2008, and expires May 9, 2009. Contact: Kevin Eidson; DCI, Board of Pharmacy; (615-741-2718)