State Regulatory Developments
MAY 2015

CALIFORNIA

Controlled Substances/Naloxone Hydrochloride - Proposed rule of the Department of Consumer Affairs, Board of Pharmacy, adopts regulations under 16 CCR 1746.3 to establish the protocol for pharmacists furnishing naloxone hydrochloride without a doctor's prescription. The rule is currently in effect as an emergency rule. Hearing requests are due June 22, 2015. Comments are due July 6, 2015. Contact: Karen Halbo; DCA, Board of Pharmacy; (916-574-7948)
--California Regulatory Notice Register (05/22/2015)

Drug Product Substitution - Final rule of the Board of Pharmacy amends regulations under IDAPA 27.01.01.010, .011, and .130 regarding biosimilar substitution. The rule allows biosimilar products to be substituted for a prescribed biological product upon the determination by the FDA that the biosimilar product is interchangeable. The rule also incorporates the recently released Purple Book by the FDA. The rule is effective April 11, 2015. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)
--Idaho Administrative Bulletin (05/06/2015)

Outsourcing Drug Outlets - Final rule of the Board of Pharmacy amends regulations under IDAPA 27.01.01.011, .021, .074, .600 and .740 regarding outsourcing drug outlets. The rule defines "outsourcing drug outlet," creates a new registration category and requirements, adds registration and renewal fees, and establishes practice standards for such facilities. The rule is effective April 6, 2015. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)
--Idaho Administrative Bulletin (05/06/2015)

Compounding Drug Products - Final rule of the Board of Pharmacy adopts regulations under IDAPA 27.01.01.144 and .239 through .242 regarding compounding drug products. The rule establishes labeling standards for distributed compounded drug products and general compounding standards. The rule also limits pharmacy distribution of nonsterile compounded drug products and addresses requirements for sterile compounding and hazardous drugs. The rule is effective April 11, 2015. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)
--Idaho Administrative Bulletin (05/06/2015)

Drug Distribution, Pharmacy Standards, Pharmacists - Final rule of the Board of Pharmacy amends regulations under IDAPA 27.01.01.031 through .710 (nonconsecutive) and repeals regulations under IDAPA

FLORIDA

Prescription Drugs and Devices/Forms - Proposed Rule of the Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics, repeals regulations under FAC 61N-1.020 regarding forms for applications and permitting of prescription drugs, devices and cosmetics. Comments are due June 1, 2015. Contact: Brittany Griffith; DBPR; (850-488-0062)
--Florida Administrative Weekly (05/11/2015)

Compounding Drug Products

IDAHO

Wholesale Drug Distribution Act - Final rule of the Board of Pharmacy adopts IDAPA 27.01.01.615 and repeals regulations under IDAPA 27.01.01.270 and .809 and regarding the Wholesale Drug Distribution Act. The rule addresses provisions concerning compounded drug product distribution and office use. The rule also includes the list of statutorily allowed pharmacy distribution, adds an exemption and describes prohibited acts. The rule is effective April 11, 2015. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)
--Idaho Administrative Bulletin (05/06/2015)
27.01.01.304 regarding drug distribution. The rule addresses the repackaging of dispensed prescription drugs into unit dose packaging, wholesale drug distribution and telepharmacy. The rule also clarifies provisions concerning standard prescription drug labeling, technician-in-training renewal limitations, foreign pharmacist graduate experience hours, nonresident pharmacist practice standards, annual controlled substance inventory dates, pharmacy authorized entry and pharmacy security. The rule is effective April 11, 2015. Contact: Mark Johnston; Board of Pharmacy; (208-334-2356)
--Idaho Administrative Bulletin (05/06/2015)