HealthRISC (Regulatory Intelligence and Simplified Compliance) Report
Monthly Update

50 States + D.C. Legislative and Regulatory Tracking Report
Date range: 1/1/23-1/31/23
Keywords: 503B Outsourcing Facilities, NABP Drug Distributor Accreditation, Out-of-State Manufacturers, Reverse Distributor, Third Party Logistics Providers, VAWD, Virtual Wholesalers, Wholesale Drug Distributors

NEW ITEMS

Regulation – FDA - Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

Solutions' keyword summary	The FDA announced the availability of a final guidance on compounding ibuprofen oral suspension products under section 503(b), describing the FDA's regulatory and enforcement priorities regarding compounding certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals and health systems.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"We are announcing the availability of a guidance for industry entitled "Compounding Certain Ibuprofen Oral Suspension Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act." This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately to bolster access to ibuprofen oral suspension products in hospitals and health systems during the current surge in respiratory infections, but it remains subject to comment in accordance with the Agency's good guidance practices. This guidance describes the Agency's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals and health systems. The United States is currently experiencing a surge in three viruses: Coronavirus Disease 2019 (COVID-19), respiratory syncytial virus (RSV), and influenza. Each of these viruses may produce fever in young children. FDA has received reports related to increased demand for pediatric fever-reducing medications, including ibuprofen oral suspension products. Further, FDA has received a number of reports related to hospitals and health systems experiencing challenges with obtaining these medications to use in the treatment of pediatric patients with fevers as well as for adults who are unable to swallow solid oral dosage forms (e.g. persons with feeding tubes). FDA is continually assessing the needs and circumstances related to the temporary policy set forth in this guidance, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate." Vol. 88, Issue 16, Federal Register 01/25/2023 pp. 4828-4830
Status	Filed 1/23/22

Regulation – Mississippi Board of Pharmacy - Pharmaceutical Facility Permits

Solutions' keyword summary	This regulation, proposed on 1/23/23, with a comment deadline of 2/17/23, makes a number of amendments to the rules on pharmaceutical facility permits. The rule includes necessary application information; introduces a requirement to have a criminal background check on the designated representative, including fingerprinting report; specifies appropriate inspection reports; information on storage conditions, labeling, facilities, recordkeeping, policies and procedures, and repackaging. The regulation also specifies prohibited acts, including how no facility/business may engage in wholesale distribution of a prescription drug, APIs, or devices in or into Mississippi unless the facility/business is licensed/permitted: (1) By the state from which the drug, API, or device is distributed; and (2) By the state into which the drug, API, or device is distributed.
Published summary	Proposes amendments to rule regarding pharmaceutical facilities due to new updates in federal regulations and guidance.
Relevant keyword reference within document including citation (if applicable)	"11. Prohibited Acts A. No facility/business may engage in wholesale distribution of a prescription drug, API's, or device in or into Mississippi unless the facility/business is licensed/permitted: (1) By the state from which the drug, API, or device is distributed; and (2) By the state into which the drug, API, or device is distributed. B. No facility/business engaged in wholesale distribution is allowed to acquire prescription drugs, API's, or devices from a dispenser for resale within the State of Mississippi. The return by a dispenser of prescription drugs, API's, or devices originally purchased from that facility/business is exempt from this requirement. C. Any facility/business permitted by the Mississippi Board of Pharmacy shall not sell or distribute a prescription drug, API, or device to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess prescription drugs, API's, or devices by an agency of the state in which the individual or business is located. D. Any facility/business permitted by the Board shall not distribute prescription drugs, API's, or devices to persons in this state unless such person is either a licensed physician, osteopath, podiatrist, or physician's assistant licensed by the Mississippi Board of Medical Licensure; a licensed dentist, licensed by the Mississippi Board of Dental Examiners; a licensed veterinarian, licensed by the Mississippi Board of Veterinary Medicine; or a drug supply chain facility/business permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs or devices as authorized by said Board of Optometry. An advanced practice registered nurse, licensed by the Mississippi Board of Nursing may purchase prescription drugs or devices as authorized by said Board of Nursing." Title 30, Part 3001, Article XXXII
Status	Proposed Rule 1/23/23; Comment Deadline: 2/17/23; Mississippi Administrative Bulletin 1/25/23

Minutes – Delaware Board of Pharmacy - November 16, 2022 - Minutes

Solutions' keyword summary	During this meeting, the Board reviewed a wholesale distributor application. The wholesaler had discipline relating to failure of timely disclosing changes in ownership in other jurisdictions. The Board decided to deny the application on the basis that the permit was sanctioned in another jurisdiction.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"Crown Laboratories Inc.- Pharmacy Wholesale Distributor Application for Review The Board reviewed the application for pharmacy wholesale for Crown Laboratories Inc. This facility had disciplines relating to failure to timely disclose changes in ownership in various other jurisdictions. A motion was made by Dr. Freebery and seconded by Dr. Juliano, to propose to deny this application for pharmacy- wholesale distributor the basis that Crown Laboratories' permit in another jurisdiction was sanctioned per 24 Del. C. Regulation 8.3.5. The motion unanimously carried."
Status	Filed1/18/23

Minutes – Iowa Board of Pharmacy - October 25, 2022 - Minutes

Solutions' keyword summary	During this meeting, the Board heard requests from two companies to waive a regulation requiring evidence of Drug Distributor Accreditation as a condition or license renewal. The company that was already licensed as a wholesale distributor was approved until 12/31/25. The company that has a pending wholesale distributor application on file was approved for 6 months.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"4. Request to waive 657 IAC 17.3(1)"c" requiring evidence of Drug Distributor Accreditation as a condition for license renewal – Americares Foundation, Wholesale Distributor license 6654, Stamford, CT Motion by Sherill Whisenand, second by Dane Nealson to approve the request as submitted to December 31, 2025. Motion passed unanimously. 5. Request to waive 657 IAC 17.3(1)"c" requiring evidence of Drug Distributor Accreditation as a condition for licensure – Padagis South Carolina, Wholesale Distributor license applicant, Piedmont, SC Motion by Dane Nealson, second by Sherill Whisenand, to approve the request for six months. Motion passed unanimously."
Status	Filed1/17/23

Minutes – Ohio Board of Pharmacy - Minutes - October 11, 2023

Solutions' keyword summary	During this meeting, the Board issued Settlement Agreements with two Wholesale Distributors of Dangerous Drugs. The first Wholesaler was investigated by the Board for sales of dangerous drugs to Ohio entities not licensed by the Board. Although the Wholesaler neither admitted nor denied the allegations, the Board had sufficient evidence to sustain the allegations and so the Wholesaler agreed to pay a fine of $3750. The second Wholesaler was investigated for illegal sales of dangerous drugs without a Board-issued license, and was fined $2500.

Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"1. The Board initiated an investigation of A.F. Hauser, Inc Wholesaler Distributor of Dangerous Drugs License No. 01-1552500, related to A.F. Hauser, Inc's sales of dangerous drugs to Ohio entities not licensed by the Board. 2. On or about October 25, 2021, the Board sent a Notice of Opportunity for Hearing to A.F. Hauser, Inc which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Settlement of this matter was reached prior to administrative hearing. 3. On or about July 28, 2022, A.F. Hauser, Inc filed a Notice of Discontinuation of Business with the Board. It was approved by the Board on or about August 25, 2022 and the WDDD license is inactive."
Status	Filed 1/13/23

Minutes – Ohio Board of Pharmacy - Minutes - December 5-6, 2022

Solutions' keyword summary	During this meeting, the Board issued Settlement Agreements with six Wholesale Distributors of Dangerous Drugs. Two Wholesalers were investigated by the Board for illegal sales of medical oxygen to an entity operating without a Board-issued licensed. Although the Wholesalers neither admitted nor denied the allegations, the Board had sufficient evidence to sustain the allegations and so the Wholesalers agreed to pay a fine of $275 and $75, respectively. The third Wholesaler was investigated related to their self-report to the Board on 10/26/20. The Board sent a Notice of Opportunity for Hearing to the Wholesaler, and after requesting through counsel an administrative hearing, the matter was settled prior to the hearing. The Board agreed to dismiss their Notice, and the Wholesaler agreed it will not institute any actions against the Board. The fourth Wholesaler was investigated for the illegal purchases of dangerous drugs from an entity without a Board-issued license, and paid a fine of $2750. The fifth and sixth Wholesalers were investigated for the illegal sales of dangerous drugs without obtaining a Board-issued license, and paid a fine of $2750 and $1300, respectively.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"1. The Board initiated an investigation of Celgene, Wholesale Distributor of Dangerous Drugs license number 01-2212350, related to Celgene's self-report to the Board on October 26, 2020. 2. On or about March 22, 2022, the Board sent a Notice of Opportunity for Hearing to Celgene, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. 3. On or about April 15, 2022, Celgene, through counsel Adam Yoffie, timely requested an administrative hearing, which was subsequently scheduled for September 14, 2022. This matter was settled prior to hearing."
Status	Filed 1/13/23

Minutes – South Carolina Board of Pharmacy - Minutes - November 16-17, 2022

Solutions' keyword summary	During these meeting minutes, Denise Frank made a presentation on the National Coalition for Drug Quality & Security (NCQS) Programs. One member made a motion to approve the inspections as part of the

	SC Board of Pharmacies package to gain licensure in the state, but according to the minutes it was not seconded, or carried.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"c. National Coalition for Drug Quality & Security (NCQS) Programs Presentation-Denise Frank, NCDQS Motion: Mr. McKnight mad a motion to approve the inspections as par of the SC Board of Pharmacies package to gain licensure in the state."
Status	Filed 1/19/23

Minutes – Tennessee Board of Pharmacy - Minutes - November 8-9, 2022

Solutions' keyword summary	During these meeting minutes, Denise Frank spoke to the Board about receiving guidance on how to have their NCDQS inspections accepted by the Board. After discussing, a motion carried to allow the Executive Director to approve the waiver when it is submitted.
Published summary	N/A
Relevant keyword reference within document including citation (if applicable)	"Denise Frank, D.Ph. spoke to the board about National Coalition for Drug Quality and Security concerning inspections for out of state manufacturer, wholesale/distributor, and 3PL's. National Coalition for Drug Quality and Security is seeking guidance on how to have their inspection accepted by the Board. After discussion, Dr. Blane made the motion to allow Dr. Shell to approve the waiver when it is submitted. Dr. Breeden seconded the motion. The motion carried."
Status	Filed 1/26/22