

CHAPTER 293

PROFESSIONS AND OCCUPATIONS

SENATE BILL 07-217

BY SENATOR(S) Boyd;
 also REPRESENTATIVE(S) Benefield, Borodkin, Frangas, Gibbs, Jahn, Kerr A., Labuda, Merrifield, Peniston, Rice, and Todd.

AN ACT**CONCERNING PRESCRIPTION DRUG WHOLESALERS.***Be it enacted by the General Assembly of the State of Colorado:*

SECTION 1. 12-22-801 (1) (b), (1) (d), (1) (f), and (1) (h), the introductory portion to 12-22-801 (1) (i), and 12-22-801 (1) (o), (1) (p), and (2) (j), Colorado Revised Statutes, are amended, and the said 12-22-801 (1) is further amended BY THE ADDITION OF A NEW PARAGRAPH, to read:

12-22-801. Definitions - exemption from licensing requirements. (1) As used in this section, unless the context otherwise requires:

(b) "Authorized distributor of record" means a wholesaler with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between a wholesaler and a manufacturer when the wholesaler, including any affiliated group of the wholesaler as defined in section 1504 of the federal "Internal Revenue Code of 1986", complies with ~~either~~ of the following:

(I) The wholesaler has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; ~~or~~ AND

(II) The wholesaler is listed on the manufacturer's current list of authorized distributors of record, which list is updated by the manufacturer on no less than a monthly basis.

(c.5) "BOARD-REGISTERED OUTLET" MEANS A PRESCRIPTION DRUG OUTLET, AN ENTITY LICENSED PURSUANT TO SECTION 12-22-304, AN OTHER OUTLET, A

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

NONRESIDENT PRESCRIPTION DRUG OUTLET, A WHOLESALER, OR A MANUFACTURER.

(d) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies or other chain pharmacy warehouses that are under common ownership or control. NOTWITHSTANDING ANY OTHER PROVISION OF THIS PART 8, A CHAIN PHARMACY WAREHOUSE RECEIVING DISTRIBUTIONS ON BEHALF OF, OR MAKING DISTRIBUTIONS TO, AN INTRACOMPANY PHARMACY IS NOT REQUIRED TO BE AN AUTHORIZED DISTRIBUTOR OF RECORD TO BE CONSIDERED PART OF THE NORMAL DISTRIBUTION CHANNEL.

(f) "Drop shipment" means the sale by a manufacturer of the manufacturer's prescription drug, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor to a wholesaler whereby the wholesaler takes title to, but not possession of, such prescription drug and the wholesaler invoices the ~~pharmacy or chain pharmacy warehouse~~ BOARD-REGISTERED OUTLET OR PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE THE PRESCRIPTION DRUG and the ~~pharmacy or chain pharmacy warehouse~~ BOARD-REGISTERED OUTLET OR THE PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE THE PRESCRIPTION DRUG receives delivery of the prescription drug directly from the manufacturer of such drug, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor.

(h) "Manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to the manufacturer's prescription drug but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor ~~must~~ SHALL be licensed as a wholesaler under this part 8 AND TO BE CONSIDERED PART OF THE NORMAL DISTRIBUTION CHANNEL, SHALL ALSO BE AN AUTHORIZED DISTRIBUTOR OF RECORD.

(i) "Normal distribution channel" means a chain of custody for a prescription drug that goes DIRECTLY OR BY DROP SHIPMENT from a manufacturer of the prescription drug to:

(o) "Specialty wholesaler" means a person who exclusively distributes a prescription drug to a specific group of specialty pharmacies or licensed practitioners and who has certified to the board that the distribution of such products will only occur in the limited situations described ~~herein~~ IN THIS PARAGRAPH (o). Such specialty wholesale distributors shall be separately licensed and designated as specialty wholesale distributors by the board.

(p) "Third-party logistics provider" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider ~~must~~ SHALL be licensed as a wholesale distributor under this part 8.

(2) For the purposes of this part 8, "wholesale distribution" means distribution of

prescription drugs to persons or entities other than a consumer or patient. "Wholesale distribution" does not include:

(j) ~~Drop shipments of a prescription drug from a manufacturer, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor to a pharmacy or chain pharmacy warehouse;~~

SECTION 2. 12-22-802 (1), the introductory portion to 12-22-802 (3) (a), and 12-22-802 (3) (b) and (4), Colorado Revised Statutes, are amended to read:

12-22-802. Wholesaler license requirements. (1) A wholesaler that resides in this state shall be licensed by the board. A wholesaler that does not reside in this state shall be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state. The board shall exempt a manufacturer and that manufacturer's third-party logistics providers to the extent involving that manufacturer's drugs under contract from any licensing QUALIFICATIONS and other requirements, INCLUDING THE REQUIREMENTS IN SUBPARAGRAPHS (VI) AND (VII) OF PARAGRAPH (a) OF SUBSECTION (3) of this section, SUBSECTIONS (4) TO (6) OF THIS SECTION, AND SECTION 12-22-803, to the extent the requirements are not required by federal law or regulation, unless the particular requirements are deemed necessary and appropriate following rulemaking by the board.

(3) (a) An applicant for a wholesaler license shall provide to the board the following information, and any other information deemed appropriate by the board on a form provided by the board: ~~at the time of application and each calendar year thereafter:~~

(b) A licensee shall complete and return ~~the~~ A form ~~provided~~ APPROVED by the board ~~each calendar year within thirty days after the receipt of the form~~ AT EACH RENEWAL PERIOD. The board may suspend or revoke the license of a wholesaler if the board determines that the wholesaler no longer qualifies for a license.

(4) Prior to issuing a wholesaler license to an applicant, the board, state board of pharmacy, or board-approved accreditation body ~~shall~~ MAY conduct a physical inspection of the facility at the business address provided by the applicant. Nothing in this subsection (4) shall preclude the board from inspecting a wholesaler.

SECTION 3. 12-22-803, Colorado Revised Statutes, is amended to read:

12-22-803. Criminal history record check. Prior to submission of an application, each ~~applicant~~ DESIGNATED REPRESENTATIVE shall have his or her fingerprints taken by a local law enforcement agency for the purpose of obtaining a fingerprint-based criminal history record check. The ~~applicant~~ DESIGNATED REPRESENTATIVE is required to submit payment by certified check or money order for the fingerprints and for the actual costs of said record check at the time the fingerprints are submitted to the Colorado bureau of investigation. Upon receipt of fingerprints and receipt of the payment for costs, the Colorado bureau of investigation shall conduct a state and national fingerprint-based criminal history record check utilizing records of the Colorado bureau of investigation and the federal bureau of investigation.

SECTION 4. 12-22-804 (1), (2), and (3), Colorado Revised Statutes, are amended to read:

12-22-804. Restrictions on transactions. (1) A wholesaler shall receive prescription drug returns or exchanges from a pharmacy or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesaler distributor and the pharmacy or chain pharmacy warehouse. The returns or exchanges ~~shall include the returns~~ of expired, damaged, ~~and~~ recalled, OR OTHERWISE UNSALEABLE pharmaceutical product SHALL BE DISTRIBUTED BY THE RECEIVING WHOLESALER ONLY to either the original manufacturer or to a third-party returns processor. ~~and such~~ THE returns or exchanges OF PRESCRIPTION DRUGS, SALEABLE OR UNSALEABLE, INCLUDING ANY REDISTRIBUTION BY A RECEIVING WHOLESALER shall not be subject to the pedigree requirements of section 12-22-805, SO LONG AS THE DRUGS ARE EXEMPT FROM THE PEDIGREE REQUIREMENT OF THE FEDERAL FOOD AND DRUG ADMINISTRATION'S CURRENTLY APPLICABLE "PRESCRIPTION DRUG MARKETING ACT OF 1987" GUIDANCE. The pharmacies, chain pharmacy warehouses, and cooperative pharmacy warehouses shall be responsible for ensuring that the prescription drugs returned are what they purport to be and shall ensure that those returned prescription drugs were stored under proper conditions since their receipt. Wholesalers shall be held accountable for policing their returns process and helping to ensure that their operations are secure and do not permit the entry of adulterated or counterfeit product. A pharmacist shall not knowingly return a medication that is not what it purports to be.

(2) A manufacturer or wholesaler shall furnish prescription drugs only to a ~~person licensed by the board~~ BOARD-REGISTERED OUTLET OR PRACTITIONER AUTHORIZED BY LAW TO PRESCRIBE THE DRUGS. Before furnishing prescription drugs to a person OR ENTITY not known to the manufacturer or wholesaler, the manufacturer or wholesaler shall affirmatively verify that the person OR ENTITY is legally authorized to receive the prescription drugs by contacting the board.

(3) ~~Prescription drugs furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the license. The manufacturer or wholesaler may furnish prescription drugs to an authorized person or agent of the person listed on the license if the identity and authorization of the recipient is properly established and the method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person or agent.~~

SECTION 5. 12-22-805 (5), Colorado Revised Statutes, is amended to read:

12-22-805. Records - study - authentication - pedigree. (5) A purchaser or wholesaler shall maintain each pedigree for three years ~~from~~ AFTER the date of the sale or transfer of the prescription drug and shall make the pedigree available for inspection or use within five business days upon the request of an authorized law enforcement officer OR AN AUTHORIZED AGENT OF THE BOARD.

SECTION 6. Effective date. This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly that is allowed for submitting a referendum petition pursuant to article V, section 1 (3) of the state constitution, (August 8, 2007, if adjournment sine

die is on May 9, 2007); except that, if a referendum petition is filed against this act or an item, section, or part of this act within such period, then the act, item, section, or part, if approved by the people, shall take effect on the date of the official declaration of the vote thereon by proclamation of the governor.

Approved: May 25, 2007