Clearinghouse Rule 08-051

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	:	
PROCEEDINGS BEFORE THE	:	ORDER ADOPTING
PHARMACY EXAMINING BOARD	:	EMERGENCY RULES

ORDER

An order of the Pharmacy Examining Board to repeal Phar 13.02 (11) (b) to (e), 13.03, 13.04 and 13.06 (3); to renumber Phar 13.02 (11) (f); to renumber and amend Phar 13.02 (6); to amend Phar 13.02 (8), (9), (11) (intro.) and (a), 13.05 (2), 13.08, 13.09 (intro.) and (3), 13.10 (3), 13.11 (1) to (4), 13.12 (1) to (3), 13.13 (title) and (1) to (4), 13.14 (1) (intro.), (a) to (c), and (2), 13.15 (4), 13.16 and 13.17 (1); and to create Phar 13.02 (3m), (11) (b) to (d) and (f) to (m), and 13.055, relating to the regulation of wholesale prescription drug distributors.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes interpreted:

Sections 450.02 (3), 450.07 (4) (c), 450.071 (3) (b) and 450.073 (3), Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2), 450.02 (3), 450.07 (4) (c), 450.071 (3) (b) and 450.073 (3), Stats.

Explanation of agency authority:

The Wisconsin Pharmacy Examining Board has authority under ch. 450, Stats., as amended by 2007 Wisconsin Act 20, to promulgate rules for the regulation of wholesale prescription drug distributors.

Related statutes or rules:

Ch. 961, Stats., 21 CFR s. 203.50.

Plain language analysis:

This emergency rule implements the statutory changes set forth in the drug distributor portions of 2007 Wisconsin Act 20. Several key areas are addressed by this emergency

rule including, newly required enhanced qualifications for distributor licensing, inspection requirements, identification and qualification of a designated representative, bonding requirements and additional recordkeeping requirements including where appropriate, the maintaining of drug distribution pedigrees.

SECTION 1 requires a licensed manufacturer to maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

SECTION 2 defines "department."

SECTION 3 amends the definition of "wholesale distributor."

SECTION 4 amends the definitions of "facility" and "manufacturer."

SECTION 5 amends the definition of "wholesale distribution."

SECTION 6 repeals portions of the definition of "wholesale distribution" which are no longer applicable.

SECTION 7 amends the definition of "wholesale distribution."

SECTION 8 renumbers and SECTION 9 creates additional provisions for the definition of "wholesale distribution."

SECTION 10 repeals two licensure provisions no longer statutorily required.

SECTION 11 amends a licensure requirement to require proof of an inspection.

SECTION 12 creates a licensure requirement to require a surety bond or irrevocable letter of credit to be filed with the department.

SECTION 13 repeals a requirement that is not statutorily required.

SECTIONS 14 to 19 remove the reference to "devices."

SECTION 20 amends a recordkeeping requirement.

SECTION 21 amends a recordkeeping requirement.

SECTION 22 adds "designated representative" to the list of required responsible persons.

SECTION 23 amends compliance with federal, state and local laws to include the requirement of an electronic track and trace drug pedigree under certain conditions.

Summary of, and comparison with, existing or proposed federal regulation:

21 CFR § 203 included federal regulations relating to drug distributorships and drug pedigrees. Only portions of the enacted regulations could be applied after a preliminary injunction that stayed certain provisions was ordered on December 5, 2006 in RXUSA Wholesalers, Inc. v. HHS.

Comparison with rules in adjacent states:

Minnesota:

Statutes: Ch. 151
Each separate facility is required to be licensed (with an annual renewal) and must satisfy a number of conditions relating to storage, security, container labeling, records retention (must be separately maintained and available for inspection within 2 working days of a board request), management and ownership, inspection procedures. An annual report to the board is required. The board may adopt reciprocity rules if the other state has comparable legal standards and that state would also extend reciprocal treatment.

Rules: § 6800 – 1400
Distributors must track the source of all drugs, along with the name and address of the seller or transferor and the address of the location from where the shipment was sent. Records must be kept for two years, and lists of responsible persons must be maintained with a description of duties and qualifications.

Iowa:

Rules: § 657
An annual renewal is required. Board inspectors inspect new distribution locations in Iowa. Minimum qualifications are specified in rule. Lists of officers, directors, managers and others in charge must be maintained. Distributors must verify the authority of the person or business to whom the distribution is intended prior to distribution. If distribution is to sales or manufacturers' representatives, distributors must ensure they maintain distribution records. There are facility, security, storage and record-keeping requirements included. Transaction records must include the source of the drug, name and address of seller/transferor, and the address from where it is shipped, in addition to the recipient, the name and address of the purchaser or transferee and the address where drugs are shipped. Records must be maintained for two years. The code contains an ethical conduct provision.

Illinois:

Rules: Chapter 111
It is unlawful to distribute a drug for less than fair market value not in accordance with law.

Michigan:

Statute: Chapter 333
May designate an individual to be the pharmacy, manufacturer, or wholesale distributor licensee.

Rules: § 338
All locations used in connection with distribution must be listed in the application. Includes requirements for storage, handling and records. Inspections may be performed "at reasonable times in reasonable places." A manufacturer or distributor may only distribute to persons licensed by the board or licensed to prescribe. Procedures for examining containers received and sent for identity to prevent contamination and ensure fitness for distribution. Must record the source and address of the seller or transferor and the location from where the drugs were shipped. Records must be maintained for two years. There must be written policies for receipt, security, storage, inventory and distribution of drugs, plus a crisis management policy. Identity information for persons in charge of distribution, storage and handling must be maintained.

Summary of factual data and analytical methodologies:

Department staff reviewed the portions of 2007 Wisconsin Act 20 that pertain to drug distributorships and laws and rules from other states prior to preparing the emergency rules.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact report:

The statute requires an inspection of drug distributors to be completed prior to the June 1, 2008 effective date of the rule. A review of the department's license files revealed there are approximately 100 distributors licensed in Wisconsin that may not have been inspected within the three years prior to being licensed. The board set the bond or letter of credit amount at $5,000 after a review of the statutory language and other states' requirements.

Section 227.137, Stats., requires an "agency" to prepare an economic impact report before submitting the proposed rule-making order to the Wisconsin Legislative Council. The Department of Regulation and Licensing is not included as an "agency" in this section.

Anticipated costs incurred by private sector:

The department finds that this rule has no significant fiscal effect on the private sector.

Fiscal estimate:

The department estimates that this rule will require staff time in the Office of Legal Counsel. The total one-time salary and fringe costs are estimated at $2,457.

Effect on small business:

These rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. The $5,000 bond or letter of credit is estimated to cost $200.00 to purchase. The Department's Regulatory Review Coordinator may be contacted by email at larry.martin@drl.state.wi.us, or by calling 608-266-8608.

Agency contact person:

Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-266-0495; email at pamela.haack@drl.state.wi.us.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Pamela Haack, Paralegal, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 152, P.O. Box 8935, Madison, Wisconsin 53708, email at pamela.haack@drl.state.wi.us. Comments must be received on or before July 1, 2008, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 12.06 is created to read:

Phar 12.06 Authorized distributors of record. A manufacturer shall maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

SECTION 2. Phar 13.02 (3m) is created to read:

Phar 13.02 (3m) "Department" means the department of regulation and licensing.

SECTION 3. Phar 13.02 (6) is renumbered 13.02 (12) and is amended to read:

Phar 13.02 (12) ~~"Distributor"~~ "Wholesale distributor" means ~~any~~ a person engaged in the wholesale distribution of prescription drugs ~~or devices~~, including~~, but not limited to,~~ manufacturers; ~~repackers~~ repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses~~, chain drug warehouses, and wholesale drug warehouses~~; manufacturers' exclusive distributors; manufacturers' authorized distributors of record; prescription drug wholesalers and distributors; independent wholesale prescription drug traders; ~~and pharmacies that conduct wholesale distributions not coincident to the compounding, packaging, labeling and dispensing of prescription drugs and devices~~ 3rd party logistics

providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

SECTION 4. Phar 13.02 (8) and (9) are amended to read:

Phar 13.02 (8) "Facility" means a location ~~at which~~ where a wholesale ~~distribution operations are conducted~~ distributor stores, handles, repackages, or offers for sale prescription drugs.

(9) "Manufacturer" means ~~any~~ a person ~~who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or device~~ licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" under the federal food and drug administration's regulations and interpreted guidance implementing the federal prescription drug marketing act.

SECTION 5. Phar 13.02 (11) (intro.) and (a) are amended to read:

Phar 13.02 (11) (intro.) "Wholesale distribution" means distribution of a prescription ~~drugs or devices to persons~~ drug to a person other than a consumer or patient~~. The term does not include~~, but does not include any of the following:

(a) Intracompany sales~~,~~ of prescription drugs which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under ~~the~~ common ownership ~~and~~ or control of a corporate entity or any transaction between co-licensees or a co-licensed product.

SECTION 6. Phar 13.02 (11) (b) to (e) are repealed.

SECTION 7. Phar 13.02 (11) (b) to (d) are created to read:

Phar 13.02 (11) (b) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(c) The distribution of prescription drug samples, if the distribution is permitted under 21 CFR 353 (d).

(d) Drug returns, when conducted by a hospital, health care entity, or charitable institution as provided in 21 CFR 203.23.

SECTION 8. Phar 13.02 (11) (f) is renumbered 13.02 (11) (e).

SECTION 9. Phar 13.02 (11) (f) to (m) are created to read:

Phar 13.02 (11) (f) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(g) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets.

(h) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer states in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the drug and the supplying authorized distributor of record states in writing that the drug has previously been exclusively in the normal distribution channel.

(i) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the drug.

(j) A transaction excluded from the definition of "wholesale distribution" under 21 CFR 203.3 (cc).

(k) The donation or distribution of a prescription drug under s. 255.056, Stats.

(L) The transfer from a retail pharmacy or pharmacy warehouse of an expired, damaged, returned, or recalled prescription drug to the original manufacturer or original wholesale distributor or to a 3rd-party returns processor or reverse distributor.

(m) The return of a prescription drug, if the return is authorized by the law of this state.

SECTION 10. Phar 13.03 and 13.04 are repealed.

SECTION 11. Phar 13.05 (2) is amended to read:

Phar 13.05 (2) Pass an inspection of the facility conducted by the board or its representative <u>in the 3-year period immediately preceding the date of the application by the board, a pharmacy examining board of another state, the National Association of Boards of Pharmacy, or another accrediting body recognized by the board, with the date of each inspection</u> to determine if the location meets standards specified in ss. Phar 13.08 to 13.11~~, 21 USC 351 and 352 and 21 CFR 211.142 (b)~~.

SECTION 12. Phar 13.055 is created to read:

Phar 13.055 Surety bond, irrevocable letter of credit. The applicant shall supply a surety bond or irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in Wisconsin. The form of the bond or letter of credit shall be approved by the department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this section more than one year after the date on which the applicant's wholesale distributor's license expires.

SECTION 13. Phar 13.06 (3) is repealed.

SECTION 14. Phar 13.08 is amended to read:

Phar 13.08 Personnel. A distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs ~~and devices~~.

SECTION 15. Phar 13.09 (intro.) and (3) are amended to read:

Phar 13.09 Facility requirements. (intro.) All facilities at which prescription drugs ~~or devices~~ are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(3) Have a quarantine area for storage of prescription drugs ~~or devices~~ that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;

SECTION 16. Phar 13.10 (3) is amended to read:

Phar 13.10 (3) Entry into areas where prescription drugs ~~or devices~~ are held is limited to authorized personnel;

SECTION 17. Phar 13.11 (1) to (4) are amended to read:

Phar 13.11 Storage requirements. (1) All prescription drugs ~~and devices~~ stored in a facility shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such products, or with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug ~~or device~~, the product may be held at a controlled room temperature, as defined in an

official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, ~~devices, and/or~~ or logs shall be utilized to document proper storage of prescription drugs ~~and devices~~.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all stored drugs ~~and devices~~.

SECTION 18. Phar 13.12 (1) to (3) are amended to read:

Phar 13.12 Examination of materials requirements. (1) Upon receipt by a facility, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs ~~or devices~~, or prescription drugs ~~or devices~~ that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment from a facility shall be carefully inspected for identity of the prescription drug ~~or device~~ and to ensure that there is no delivery of prescription drugs ~~or devices~~ that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in s. Phar 13.14 shall be followed for all incoming and outgoing prescription drugs ~~and devices~~ at a facility.

SECTION 19. Phar 13.13 (title) and (1) to (4) are amended to read:

Phar 13.13 (title) Returned, damaged and outdated prescription drug ~~and device~~ requirements. (1) Prescription drugs ~~and devices~~ in a facility that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs ~~and devices~~ until they are destroyed or returned to their supplier.

(2) Any prescription drugs ~~or devices~~ in a facility whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs ~~and devices~~ until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug ~~or device~~ has been returned to a facility cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a product has been returned cast doubt on its safety, identity,

strength, quality, or purity, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in s. Phar 13.14 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs ~~and devices~~.

SECTION 20. Phar 13.14 (1) (intro.) and (a) to (c), and (2) are amended to read:

Phar 13.14 Recordkeeping requirements. (1) (intro.) A distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs ~~and devices~~. These records shall include the following information:

(a) The source of the drugs ~~or device~~, including the name and principal address of the seller or transferor, and the address of the location from which the drugs ~~or devices~~ were shipped;

(b) The identity and quantity of the drugs ~~or devices~~ received and distributed or disposed of; and

(c) The dates of receipt and distribution or other disposition of the drugs ~~or devices~~.

(2) Inventories and records shall be made available for inspection and copying by the board, its authorized representatives, and authorized representatives of federal, state and local law enforcement agencies for a period of ~~2~~ 3 years following distribution or other disposition of the drugs ~~or devices~~.

SECTION 21. Phar 13.15 (intro.), (1), (2) (intro.) and (b), and (4) are amended to read:

Phar 13.15 Written policies and procedures. (intro.) A distributor shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs ~~and devices~~, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. A distributor shall include in their written policies and procedures the following:

(1) A procedure to ensure that the oldest approved stock of a prescription drug ~~or device~~ is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

(2) (intro.) A procedure to be followed for handling recalls and withdrawals of prescription drugs ~~and devices~~. The procedure shall be adequate to deal with recalls and withdrawals due to:

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs ~~or devices~~ from the market; or

(4) A procedure to ensure that any outdated prescription drugs ~~or devices~~ are segregated from other products and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs ~~or devices~~. This documentation shall be maintained for ~~2~~ 3 years after disposition of the outdated drugs ~~or devices~~.

SECTION 22. Phar 13.16 is amended to read:

Phar 13.16 Responsible persons. A distributor shall establish and maintain lists of officers, directors, managers, and ~~other persons~~ the designated representative in charge of wholesale drug ~~and device~~ distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

SECTION 23. Phar 13.17 (1) is amended to read:

Phar 13.17 Compliance with federal, state and local laws. (1) A distributor shall operate in compliance with applicable federal, state, and local laws and regulations. A distributor shall operate in compliance with any applicable federal electronic track and trace pedigree system implemented after July 1, 2011, unless an earlier implementation date is mandated by federal law which explicitly preempts state law. A distributor that deals in controlled substances shall register with the drug enforcement administration.

FINDING OF EMERGENCY

The board has made a finding of emergency. The board finds that failure to have the proposed rules in effect on June 1, 2008, the effective date of the applicable provisions of 2007 Wisconsin Act 20, will create a danger to the public health, safety and welfare, by disrupting the wholesale distribution of prescription drugs in the state of Wisconsin.

This emergency rule shall take effect on June 1, 2008.

Dated: May 20, 2008

Agency: Greg Weber, R.Ph.
Chairperson
Pharmacy Examining Board