STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 05-029)

ORDER

An order of the Pharmacy Examining Board to amend Phar 7.04 (2) (intro.) and (b); and to create Phar 7.04 (1) (c) to (f), (2) (d) and (e), (3m), (5), and two Notes following Phar 7.04 (5), relating to the return or exchange of health items.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statute interpreted:

Section 450.09 (7m), Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) and 450.02 (3) (a), (b), (d) and (e), Stats.

Explanation of agency authority:

The Wisconsin Pharmacy Examining Board is granted the authority to protect the public health, safety and welfare by establishing security standards for pharmacies, enforcing chapters 450 and 961, Stats, and establishing minimum standards for the practice of pharmacy and the dispensing of drugs. The return or exchange of health items is addressed specifically in the instance of state prisons, s. 450.09 (7m), Stats. The board also regulates this area of pharmacy practice in the non-state prison context in s. Phar 7.04.

Related statute or rule:

Cancer drug returns and redispensing are allowed provided the pharmacy follows the requirements in proposed ch. HFS 148, which has not become final.

Plain language analysis:

The Pharmacy Examining Board is amending the requirements of s. Phar 7.04, pertaining to the return or exchange of health items, to allow for their return or exchange from community-based residential facilities (CBRFs), jails, and juvenile secured facilities. The amended rules set forth those circumstances under which a return or exchange of health items is allowed.

SECTION 1 adds new definitions for "original container," "resident health care patient," "secured institutional health care patient," and "tamper-resistant package."

SECTION 2 clarifies that health item returns may only be made to the pharmacy that dispensed them, and substitutes the term "beyond use date" for "expiration."

SECTION 3 lists the requirements for when health items may be returned to a pharmacy that dispensed them for the purpose of redispensing. The rule allows returns and redipsensing of health items from secured institutional or resident health care patients, and for prepackaged non-narcotic, non-prescription drugs from any patient. Secured institutional patients include both jail inmates subject to the Department of Corrections approved policy and procedures manual for the control and administration of medications and juvenile patients residing in certain secured institutions whose health items are maintained by Department of Corrections staff.

For returns of health items from secured institutional health care patients, the rules also require those items to be segregated and prohibits the pharmacy from redispensing those items other than to a secured institutional health care patient.

Exempted from the definition of a "return" is the delivery to a pharmacy of a drug or device that was previously dispensed if the purpose of the delivery is for destruction at the pharmacy or by another authorized person or entity.

Also added are two notes referring to cancer drug returns and state prison pharmacy returns, which are governed by different statutory and rule authority.

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

1. 21 U.S.C. § 360(g)(1) (registration and manufacturers) provides:

The foregoing subsections of this section **shall not apply to**-

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (emphasis added)

2. Section 374(a)(2)(A) (inspection) (the Exemption) provides:

(2) The provisions of the third sentence of paragraph (1) **shall not apply to**-

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in

dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (emphasis added)

3. The Drug Enforcement Agency does not permit the return of controlled substances from non DEA registrants.

Comparison with rules in adjacent states:

Minnesota

6800.2700 RETURN OF DRUGS AND DEVICES.

Subpart 1. **Reuse.** Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any drugs, prescribed medications, chemicals, poisons, or medical devices; except that in a hospital with a licensed pharmacy, drugs, devices, or other items dispensed for hospital inpatient use may be returned to the pharmacy for disposition by a pharmacist in accordance with good professional practice.

Subp. 2. **Drugs from nursing homes.** Drugs from nursing homes may be returned to the dispensing pharmacy if:

A. the consultant pharmacist can assure proper storage conditions for the drugs in the facility as specified in the United States Pharmacopeia, (United States Pharmacopeial Convention, Inc., Rockville, Maryland);

B. the drugs are returned to the pharmacy which dispensed the drugs;

C. the integrity of such packaging remains intact (no reconstituted drugs, drugs requiring refrigeration, or controlled substances may be so returned); and

D. the drugs are received by the pharmacy in the original manufacturer's packaging or pharmacist packager's unit-dose, unit-of-use, or strip packaging with each tablet or capsule individually wrapped and labeled, or in blister cards, which indicate the drug name and strength, the packager's name, and the manufacturer's or packager's lot or batch number. Drugs packaged by a pharmacy may be returned only if the pharmacy can demonstrate to the board that its packaging material and procedures will provide a package that will meet or exceed the criteria for class B packaging established by the United States Pharmacopeia, (United States Pharmacopeial Convention, Inc., Rockville, Maryland), and that procedures have been developed and implemented to prevent the commingling of dosage units of different lot numbers.

Subp. 3. **Commingling**. Commingling of returned medication or mixing of lot numbers of returned medication, upon or prior to repackaging, shall result in such medication being

deemed misbranded and subject to embargo under Minnesota Statutes, section 151.38. This prohibition shall not apply to the return of medical devices provided that proper sanitary procedures are used prior to the reuse, resale, or rerent thereof.

STAT. AUTH: MS s. 151.06

HIST: 18 SR 1145

Current as of 10/27/03

Illinois:

Section 1330.91 Division I Pharmacies

a) Retail pharmacies which engage in general community pharmacy practice and are open to, or offer pharmacy service to, the general public shall, in addition to any other requirements of the Act and this Part, comply with Section 1330.91. A retail pharmacy which, in addition to offering pharmacy services to the general public, provides pharmacy services to an institution or facility listed in Sections 1330.92(a) need not register as a Division II pharmacy if the sales do not exceed 49% of total sales, but the pharmacy shall comply with requirements of Sections 1330.92(b), (c) and (d).

f) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale any dispensed medications, chemicals, poisons or medical devices except for:

1) Medical devices which can be properly sanitized prior to reuse, resale or rerent; and

2) Medications and medical devices that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by the current United States Pharmacopoeia (U.S.P.)/National Formulary or by the United States Pharmacopeial Convention, Inc.

Section 1330.92 Division II Pharmacies

a) Pharmacies which are not located in the facilities they serve and whose primary service is to provide services to patients or residents of facilities licensed under the Nursing Home Care Reform Act of 1979 or the Hospital Licensing Act, or the University of Illinois Hospital Act shall, in addition to any other requirements of the Act and this Part, comply with this Section.

f) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale any dispensed medications, chemicals, poisons or medical devices except for:

1) Medical devices which can be properly sanitized prior to reuse, resale or rerent; and

2) Medications and medical devices that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by the current United States Pharmacopoeia (U.S.P.)/National Formulary or by the United States Pharmacopoeial Convention, Inc.

Section 1330.93 Division III Pharmacies

a) Pharmacies which are located in facilities licensed under the Nursing Home Care Reform Act of 1979, the Hospital Licensing Act, or the University of Illinois Hospital Act, or are operated by the Department of Human Services or the Department of Corrections, and which provide pharmacy services to residents, patients, employees, prescribers and students of these facilities, shall, in addition to other requirements of the Act and this Part, comply with this Section.

d) Staffing of the Pharmacy

8) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, or resale dispensed medications, chemicals, poisons or medical devices except for:

A) Medical devices which can be properly sanitized prior to reuse, resale or rerent; and

B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopoeia/National Formulary published by the United States Pharmacopoeial Convention, Inc.

Section 1330.94 Division IV Pharmacies

a) Pharmacies which provide and/or offer for sale radiopharmaceuticals shall in addition to any other requirements of the Act and this Part comply with this Section 1330.94.

//(NONE)

Section 1330.95 Division V Pharmacies

a) Pharmacies Required to Hold Division V Licenses

1) Pharmacies which are located in or provide service to ambulatory care facilities, schools of veterinary medicine or other institutions or facilities. In addition to other requirements of the Act and this Part, these pharmacies shall comply with this Section.

2) Pharmacies that hold Division II licenses and provide pharmacy services to the general public. In addition to other requirements of the Act and Rules, these pharmacies shall comply with Section 1330.92 and this Section.

3) Pharmacies that hold Division III licenses and provide pharmacy services to the general public. In addition to other requirements of the Act and Rules, these pharmacies shall comply with Section 1330.93 and this Section.

f) Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, or resale any dispensed medications, chemicals, poisons or medical devices except for:

1) Medical devices that can be properly sanitized prior to reuse, resale or rerent; and

2) Medications and medical devices that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by the current United States Pharmacopoeia (U.S.P.)/National Formulary or by the United States Pharmacopoeial Convention, Inc.

IOWA:

657—6.15(124,126) Return of drugs and other items. For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) *Integrity maintained.* Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised.

6.15(2) *Controlled substances*. Under no circumstances shall pharmacy personnel accept from a patient or a patient's agent any controlled substances for return, exchange, or resale except to the same patient.

6.15(3) *Noncontrolled substance returns.* Prescription drugs, excluding controlled substances, may be returned and reused as authorized in 657—subrule 11.1(6).

6.15(4) *Personal contact items.* Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.

Indiana-returns

856 IAC 1-21 Resale of returned substances
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25
Sec. 1. (a) This section implements and interprets IC 25-26-13-15(h) concerning the resale or redistribution of medications.
(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.

(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:
(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and
(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.
(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier. *(Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334)*

Michigan-returns

R 338.472 Prescription drugs and devices; returns or exchange for resale prohibited,
Rule 2. For the protection of the public health and safety, prescription drugs or devices which have been dispensed and which have left the control of the pharmacist shall not be returned or exchanged for resale.

Summary of factual data and analytical methodologies:

In view of rising health care costs in general and the escalating cost of pharmaceuticals in particular, the Pharmacy Examining Board recognized the need to change its rules to allow for the return and redispensing of prescription drugs and devices that were previously destroyed. The board considered correspondence from policy makers and legislators, the experience of its own members, expertise provided by other state agencies, and legal counsel summarization of current rules and regulations that apply to resident health care patients and secured institutional health care patients, in addition to recent legislation governing the return of cancer drugs and drugs from patients in state prisons.

Determination of significant fiscal effect on the private sector:

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

Fiscal estimate:

The proposed rule will have no impact on the department's funds.

Effect on small business:

These proposed rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1), Stats. 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, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 171, P.O. Box 8935, Madison, Wisconsin 53708-8935. Telephone: (608) 266-0495. Email: pamela.haack@drl.state.wi.us.

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

Comments may be submitted to Pamela Haack, Department of Regulation and Licensing, 1400 East Washington Avenue, Room 171, P.O. Box 8935, Madison, Wisconsin 53708-8935, or by email at pamela.haack@drl.state.wi.us. Comments must be received on or before July 6, 2005 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Phar 7.04 (1) (c) to (f) are created to read:

Phar 7.04 (1) (c) "Original container" means the container in which a health item was sold, distributed or dispensed.

(d) "Resident health care patient" means a patient residing in a community-based residential facility that controls a resident's prescribed and over-the-counter medications as specified by s. HFS 83.33 (3) (b) 2.

(e) "Secured institutional health care patient" means any of the following:

1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.

2. A juvenile patient who resides in a secured correctional facility, as defined in s. 938.02 (15m), Stats.; a secured child caring institution, as defined in s. 938.02 (15g), Stats.; a secured group home, as defined in s. 938.02 (15p), Stats.; a secured detention facility, as defined in s. 938.02 (16), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.

(f) "Tamper-resistant package" means a container bearing a beyond use date that is sealed so that the contents cannot be used without obvious destruction of the seal.

SECTION 2. Phar 7.04 (2) (intro.) and (b) are amended to read:

Phar 7.04 (2) (intro.) No health items after taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:

(b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their ~~expiration~~ beyond use date.

SECTION 3. Phar 7.04 (2) (d) and (e), (3m), (5) and two Notes following Phar 7.04 (5) are created to read:

Phar 7.04 (2) (d) For a secured institutional health care patient or resident health care patient where all of the following apply:

1. The health item was never in the possession and control of the patient.

2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number.

3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient.

4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.

(e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:

1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered.

2. The pharmacist determines the contents are not adulterated.

(3m) Health items returned from a secured institutional health care patient to a pharmacy pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or redispensed other than to a secured institutional health care patient.

(5) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

Note: Cancer and chronic disease drug returns and redispensing pursuant to ch. HFS 148 are allowed provided the pharmacy follows the requirements in ch. HFS 148.

Note: A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

(END OF TEXT OF RULE)

The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated _____ Agency _____

Chairperson
Pharmacy Examining Board

Phar 7.04 CR05-029 (Return-Exchange of Health Items) Final for Adoption 9-23-05