Chapter Phar 1

PHARMACY AND EQUIPMENT

Phar 1.01 Permit. (1) Before establishing a drug store, pharmacy, apothecary shop, or any similar place of business, a permit therefore, must first be obtained by making application to the board of pharmacy. Application for permit to establish a drug store should be on file at least 30 days prior to the opening date. The pharmacy shall not be open for business until the permit is issued.

(2) Such permit must be renewed annually on or before June 1st, and is not transferable. Any change in ownership—in whole or in part—in any store, whether individually owned or a partnership, requires a new permit.

(3) Such permit and renewal must be displayed in the front window or door of such pharmacy.

(4) At the time of application, renewal, or change, the following information must be submitted relative to all professional personnel (full or part-time employed): Names and weekly schedules of the following: Pharmacists, assistant pharmacists, apprentices (interns).

(5) No permit for the operation of a pharmacy shall be continued if the requirments for the registration thereof, existing at the time of said registration, are not being complied with at the time of the filing of the application for renewal of the permit.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57; cr. (5), Register, September, 1962, No. 81, eff. 10-1-62.

Phar 1.02 Pharmacist in charge and ownership. A pharmacist may be in charge of only one pharmacy, but he may own more than one such place of business.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.04 Pharmacy licensing standards. (1) PROFESSIONAL SERVICE AREA. The area devoted to the compounding and dispensing of prescription drugs and devices, patient consultation area, sale of USP and NF drugs, hypodermic needles, syringes, schedule V controlled substances, contraceptives, and poisons shall be equal to not less than 15% of the general merchandising area and in no instance less than 250 sq. ft.

If the general merchandising area is greater than 6,667 sq. ft., the professional service area need not exceed 1,000 sq. ft. No more than 20% of this space shall be for storage of bulk pharmaceuticals.

(2) PRESCRIPTION COUNTER SPACE. There shall be a prescription counter on which to work and the free working surface shall not be less than 18 inches in width and not less than 12 square feet in area. This minimum free working surface must be kept clear at all times for the compounding of prescriptions, other pharmaceutical manufacturing and activities incident thereto.

(3) AISLE SPACE IN PRESCRIPTION DEPARTMENT. The free floor space behind the prescription counter shall be not less than 8 feet in length and 3 feet in width.

(4) PRESCRIPTION DEPARTMENT SANITARY FACILITIES. There shall be provided in the prescription department a sink easily accessible to the prescription counter and at a workable height which is equipped with running hot and cold water, soap or detergent and which is suitable for the cleaning of required pharmaceutical equipment. There shall also be provided a disposal container for wastes.

(5) NARCOTIC STORAGE. There shall be provided in the prescription department a secure facility for the storage of narcotics.

(6) PRESCRIPTION DEPARTMENT REFRIGERATOR. There shall be provided in the prescription department a refrigerator for the storage of biologicals and other drug items requiring refrigeration.

(7) STORAGE SPACE. There shall be provided in the prescription department sufficient shelf, drawer or cabinet space for the proper storage of a representative stock of prescription labels, an assorted stock of prescription containers, an adequate stock of prescription drugs and chemicals and the required equipment.

(8) EQUIPMENT. There shall be provided in the prescription department the following:

(a) One prescription balance capable of weighing ¼ grain or less.

(b) One set of accurate Apothecary weights, ½ grain to 2 drams.

(c) One set of accurate Metric weights, 50 mg. to 20 gm.

(d) Graduates-measuring volumes up to at least 16 fluid ounces; and from 1 cc to at least 500 cc consisting of at least two each measuring 2 drams, 1 ounce and 4 ounces; one each measuring 8 ounces and 16 ounces. (Graduates are to be of clear transparent glass; those measuring volumes of 4 drams and less must be of the single scale-cylindrical type; those measuring volumes greater than 4 drams may be either cylindrical or conical).

(e) Mortars and Pestles-at least one glass 2 ounce and one glass 8 ounce.

(f) Spatulas-stainless steel, at least 3 assorted sizes; and one non-metallic (rubber or bone), medium size.

(g) Funnels-glass, one 2 ounce, one 8 ounce.

(h) Stirring Rods-glass, at least 2.

(i) A prescription numbering machine (duplicating).

(j) Heating apparatus-tripod and bunsen burner or alcohol lamp; or, gas or electric plate.

(k) U. S. Pharmacopoeia (latest revision and supplements).

(l) National Formulary (latest revision and supplements).

(m) Exempt Narcotic, Poison and Hypodermic Syringe and Needle Registers.

(n) Latest revision of Federal and State Pharmacy Laws consisting of:

1. Federal Food Drug and Cosmetic Act.

2. General Regulations for the Enforcement of the Federal FDC Act.

3. Drug Enforcement Administration Regulations 21 Code of Fed. Regs. Part 1300 to End.

4. Wisconsin Pharmacy Law (ch. 450, Stats.).

5. Wisconsin Controlled Substances Act (ch. 161, Stats.).

6. Wisconsin Administrative Code, Rules of the State Board of Pharmacy. [Pharmacy Examining Board]

Note: (Federal laws and regulations may be obtained from the Superintendent of Documents, Government Printing Office, Washington, D. C. 20402)

All weights and measures (e.g. balances, metric and apothecary weights, graduates) are subject to inspection by the Weights and Measures Section of the State Department of Agriculture or their designated representatives. Specifications, tolerances and regulations recommended by the National Bureau of Standards in NBS Handbook 44, second edition (1955), are followed.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57; am. (1), (2), (3), Register, April, 1959, No. 40, eff. 5-1-59; cr. (8), Register, February, 1962, No. 74, eff. 3-1-62; r. and recr. (1), Register, June, 1974, No. 222, eff. 7-1-74.

Phar 1.05 Professional coverage. No pharmacy shall at any time be open for business unless there is present therein and in charge thereof a licensed pharmacist. An assistant licensed pharmacist may be in charge of a pharmacy in a town, village or city with a population of less than 500. In case a pharmacy loses the services of its pharmacist, the pharmacy shall close until another registered pharmacist is placed "in charge". The language "in charge" in s. 450.04 (2), Stats., shall mean the physical presence of the pharmacist on the premises. He shall be permitted momentary or brief necessary absence for a meal period during which time he must be immediately available to the pharmacy, and provided no drugs are sold or prescriptions compounded or dispensed during his absence. A meal period shall be construed as meaning a period at mid-day and/or during the evening hours in which a meal is normally consumed. In no instance shall such period exceed 60 minutes. Every pharmacy must be in continuous daily charge of a registered pharmacist. Being in charge means having direct control of and supervision over the pharmaceutical operations of the pharmacy. An unregistered owner must also comply strictly with the above provision, and provide a registered pharmacist and give him complete power over the pharmaceutical affairs of said pharmacy. The license of any pharmacy shall be inoperative if the registered pharmacist in whose name the store license was issued ceases to be engaged in such pharmacy, and the owner shall close said pharmacy until he has employed another registered pharmacist in

the same capacity. The registered pharmacist in whose name the license was obtained must at the time he ceases to be employed in such pharmacy, report within 5 days to the secretary of the board the fact that such pharmacy is no longer under his supervision.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57; am. Register, September, 1962, No. 81, eff. 10-1-62.

Phar 1.06 Display of certificates and renewals. (1) Certificates of all pharmacists and assistant pharmacists shall be framed and displayed conspicuously to the public view.

(2) Yearly renewal cards shall be placed in the lower right hand corner of the certificate and shall be posted when received. Only current renewal cards may be posted.

(3) The above are to be kept in a clean and orderly condition. Only valid current Wisconsin certificates of persons actually employed in a pharmacy may be displayed.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.07 Required professional volumes. All drug stores and pharmacies are required to have in their prescription rooms the latest revisions of U.S.P. and N.F. and their supplements; and a copy of the Wisconsin pharmacy laws and rules.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.08 Prescription records. (1) A file shall be kept of all prescriptions filled for a period of 5 years.

(2) A record of all prescriptions refilled shall be maintained by indicating on the original prescription the date and amount of such refills.

(3) A separate file shall be kept for all narcotic prescriptions filled, said prescriptions being preserved for a period of 5 years.

(4) On all prescriptions for class A narcotic medication and amphetamine and barbiturate medication there shall be written in ink, on the reverse side thereof, the signature and the address of the person accepting the medication from the pharmacist as well as the date and time of receipt of the medication, if such person is not personally known to the pharmacist dispensing said medication.

(5) Written or verbal copies of prescription orders for any prescription drug, given by a pharmacy from which the medication was dispensed pursuant to an original prescription order, shall be identified respectively in writing or verbally as "COPY—FOR INFORMATION ONLY." Such information copy has no legal status under federal or state law. The recipient pharmacist of such copy shall contact the prescribing practitioner for authorization to dispense the prescription, which is the same as obtaining an original prescription. The provider or transferor of such written or verbal copy shall invalidate the prescription order in its file as of the date the copy is given.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57; am. Register, May, 1962, No. 77, eff. 6-1-62; r. and recr. (5), Register, May, 1978, No. 269, eff. 6-1-68.

Phar 1.09 Sale of hypodermic syringes and needles. When a buyer of hypodermic syringes and needles has not previously been properly recorded by the pharmacist, it is the latter's responsibility to record the name and address of the purchaser and the intended use of these items,

as well as the name of the attending physician, in the exempt narcotic record book, or a separate record book kept for that purpose.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.10 Supply of drugs and chemicals. (1) The owner of a pharmacy shall maintain in such pharmacy a supply of drugs and chemicals.

(a) Such drugs and chemicals shall meet all standards of strength and purity as established in the current edition of U.S.P. and N.F. and shall be properly stored.

(b) Pharmaceuticals which vary from the purity specified on the label or are unfit for use due to deterioration or other causes shall not be carried in stock, and shall be destroyed when so ordered by the board.

(2) The owner of a pharmacy shall maintain in such pharmacy a representative stock, as commonly found in drug stores of the following: fluid extracts; tinctures; spirits; medicinal waters; elixirs; household drugs, both wet and dry; pills and tablets; chemicals; ointments; extracts; pharmaceuticals; and biologics, also such prescription items of legend and non-legend categories as are prescribed to fulfill pharmaceutical demands. The board in its discretion may order the stocking of additional drugs when that appears to be necessary.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.11 Drugs, exempted narcotic preparations and poisons. Storage of drugs, exempted narcotic preparations and poisons must be in a place not readily available to the general public. Self-service display of drugs, exempted narcotic preparations and poisons is strictly prohibited. These items may be sold only by persons authorized to do so by the board of pharmacy under ch. 450, Stats., and except as otherwise provided by s. 450.10, Stats. Exempted narcotic preparations are those medicinal preparations containing along with therapeutically active non-narcotic ingredients, in one fluid or avoirdupois ounce, not more than one grain of codeine or any of its salts, or along with either active or inactive non-narcotic ingredients of the type used in medicinal preparations, noscapine, papaverine, narceine, cotarnine or nalorphine.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57; am. Register, April, 1959, No. 40, eff. 5-1-59; am. Register, February, 1962, No. 74, eff. 3-1-62.

Phar 1.12 Records of wholesale sales. Drug wholesalers and retail pharmacies must keep separate records of all dangerous drug sales made at wholesale to any person, firm or corporation. Such records shall be open to periodic inspection by the board or their duly authorized representatives.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.13 Return or exchange of drugs prohibited. Drugs, medicines, sick room supplies, and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.

History: Cr. Register, 1956, No. 12, eff. 1-1-57.

Phar 1.14 Vending of drugs by mechanism prohibited. No person, firm or corporation shall purchase or rent or have in his or its possession or under his or its control any slot machine, vending machine or other

mechanism or means so designed and constructed as to contain and hold any drugs of any kind and to release the same upon the deposit therein of a coin or other thing of value. The sale or distribution of any drugs by any manner or device by means of such slot machine, vending machine, or other mechanism is prohibited.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.15 Names and symbols synonymous with drug store. Any commercial or trade name or abbreviation thereof, trademark, symbol or insignia or title which through long usage and continued association with the retail drug store, pharmacy or apothecary has become associated with drugs is, therefore, regarded as synonymous with the title "drug store" within the meaning of s. 450.02 (8), Stats.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.16 Damaged drug merchandise. Following a fire, or other catastrophy, in which pharmaceutical preparations, devices, or appliances are damaged it shall be unlawful for the store owner to dispose of said damaged merchandise in any manner unless it has first been inspected and declared safe by the state board of pharmacy. In event that the preparations, appliances, or devices are considered unsafe, or unfit for use, the state board will see that they are destroyed.

History: Cr. Register, December, 1956, No. 12, eff. 1-1-57.

Phar 1.19 Compounding and dispensing. The practice of compounding and dispensing a prescription includes, but is not limited to the following acts, which shall be performed only by a pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

(1) Receipt of oral prescription orders from the prescriber and review of all original and refill prescription orders, written or oral, along with the patient medication profile for determining therapeutic compatability and legality of the prescription order. Such review shall include, when necessary, appropriate consultation with the prescriber.

(2) Reading and interpretation of the prescriber's directions for use for purposes of transcription to the label in a manner that precisely communicates them with assurance of understanding by the patient.

(3) Selecting, compounding, mixing, combining, measuring, counting or otherwise preparing the drug or drugs needed to fill the individual prescription except that an agent of the pharmacist may procure, measure or count pre-fabricated dosage forms provided a pharmacist verifies their accuracy.

(4) A final check on the accuracy and correctness of the prescription shall be performed by the pharmacist. The medication profile record or prescription shall be initialed by the pharmacist responsible for the prescription or both original and refill dispensing as certification of the final check.

(5) Final transfer of completed prescription medication to, and appropriate consultation with the patient or agent of the patient, except that completed prescription medication may be delivered by an agent of the pharmacist to the patient's residence if the delivery is accompanied by appropriate consultation and an indication that professional communication and consultation are available by contacting the pharmacist.

(6) Obtaining, when required by law and in the best professional practice, permission to refill from authorized prescribers, and noting on the reverse side of the prescription or the medication profile record the following data:

(a) Date refilled

(b) Name of practitioner authorizing refill, if different from original prescriber

(c) Quantity of drug dispensed, if different from the original prescription

(d) Written initials or signature of the pharmacist refilling prescription

(7) Nothing in subsections (1) and (5) of this regulation shall prevent hospital pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications via accepted in-patient institutional drug distribution systems. Subsections (1) - (6) are fully applicable to any hospital pharmacy outpatient dispensing activities, including discharged patients' take-home prescriptions.

(8) A pharmacist shall supervise at any one time, no more than one intern and/or one non-pharmacist working within the definition of compounding and dispensing as described in subsections (1) - (6).

(9) Any system not in conformance with the above prescribed practices shall be reviewed by the pharmacy examining board for approval prior to adoption of the system.

History: Cr. Register, September, 1975, No. 237 eff. 10-1-75.

Phar 1.20 Prescription refill limitations. A prescription for any drug other than controlled substances, which bears pro re nata refill authorization permitting the pharmacist to refill the prescription as needed by the patient, may only be refilled in keeping with the number of doses ordered and the directions for use, but in no instance shall such prescription be refilled beyond one year from the date originally dispensed. If additional medication is needed thereafter, the original prescription shall be voided and a new prescription obtained. No prescription containing either specific or pro re nata refill authorization shall be refilled after cessation of practice in the same locality by the prescribing practitioner.

History: Cr. Register, September, 1975, No. 237 eff. 10-1-75.

Phar 1.21 Prescription label; name of drug dispensed. No prescription drug shall be dispensed unless the label required in s. 450.07 (4) Stats. discloses the name of the drug dispensed. This requirement does not apply when the prescribing practitioner requests omission from the prescription label of the name of the drug dispensed.

History: Cr. Register, September, 1975, No. 237 eff. 10-1-75.