

DEPARTMENT OF COMMUNITY HEALTH

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

(By authority conferred on the director of the department of community health by sections 16145(3) and 17701 of 1978 PA 368, MCL 333.16145(3) and 333.17701 et seq. and Executive Reorganization Order Nos. 1996-1, 1996-2, and 2003-01, being MCL 330.3101, 445.2001, and 445.2011)

PART 1. GENERAL PROVISIONS

R 338.471 Repealer.

Rule 1. All rules and regulations previously adopted by the state board of pharmacy, hereinafter referred to as the board, are hereby repealed and set aside.

History: 1979 AC.

R 338.471a Definitions.

Rule 1a. As used in these rules:

(a) "Accredited college or school of pharmacy" means a college or school of pharmacy that is accredited by the accreditation council for pharmacy education, as provided in R 338.474(1)(a).

(b) "Board" means the board of pharmacy.

(c) "Code" means 1978 PA 368, MCL 333.1101.

(d) "Department" means the department of community health.

(e) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record. An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.

(f) "Unconventional internship" means an educational program of professional and practical experience involving those pharmacy or related pharmaceutical experiences which, by practical, on-the-job training, provide knowledge useful to the practice of the profession of pharmacy without meeting all of the criteria of a conventional internship.

History: 1980 AACCS; 1986 AACCS; 2007 AACCS.

R 338.472 Prescription drugs and devices; return or exchange for resale prohibited.

Rule 2. (1) 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.

(2) Subrule (1) of this rule does not apply to a pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail that has accepted a prescription drug for resale or redispensing, as provided under section 17766d of the code.

History: 1979 AC; 1980 AACCS; 2007 AACCS.

R 338.473 Intern licensure; eligibility; renewal; limitations.

Rule 3. (1) An applicant for a pharmacy intern license shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall establish that he

or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1)(a).

(2) An intern shall engage in the practice of pharmacy only under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist.

History: 1979 AC; 1980 AACCS; 1990 AACCS; 2007 AACCS.

R 338.473a Interns; eligibility; limited license; qualifications; supervision; notice of position change; duties; professional and practical experience; denial, suspension, or revocation of license.

Rule 3a. (1) An individual is eligible for intern licensure at the beginning of the first professional year of study in an accredited college or school of pharmacy.

(2) Upon application and payment of appropriate fees, a limited license shall be issued by the department to qualified applicants. The limited license shall remain active while the applicant is actively pursuing a degree in an accredited college or school of pharmacy and until licensure as a pharmacist or for not more than 1 year from the date of graduation from such college or school of pharmacy, unless extended by the board upon written request of the intern.

(3) An intern shall complete not less than 1,000 hours of internship experience, 500 hours of which shall be completed during the 18 months immediately preceding the examination for pharmacist licensure. An intern working in Michigan shall hold an intern license in order to earn the hours of internship experience required in Michigan. The minimum number of hours of internship experience may be satisfied by complying with any of the following provisions:

(a) Obtaining the minimum number of hours of experience under the personal charge of a qualified, approved preceptor.

(b) Completing a board-approved, structured practical experience program within the college or school of pharmacy curriculum.

(c) Through a combination of subdivisions (a) and (b) of this subrule.

(4) When eligible, a student shall apply for licensure as an intern.

(5) Hours of internship experience shall be computed from the date of board certification as a licensed intern. In computing the hours of internship experience, all of the following provisions shall apply:

(a) Experience shall be granted only upon verification by an approved pharmacy preceptor or other person previously approved by the board.

(b) The board may grant internship experience gained in unconventional internship programs. Up to 400 hours of internship experience may be granted for such unconventional education experiences.

(c) A maximum of 40 hours of internship experience shall be granted per calendar week served by the intern.

(d) A maximum of 16 hours of non-college-sponsored internship experience shall be granted per calendar week while the intern is a full-time student in a college or school of pharmacy, except during authorized vacation periods.

(e) The board may grant credit for internship experience obtained through practice as an intern in another jurisdiction if the experience was comparable to the minimum standards set forth in these rules.

(f) The board may accept experience as a licensed pharmacist in another jurisdiction as the equivalent of internship experience.

(6) An intern shall be supervised by an approved pharmacist preceptor and shall, at all times, practice only under the personal charge of a pharmacist. The intern shall be responsible for verifying board approval of his or her pharmacy preceptor.

(7) Within 30 days, an intern also shall notify the board if he or she is no longer actively enrolled in a pharmacy degree program at an accredited college or school of pharmacy.

(8) Interns shall complete and submit such forms or examinations, or both, as deemed necessary by the board.

(9) Interns shall receive professional and practical experience in at least all of the following areas:

(a) Pharmacy administration and management.

(b) Drug distribution, use, and control.

(c) Legal requirements.

(d) Providing health information services and advising patients.

(e) Pharmacists' ethical and professional responsibilities.

(f) Drug and product information.

(10) Interns shall keep abreast of current developments in the internship program and the pharmacy profession.

(11) The board may deny, suspend, or revoke the license of an intern or may deny hours of internship for failure to comply with pharmacy law or rules relating to pharmacy practice or internship.

History: 1979 AC; 1980 AACS; 1986 AACS; 2007 AACS.

R 338.473b Rescinded.

History: 1979 AC; 1980 AACS; 1986 AACS.

R 338.473c Preceptors; approval; qualifications; duties; denial, suspension, or revocation of preceptor approval.

Rule 3c. (1) Before training an intern, a licensed pharmacist in this state shall apply to the board for approval as a preceptor. A pharmacist shall have at least 1 year of practice before being approved as a preceptor.

(2) There shall be not more than 2 interns per pharmacist on duty at the same time. However, the approved preceptor is responsible for the overall internship program at the pharmacy.

(3) A preceptor is responsible for arranging the intern's training in areas of practice as defined in R 338.473a(9).

(4) A preceptor shall annually submit internship training affidavits on forms provided by the board.

(5) The preceptor shall determine the degree of professional skill possessed by the intern and shall develop a training program whereby the intern will be able to improve upon and develop his or her ability in the practice of pharmacy.

(6) The preceptor shall allow sufficient time to instruct the intern in the practice of pharmacy and to frequently review and discuss his or her progress.

(7) Upon completion of the intern training, the preceptor under whom the training was obtained shall give the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the board may require further training before allowing the intern to take the examination for licensure as required by R 338.474.

(8) The board may deny, suspend, or revoke the preceptor's approval for failure to properly supervise the intern during the internship training program or for violation of the laws and rules relating to the practice of pharmacy or the internship program.

(9) The board may deny, suspend, or revoke the preceptor's approval of a pharmacist who has been convicted of any violation of a federal, state, or local law, ordinance, or rules relating to pharmacy practice within 5 years of the application for approval as a preceptor.

History: 1980 AACS; 1986 AACS.

R 338.473d Graduates of a non-accredited college or school of pharmacy; requirements; internship.

Rule 3d. (1) An applicant who is a graduate of a non-accredited college or school of pharmacy may be granted an intern license to comply with the requirements of R 338.473a(3) upon making application, payment of appropriate fees, and providing evidence of successful completion of the Foreign Pharmacy Graduate Examination Committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056.

(2) An intern license issued in accordance with this rule is valid for not more than 2 years from the date of issuance, unless extended by the board upon written request by the intern.

History: 1986 AACS; 2007 AACS.

R 338.474 Pharmacist licensure; eligibility; examination.

Rule 4. (1) An applicant for licensure as a pharmacist shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall comply with all of the following requirements:

(a) Have completed the requirements for a degree in pharmacy from an accredited college or school of pharmacy education approved by the board or successfully completed the Foreign Pharmacy Graduate Examination Committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056. The board adopts by reference the standards of the Accreditation Council for Pharmacy Education, 20 North Clark St., Suite 2500, Chicago, IL 60602. The standards are set forth in the documents entitled "Standards and Guidelines for Accreditation of Professional Degree Programs in Pharmacy", 8th edition, January 1995; and, the "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree", adopted June 14, 1997, of the Accreditation Council for Pharmacy Education. Copies of the standards are available at no cost from the Council's website at <http://www.acpe-accredit.org/standards>.

Copies of the guidelines also are available for inspection and distribution at cost from the Michigan Board of Pharmacy, Department of Community Health, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

(b) Have completed a program of internship pursuant to these rules.

(c) Pass a jurisprudence examination, approved by the board, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy with a scaled score of not less than 75.

(d) Pass an examination, approved by the board, which measures an applicant's theoretical and practical knowledge of pharmacy with a scaled score of not less than 75.

(2) An applicant who has not achieved a passing score on either of the examinations identified in subrule (1)(c) and (d) of this rule after 6 attempts may be reexamined only after meeting the requirements set forth in R 338.474a.

History: 1979 AC; 1980 AACS; 1988 AACS; 2007 AACS.

R 338.474a Licensure; reexamination.

Rule 4a. An applicant may take the examinations required by these rules on 6 separate occasions. An applicant who has not received a passing score on an examination after 6 attempts shall not take the examination a seventh or subsequent time, unless the applicant can demonstrate to the board that the applicant has complied with all of the following:

(a) Has enrolled as a student in a pharmacy education program approved by the board.

(b) Has taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination.

(c) Has submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.

History: 1983 AACS; 2007 AACS.

R 338.475 Licensure by endorsement; examination.

Rule 5. An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and administrative rules promulgated pursuant thereto, an applicant shall satisfy both of the following requirements:

(a) Pass an examination, approved by the board, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy with a scaled score of not less than 75.

(b) Satisfy those requirements in existence in this state at the time he or she was licensed in another state.

History: 1979 AC; 1980 AACS; 1990 AACS; 2007 AACS.

R 338.476 Rescinded.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.477 Pharmacy licenses; applications; notice of changes; self-inspection reports.

Rule 7. (1) Each separate pharmacy location where drugs are prepared or dispensed shall be licensed by the board under section 17741 of the code. If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required.

(2) A licensee who is moving to a new location shall apply and be approved for a new license for each location before moving. The department shall provide license applications. A licensee shall pay a license fee to the department for each new location.

(3) An applicant that is a partnership or corporation or that operates under an assumed name shall file, with its application for a pharmacy license, certified copies of its partnership certificates, corporate articles, or assumed name certificate. This requirement shall be waived if the application is for additional units and the additional units will be under the same ownership.

(4) A partnership, corporation, or entity operating under an assumed name shall provide the board with written notification of a change in any of the following entities:

- (a) Partners.
- (b) Stockholders.
- (c) Officers.
- (d) Members of the board of directors.

(e) The individual pharmacist who is designated as the pharmacy licensee of a licensed pharmacy. A partnership or corporation shall notify the board within 30 days of the change. A publicly held corporate pharmacy need not report changes in stockholders.

(5) A person who applies for a new pharmacy license or pharmacy relocation shall send an application and a completed self-inspection report on forms provided by the department.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.477a Application for license by governmental entity.

Rule 7a. An application by a governmental entity for a new or renewal pharmacy, drug manufacturer's, or wholesaler's license shall designate an individual to be the licensee. That individual and the pharmacist on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy.

History: 1979 AC.

R 338.477b Requirements for relicensure.

Rule 7b. (1) An applicant for relicensure who has had a lapsed license for 3 years or less under the provisions of section 16201(3) of the code may be relicensed upon compliance with both of the following requirements:

(a) Submission of a completed application on a form provided by the department, together with the requisite fee.

(b) Submission of proof of completion of 30 hours of continuing education that has been earned within the 2-year period immediately preceding the application for relicensure.

(2) An applicant for relicensure who has had a lapsed license for more than 3 years under the provisions of sections 16201(4) and 17733 of the code shall, in addition to the requirements set forth in subrule (1) of this rule, take and pass the board's jurisprudence examination with a score of not less than 75 and have been licensed and engaged in the practice of pharmacy in another state during the period that the

applicant's Michigan license is expired or complete a program of practical pharmacy experience that is not less than 200 hours as follows:

- (a) The individual shall practice under the personal charge of a currently licensed pharmacist.
 - (b) The individual shall notify the board, in writing, of the name of the supervising pharmacist and the name and address of the pharmacy before beginning the required practical experience.
 - (c) When an applicant has completed the required practical experience, the supervising pharmacist shall provide the board with verification of the applicant's completion of the experience.
- (3) For purposes of subrule (2) of this rule, "completion of a program of practical pharmacy experience" means professional and clinical instruction in at least all of the following areas:
- (a) Pharmacy administration and management.
 - (b) Drug distribution, use, and control.
 - (c) Legal requirements.
 - (d) Providing health information services and advising patients.
 - (e) Pharmacist's ethical and professional responsibilities.
 - (f) Drug and product information.
- (4) For purposes of complying with the provisions of subrule (2) of this rule, an applicant may be granted a temporary, nonrenewable license to complete the practical experience.

History: 1980 AACs; 1986 AACs; 1998-2000 AACs.

R 338.478 "Person" defined.

Rule 8. The word "person," as used in all statutes, rules, and regulations relating to the profession of pharmacy, shall be construed to include individuals, partnerships, firms, corporations, associations, and governmental institutions.

History: 1979 AC.

R 338.479 Prescription drug labeling.

Rule 9. (1) All labeling of prescription drugs shall comply with the requirements of the code and the federal food, drug, and cosmetic act, 21 U.S.C. S301 et seq.

(2) All containers in which prescription medication is dispensed shall bear a label which contains, at a minimum, all of the following information:

- (a) Pharmacy name and address.
 - (b) Prescription number.
 - (c) Patient's name.
 - (d) Date the prescription was most recently dispensed.
 - (e) Prescriber's name.
 - (f) Directions for use.
 - (g) The name of the medication, unless the prescriber indicates "do not label."
- (3) If a drug is dispensed that is not the brand prescribed, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label shall indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This subrule does not apply if the prescriber indicates "do not label."
- (4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed shall be noted on the prescription.
- (5) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACs.

R 338.479a Prescription drug receipts.

Rule 9a. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt which contains all of the following information:

(a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."

(b) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."

(c) The strength of the drug, if significant, unless the prescribed indicates "do not label."

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription.

(g) The date the prescription was most recently dispensed.

(h) The name of the prescriber.

(i) The name of the patient for whom the drug was prescribed.

(j) The price for which the drug was sold to the purchaser.

(2) Notwithstanding R 338.479, the information mandated in this rule shall appear on either the prescription label or on a combination label and receipt.

(3) For prescription services that are covered by a third party pay contract, the price included in the receipt is the amount actually paid by the patient.

(4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule on the written prescription form and the retention of the form constitutes retaining a copy of the receipt. The physical presence of the prescription form in the pharmacy constitutes compliance with the requirement of having the name and address of the pharmacy on the form.

(5) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACs.

R 338.479b Noncontrolled prescriptions.

Rule 9b. (1) A prescriber who issues a prescription for a noncontrolled legend drug shall date and sign the prescription and shall ensure that the prescription contains all of the following information:

(a) The full name of the patient for whom the drug is being prescribed.

(b) The prescriber's printed name and address.

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

(2) A prescriber shall ensure that a prescription is legible and that the information specified in subrule (1)(c) to (f) of this rule is clearly separated.

(3) A prescriber shall not prescribe more than the following on a single prescription form as applicable:

(a) For a prescription prescribed in handwritten form, up to 4 prescription drug orders.

(b) For a prescription prescribed on a computer-generated form or a preprinted list or produced on a personal computer or typewriter, up to 6 prescription drug orders.

(4) A prescriber shall not add handwritten drugs to a preprinted form and shall clearly designate which drugs are to be dispensed.

(5) A prescriber shall not prescribe a controlled and noncontrolled substance on the same prescription form.

(6) A prescription is valid for 1 year from the date the prescription was issued.

(7) A prescriber shall clearly indicate the total number of drugs prescribed for each prescription.

(8) A noncontrolled substance prescription may be transmitted electronically from the prescriber to the pharmacy of the patient's choice, and shall occur by utilizing a system that includes the following:

(a) A combination of technical security measures such as, but not limited to, those listed in R164.312 under Subpart C - Security Standards for the Protection of Electronic Protected Health Information of 45 CFR Part 164 that implements the federal Health Insurance Portability and Accountability Act of 1996, to ensure all of the following:

- (i) Authentication of an individual who prescribes or dispenses.
 - (ii) Technical non-repudiation.
 - (iii) Content integrity.
 - (iv) Confidentiality.
- (b) An electronic signature as defined in R 338.471a(e). An electronic signature is valid only when it is used to sign a prescription that is transmitted electronically from a prescriber to a pharmacy.
- (c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.
- (9) The electronic prescription shall meet any other requirements of the federal Health Insurance Portability and Accountability Act.
- (10) The electronic prescription shall permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:
- (i) The indication that no substitute is allowed, such as "dispense as written" or "DAW".
 - (ii) The indication that no substitute is allowed and that it is a unique element in the prescription.
- (11) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription shall identify the name of the pharmacy intended to receive the transmission, and shall include the information identified in subrule (1) of this rule.
- (12) The electronic prescription shall be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription shall be made available to an authorized agent of the board upon request. A secured copy shall be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and shall be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.
- (13) An electronic signature that meets the requirements of this rule shall have the full force and effect of a handwritten signature on a paper-based written prescription.
- (14) This rule does not apply to inpatient medical institutions.

History: 1998-2000 AACs; 2000 AACs; 2007 AACs.

R 338.479c Customized patient medication packages (CPMP).

Rule 9c. (1) In place of dispensing 2 or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package which is prepared by a pharmacist for a specific patient and which contains 2 or more prescribed solid oral dosage forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken. The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.

- (2) If medication is dispensed in a CPMP, then all of the following conditions shall be met:
- (a) Each CPMP shall bear a clearly readable label that states all of the following information:
 - (i) A serial number for the CPMP itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained in the CPMP.
 - (ii) The name, strength, physical description, and total quantity of each drug product contained in the CPMP.
 - (iii) The name of the prescriber for each drug product.
 - (iv) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product in the CPMP.
 - (v) The date of the preparation of the CPMP.
 - (vi) An expiration date for the CPMP. The date shall not be later than the earliest manufacturer's expiration date for any medication included in the CPMP or 60 days after the date of dispensing.
 - (vii) The name, address, and telephone number of the dispenser.
 - (viii) Any other information, statements, or warnings required for any of the drug products contained in the CPMP.

(b) A CPMP shall be accompanied by a patient package insert in case any medication in the CPMP is required to be dispensed with an insert as accompanying labeling. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

(c) In the absence of more stringent packaging requirements for any of the drug products contained in the CPMP, each CPMP shall be in compliance with the United States pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, for moisture permeation requirements for a class b single- unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened. All provisions of the poison prevention packaging act, as defined in section 17761(2) of the code, shall be complied with.

(d) When preparing a CPMP, the dispenser shall take into account any applicable compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may attend the simultaneous administration of the medications. Medications shall not be dispensed in CPMP packaging in any of the following situations:

- (i) The USP monograph or official labeling requires dispensing in the original container.
- (ii) The drugs or dosage forms are incompatible with packaging components or each other.
- (iii) The drugs are therapeutically incompatible when administered simultaneously.
- (iv) The drug products require special packaging.

(e) If 2 medications have physical characteristics that make them indistinguishable from each other, then the medication shall not be packaged together in the same CPMP.

(f) Medications that have been dispensed in CPMP packaging may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in the CPMP is changed, then a new appropriately labeled CPMP shall be prepared for the patient.

(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed shall be made and filed. At a minimum each record, shall contain all of the following information:

- (i) The name and address of the patient.
- (ii) The serial number of the prescription order for each drug product contained in the CPMP.
- (iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.
- (iv) The date of preparation of the CPMP and the expiration date assigned.
- (v) Any special labeling instructions.
- (vi) The name or initials of the pharmacist who prepared the CPMP.

History: 1998-2000 AACS.

R 338.480 Prescription records; nonapplicability to inpatient medical institution service.

Rule 10. (1) A prescription shall be numbered, dated, and initialed by the dispensing pharmacist at the time of the first filling at the pharmacy.

(2) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.

(3) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.480a Prescription refill records; manual systems; profile systems; automated data processing systems; nonapplicability to inpatient medical institution service; record confidentiality and access.

Rule 10a. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.

(2) A pharmacy may utilize a manual system of recording refills if the system is in compliance with both of the following criteria:

(a) The amount and date dispensed shall be entered on the prescription in an orderly fashion and the dispensing pharmacist shall initial the entry.

If the pharmacist only initials and dates the prescription, then the full face amount of the prescription shall be deemed dispensed.

(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.

(3) A pharmacy may utilize a uniform system of recording refills if the system is in compliance with all of the following criteria:

(a) Records shall be created and maintained in written form. All original and refill prescription information for a particular prescription shall appear on single documents in an organized format. The pharmacy shall preserve the records for 5 years. The records are subject to inspection by the board or its agents.

(b) All of the following information for each prescription shall be entered on the record:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration number, if appropriate.

(v) The number of refills authorized.

(vi) The "dispense as written" instructions, if indicated.

(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(c) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and shall initial the record each time a prescription is filled or refilled.

(d) The information required by subdivision (b) of this subrule shall be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.480.

(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system is in compliance with all of the following criteria:

(a) All information that is pertinent to a prescription shall be entered on the record, including all of the following information:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration number, if appropriate.

(v) The number of refills authorized.

(vi) Whether the drug must be dispensed as written.

(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(b) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the

information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy shall preserve the records on-site for 5 years. The records are subject to inspection by the board or its agents. A procedure shall be established to facilitate inspections.

(c) The required information shall be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.480.

(d) The recording system shall provide adequate safeguards against improper manipulation, the alteration of records, and the loss of records.

(e) The recording system shall have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trail for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other required information shall be made available to an authorized agent of the board upon request. The prescription data shall be maintained for 5 years. Data older than 16 months shall be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current 16 months shall be readily retrievable on site and available for immediate review.

(f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records.

(h) The automated data processing system shall be an integrated system that is capable of complying with all of the requirements of these rules.

(5) This rule does not apply to inpatient medical institution service.

(6) Records that are created under subrule (3) or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

History: 1992 AACS; 1998-2000 AACS.

R 338.481 Professional and technical equipment and supplies.

Rule 11. (1) A pharmacy shall be equipped with necessary drawers, shelves, storage cabinets, and prescription files. A sink that has hot and cold running water and a refrigerator of reasonable capacity shall be in the pharmacy department.

(2) A pharmacy shall have current editions or revisions of the Michigan pharmacy laws and rules and not less than 2 current or revised pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. A current electronic medium version of pharmacy reference texts meets the requirements of this subrule.

(3) A pharmacy shall have the necessary technical equipment to compound and dispense prescription drugs.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.482 Housing of pharmacy.

Rule 12. (1) All professional and technical equipment and supplies and prescription drugs shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings.

(2) All pharmacies shall have a prescription department which is devoted primarily to the compounding of prescriptions and the manufacture of pharmaceutical preparations which occupies not less than 150 square feet of space, and which includes a prescription counter that provides not less than

10 square feet of free working surface. If more than 1 pharmacist is on duty at any one time, the free working space shall be increased by not less than 4 square feet for each additional pharmacist. The prescription counter shall be kept clean and orderly. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall be permanently enclosed by partitions from the floor to the ceiling. All partitions shall be of substantial construction and shall be securely lockable so that drugs and devices that can only be sold by a pharmacist are unobtainable during the absence of the pharmacist. Identification of this department by the use of the words "drug," "medicines," or "pharmacy" or by the use of a similar term or combination of terms shall be restricted to the area that is registered by the board. The pharmacy department shall be locked when the pharmacist is not in the establishment.

History: 1979 AC; 1980 AACS.

R 338.483 Rescinded.

History: 1979 AC; 1992 AACS.

R 338.484 Rescinded.

History: 1979 AC.

ADMINISTRATIVE HEARINGS

R 338.485 - R 338.485y Rescinded.

History: 1979 AC; 1980 AACS.

R 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.

Rule 16. (1) As used in this rule:

(a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

(2) Pharmacy services shall be directed and provided by a licensed pharmacist.

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of inpatients shall be supervised by a pharmacist who is on the premises of the medical institution.

(4) The pharmacist who directs the pharmacy services shall develop, implement, supervise, and coordinate all of the services provided, including, at a minimum, all of the following:

(a) Dispensing medications in a form that minimizes additional preparation before administration to the patient, including the admixture of parenterals.

(b) Obtaining the prescriber's original medication order, a direct carbonized copy, an electromechanical facsimile, or other electronic order transmission. Security measures shall be in place to ensure that system access by unauthorized individuals is not allowed.

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the physician or nurse before administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then a limited number of medications may be stocked at the patient care areas for the administration of first doses. These medications shall be provided in a manner that ensures security and immediate availability, such as sealed or secured medication kits, carts,

or treatment trays. A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

(d) Monitoring medication therapy to promote positive patient outcomes while evaluating clinically significant chemical and therapeutic incompatibilities.

(e) Establishing the specifications for the procurement of all pharmaceuticals and related biologicals and chemicals approved for use in the medical institution.

(f) Periodically inspecting all areas in the medical institution where medications are stored to verify compliance with the standards for the safe use and storage of the medications.

(g) Maintaining proper security for all medications stored or kept within the medical institution.

(h) Providing educational programs regarding medications and their safe use.

(i) Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist shall be available on an on-call basis. Only a limited number of medications that are packaged in units of use shall be available. The medications shall be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication shall be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication shall be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number. A written order and a proof of removal and use document shall be obtained for each medication unit removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon recommendation of an interdisciplinary practitioners committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient and any identifying number shall be labeled on the medication container. The container may be the individual patients' assigned medication drawer. The directions for use shall be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use shall be on the container. The preceding provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall personally supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, dispensed to patients. However, medications in single-unit packages and intravenous solutions which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for redispensing.

(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board of pharmacy, upon request.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.487 Rescinded.

History: 1979 AC.

R 338.488 Standard clinical thermometers.

Rule 18. (1) In addition to meeting the standards approved by the board in subrule (2) of this rule, standard clinical thermometers shall be in compliance in all respects with standards set forth in section 469 of Act No. 328 of the Public Acts of 1931, as amended, being S750.469 of the Michigan Compiled Laws.

(2) The board approves and adopts by reference the standards for manufacturing clinical thermometers approved by the American society for testing and materials on August 29, 1986, and issued under the designation "E 667-86." Copies of the standards may be obtained, at no cost, from either the Board of Pharmacy, P.O. Box 30018, Lansing, Michigan 48909, or the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.

(3) To obtain certification, a manufacturer shall submit a completed application, on a form provided by the department, together with the requisite fee and 2 representative samples of each type or kind of thermometer which the manufacturer desires to offer for sale in Michigan. The manufacturer shall submit additional representative samples if requested by the board. If the board finds that the samples comply with the requirements of this rule, the board shall certify the thermometers for sale in Michigan and the department shall issue a certification to the manufacturer.

(4) Upon request, a manufacturer shall provide a signed guarantee that the standard clinical thermometers offered for sale in Michigan were certified by the manufacturer to comply with subsection 469(2) of Act No. 328 of the Public Acts of 1931, as amended, being S750.469(2) of the Michigan Compiled Laws, and this rule. A manufacturer that is issued a certification by the board shall package each standard clinical thermometer in a container that prominently displays a notification that the thermometer meets the manufacturing standards approved by the board. The notification shall be printed either on the package or the package insert.

History: 1979 AC; 1982 AACCS; 1988 AACCS; 1990 AACCS.

R 338.489 Automated devices.

Rule 19. (1) An automated device means a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription.

(2) An automated device may be used only in the following locations:

- (a) A pharmacy.
- (b) A hospital.
- (c) A county medical care facility.
- (d) A hospice.
- (e) A nursing home.
- (f) Other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109.
- (g) An office of a dispensing prescriber.

(3) An automated device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription, as defined in the code, and located within a licensed pharmacy shall be used only by a pharmacist or other pharmacy personnel under the personal charge of a pharmacist.

(4) If an automated dispensing device is used in a dispensing prescriber's office, the device shall be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office.

(a) If a dispensing prescriber delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154.

(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(c) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the dispensing prescriber for review by an agent of the board. This documentation shall include at least all of the following information:

- (i) Manufacturer name and model.

(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(iii) Policy and procedures for system operation that addresses at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

(5) An automated device that is to be used for the furnishing of medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in 1978 PA 368, MCL 333.20109, shall be supplied and controlled by a pharmacy that is licensed and located in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing a board-approved error prevention technology that complies with R 338.3154. Each such device shall comply with all of the following provisions:

(a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the pharmacy for review by an agent of the board. The documentation shall include at least all of the following information:

(i) Name and address of the pharmacy responsible for the operation of the automated device.

(ii) Name and address of the facility where the device is located.

(iii) Manufacturer name and model number.

(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(v) Policy and procedures for system operation that address at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

(I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.

(6) Records and electronic data kept by automated devices shall meet all of the following requirements:

(a) All events involving access to the contents of the automated devices shall be recorded electronically.

(b) Records shall be maintained for 5 years by the pharmacy and shall be retrievable on demand for review by an agent of the board. The records shall include all of the following information:

(i) The unique identity of device accessed.

(ii) Identification of the individual accessing the device.

(iii) The type of transaction.

(iv) The name, strength, dosage form and quantity of the drug accessed.

(v) The name of the patient for whom the drug was ordered.

(vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the device.

(7) Policy and procedures for the use of the automated device shall include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any

medication from the system for immediate patient administration. This subrule does not apply to the following situations:

(a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(i).

(b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).

(c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.

(d) In each of the situations specified in subdivisions (a) to (c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.

(e) The device is located in a dispensing prescriber's office.

(8) A copy of all policies and procedures related to the use of an automated device shall be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

History: 1979 AC; 1980 AACS; 2007 AACS.

R 338.490 Professional responsibility; "caregiver" defined.

Rule 20. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors licensed under section 17748 of the code or from other lawful channels of distribution.

(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

(a) The prescription appears to be improperly written.

(b) The prescription is susceptible to more than 1 interpretation.

(c) The pharmacist has reason to believe that the prescription could cause harm to the patient.

(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.

(3) A prescription drug shall only be dispensed when the pharmacy is open and under the personal charge of a pharmacist.

(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate, to the patient or the patient's caregiver, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient's care. All of the following provisions apply to communicating medication safety and effectiveness information:

(a) The information shall be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.

(b) The information shall be provided with each prescription for a drug not previously prescribed for the patient.

(c) If the pharmacist deems it appropriate, the information shall be provided with prescription refills.

(d) The information shall be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy. This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.

(5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code and under the personal charge of the delegating pharmacist, except as provided in R 338.486(3). A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person shall do all of the following:

(a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.

(b) Before delegating an act, task, or function, make a determination that the delegatee has the necessary knowledge and skills to safely and competently complete the act, task, or function.

- (c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.
- (d) Supervise and evaluate the performance of the delegatee.
- (e) Provide remediation of the performance of the delegatee if indicated.
- (6) A delegating pharmacist shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

History: 1979 AC; 1990 AACS; 1998-2000 AACS.

R 338.491, R 338.492 Rescinded.

History: 1979 AC.

PART 2. MANUFACTURING AND DISTRIBUTION OF PRESCRIPTION DRUGS

R 338.493a Applicability; distributions by pharmacies; license requirements.

Rule 23a. (1) These rules apply to a manufacturer or wholesale distributor that is licensed to do business in this state on or after September 1, 1992, or that applies for a license to do business in this state on or after September 1, 1992.

(2) If the total number of dosage units of all prescription drugs that are distributed by a pharmacy to a person as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the 12-month period, then the pharmacy is a wholesale distributor as defined in section 17709(2) of the code.

(3) If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code.

(4) A manufacturer or wholesale distributor that distributes prescription drugs in Michigan only from a location outside of Michigan shall obtain a license to do business in Michigan. A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in Michigan from 1 or more locations in Michigan shall obtain a separate license for each location in Michigan where prescription drugs are manufactured or distributed.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.493b Manufacturing practice; adoption by reference of standards.

Rule 23b. A manufacturer shall maintain the building, operate the equipment, and administer the controls, records, and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions of 21 C.F.R. SS211.1 to 211.208, (April 1, 1979). The criteria set forth in the provisions of 21 C.F.R. SS211.1 to 211.208 are adopted in these rules by reference. Copies of the adopted material are available from the Superintendent of Documents, United States Government Printing Office, Washington, DC 20402, at a cost as of the time of adoption of these amendatory rules of \$4.00 or from the Board of Pharmacy, Department of Commerce, P.O. Box 30018, Lansing, Michigan 48909, at a cost as of the time of adoption of these amendatory rules of \$4.00.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493c Wholesaling practice; minimum requirements.

Rule 23c. A wholesale distributor shall maintain and comply with all of the following minimum standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records:

(a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall be in compliance with all of the following provisions:

- (i) Be of a suitable size and construction to facilitate cleaning, maintenance, and proper operations.
- (ii) Have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.
- (iii) Have a quarantine area for the storage of prescription drugs which are outdated, damaged, deteriorated, misbranded, or adulterated or which are in immediate or sealed secondary containers that have been opened.
- (iv) Be maintained in a clean and orderly condition.
- (v) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) All facilities that are used for wholesale drug distribution shall be secure from unauthorized entry as specified in the following provisions:

- (i) Access from outside the premises shall be kept to a minimum and be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (ii) All facilities shall be equipped with an alarm system to detect entry after hours.
- (iii) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with label requirements or in accordance with requirements set forth in the current edition of the official compendium. If storage requirements are not established for a prescription drug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document the proper storage of prescription drugs. The recordkeeping requirements in subdivision (f) of this rule shall be followed for all stored prescription drugs.

(d) All of the following provisions apply to the examination of materials:

(i) Each outside shipping container shall be visually examined upon receipt for the identity of the prescription drug products and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damages to the contents.

(ii) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that prescription drugs that have been damaged in storage or held under improper conditions are not delivered.

(iii) The recordkeeping requirements in subdivision (f) of this rule shall be followed for all incoming and outgoing prescription drugs.

(e) All of the following provisions apply to returned, damaged, and outdated prescription drugs:

(i) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(ii) Any immediate or sealed outer or sealed secondary containers of any prescription drugs that have been opened or used shall be identified as such and the drugs shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(iii) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or

shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(iv) The recordkeeping requirements of subdivision (f) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) All of the following provisions apply to recordkeeping:

(i) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include all of the following information:

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

(b) The identity and quantity of the drugs received and distributed or disposed of.

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

(ii) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of 2 years after disposition of the drugs.

(iii) Records which are described in this subdivision and which are kept at the inspection site or can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records which are kept at a central location apart from the inspection site and which are not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(g) Wholesale distributors 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, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include all of the following procedures in their written policies and procedures:

(i) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedures may permit deviation from this requirement if the deviation is temporary and appropriate.

(ii) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(a) Any action initiated at the request of the food and drug administration, the board, or other federal, state, or local law enforcement agency or other government agency.

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

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(iii) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other situations of local, state, or national emergency.

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

(h) Wholesale distributors shall establish and maintain lists of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner.

(j) Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(k) Each person employed in any prescription drug wholesale distribution activity shall have education, training and experience, or any combination of education, training and experience, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493d License application; manufacturers and wholesale distributors.

Rule 23d. An application for a license as a manufacturer or wholesale distributor shall be made on a form provided by the department and shall contain all of the following information:

- (a) All names, addresses, and telephone numbers used by the applicant in this state.
- (b) State of incorporation.
- (c) The kind of ownership or operation, such as individually owned, partnership, association, cooperative, or corporation.
- (d) The name of the owner or operator, including, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporation officer and director.
- (e) A partnership, corporation, or an applicant who operates under an assumed name shall file certified copies of its partnership certificate, corporate articles, or assumed name certificate with its initial application.
- (f) A brief description of the buildings in this state that are owned, controlled, or used by the applicant in connection with, or for the manufacture or wholesale distribution of, prescription drugs, the address, if different from that of the principal address of the applicant, at which each building is located, and an indication of the type of activity or activities carried on in each building, such as any of the following:
 - (i) The manufacture of active ingredients.
 - (ii) Compounding.
 - (iii) Packaging.
 - (iv) Repackaging.
 - (v) Operating a quality control laboratory.
 - (vi) Recordkeeping and storage.
 - (vii) Operating a sales office.
 - (viii) Warehousing of ingredients.
 - (ix) Warehousing of finished products for distribution.
- (g) An applicant for a manufacturer's license shall also furnish information as to the formula and name or names of each prescription drug that is supplied or distributed under the manufacturer's label. An up-to-date catalog that contains information required by this subdivision may be supplied for this purpose.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493e Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.493f Inspection of applicants and licensees.

Rule 23f. The board or a board inspector may enter, at reasonable times, any building, place, or facility which is owned or controlled by any applicant for, or holder of, a license to make an inspection which is reasonably necessary to enable the board to determine whether the applicant possesses the necessary qualifications and competence for the license sought or to determine whether a license holder is, and has been, complying with the acts and rules enforced by the board. The inspection shall be carried out in a reasonable manner and shall concern only matters relevant to the applicant's or license holder's manufacturing or wholesale distributing of drugs saleable on prescription only. The inspection shall not extend to any of the following information:

- (a) Financial data.
- (b) Sales data other than shipment data.
- (c) Pricing data.
- (d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.

(e) Research data.

History: 1979 AC; 1980 AACS.

R 338.493g Persons to whom drugs may be sold or distributed.

Rule 23g. With respect to prescription drugs, a manufacturer or wholesale distributor shall only supply, distribute, sell, offer for sale, barter, or otherwise transfer drugs to persons who are licensed by the board or to persons who are licensed to prescribe drugs in this state.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493h Rescinded.

History: 1979 AC; 1980 AACS.

R 338.494 Rescinded.

History: 1979 AC; 1982 AACS; 1988 AACS.

R 338.495 Rescinded.

History: 1979 AC; 1988 AACS; 1998-2000 AACS.

R 338.496 Rescinded.

History: 1979 AC; 1998-2000 AACS.

R 338.497 Assessment of fines.

Rule 1. (1) When a fine has been designated as an available sanction for a violation of section 16221 to section 16226 of the code, in the course of assessing a fine, a board shall take into consideration the following factors without limitation:

(a) The extent to which the licensee obtained financial benefit from any conduct comprising part of the violation found by the board.

(b) The willfulness of the conduct found to be part of the violation determined by the board.

(c) The public harm, actual or potential, caused by the violation found by the board.

(d) The cost incurred in investigating and proceeding against the licensee.

(2) A fine shall not exceed the sum of \$5,000.00 for each violation found to have been committed by the licensee.

History: 1981 AACS.

PART 3. MEDICATION DRUG BOX EXCHANGE PROGRAMS FOR HOSPICE

R 338.500 Hospice emergency drug box.

Rule 30. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes pursuant to the provisions of section 17746 of the code shall establish drug boxes that are in compliance with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall assure that the hospice has developed policies and procedures that require all of the following:

(a) Maintenance by the hospice of a drug box exchange log that accounts for the hospice's receipt of the boxes from the pharmacy, assignment of the boxes to registered nurses or physicians' assistants, and return of the boxes to the pharmacy for restocking.

(b) A procedure to assure that the drug boxes are inspected at least weekly to determine if they have expired or have been opened.

(c) Procedures for the storage and control of a drug box while it is assigned to, and being used by, a registered nurse or physician's assistant.

(d) A procedure for implementing the hospice medical director's responsibility for assuring that prescriptions for drugs removed from the drug boxes are obtained from the attending physicians.

(2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.

(3) The drugs contained in each drug box shall be listed inside the front cover of the box. Each box shall be equipped with only 1 nonreuseable, tamper-evident seal or sealing system which is a color that designates that the box has not been opened and several nonreuseable, tamper-evident seals or sealing systems which are a different color that designates that the box has been opened.

(4) The drug boxes shall be numbered. A permanent record of all drug boxes shall be maintained at the pharmacy.

(5) A label that contains all of the following information shall be attached to the drug box so that it is visible from the outside of the box:

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

(c) The name of the pharmacist who last inspected and restocked the drug box.

(d) The date the drug box was last restocked.

(e) The date on which the drug box must be returned to the pharmacy for the replacement of expired drugs.

(f) The number of the drug box.

(6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreuseable, tamper-evident seal or sealing system which is the color that designates that the box has not been opened.

(7) The drug boxes shall be kept in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, registered nurse, or physician's assistant. The boxes shall be stored under conditions that will maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment shall be limited to individuals who are authorized to dispense drugs from a drug box on the order of an attending physician or the hospice medical director.

(8) The drug box shall remain sealed at all times, except when in use. The drug box shall only be opened by a registered nurse or physician's assistant on the order of an attending physician or the medical director of the hospice. All drugs removed from the box shall be recorded on a medication use form. After completing the form, the registered nurse or physician's assistant shall place the form in the box and seal the box with a nonreuseable, tamper-evident seal or sealing system which is a color that designates that the box has been opened.

(9) Each drug box under the control of the pharmacy shall be examined at least weekly to assure that the seal which designates that the box has not been opened is still intact and the expiration date has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box shall be returned to the pharmacy. When written prescriptions are required, the prescriptions of the attending physician or hospice medical director shall accompany the drug boxes that have been opened when the drug boxes are returned to the pharmacy.

(10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record shall contain all of the following information:

(a) The number of the box.

(b) The name of the hospice to which the box is released.

(c) The date the box is released to the hospice.

(d) The name and signature of the pharmacist who releases the box to the hospice.

(e) The expiration date assigned.

(f) The date the box is returned to the pharmacy for restocking.

(g) The name and signature of the pharmacist who received the box for restocking.

(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the attending physician or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed from the hospice drug box on the back of the prescriptions. The prescriptions shall be filed in the same manner as other prescriptions are maintained at the pharmacy.

History: 1995 AACs.