

**Unprofessional Conduct
Regulations from Other
Professions at DHP and from
2 Neighboring States**

MEDICINE

Part II. Standards of Professional Conduct.

18VAC85-20-25. Treating and prescribing for self or family.

A. Treating or prescribing shall be based on a bona fide practitioner-patient relationship, and prescribing shall meet the criteria set forth in § 54.1-3303 of the Code of Virginia.

B. A practitioner shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.

C. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

18VAC85-20-26. Patient records.

A. Practitioners shall comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records.

B. Practitioners shall provide patient records to another practitioner or to the patient or his personal representative in a timely manner in accordance with provisions of § 32.1-127.1:03 of the Code of Virginia.

C. Practitioners shall properly manage patient records and shall maintain timely, accurate, legible and complete patient records.

D. Practitioners shall maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

1. Records of a minor child, including immunizations, shall be maintained until the child reaches the age of 18 or becomes emancipated, with a minimum time for record retention of six years from the last patient encounter regardless of the age of the child; or

2. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or his personal representative; or

3. Records that are required by contractual obligation or federal law [may need] to be maintained for a longer period of time.

E. From October 19, 2005, practitioners shall post information or in some manner inform all patients concerning the time frame for record retention and destruction. Patient records shall

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only be destroyed in a manner that protects patient confidentiality, such as by incineration or shredding.

F. When a practitioner is closing, selling or relocating his practice, he shall meet the requirements of § 54.1-2405 of the Code of Virginia for giving notice that copies of records can be sent to any like-regulated provider of the patient's choice or provided to the patient.

18VAC85-20-27. Confidentiality.

A practitioner shall not willfully or negligently breach the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful.

18VAC85-20-28. Practitioner-patient communication; termination of relationship.

A. Communication with patients.

1. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately inform a patient or his legally authorized representative of his medical diagnoses, prognosis and prescribed treatment or plan of care. A practitioner shall not deliberately make a false or misleading statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.

2. A practitioner shall present information relating to the patient's care to a patient or his legally authorized representative in understandable terms and encourage participation in the decisions regarding the patient's care.

3. Before surgery or any invasive procedure is performed, informed consent shall be obtained from the patient in accordance with the policies of the health care entity. Practitioners shall inform patients of the risks, benefits, and alternatives of the recommended surgery or invasive procedure that a reasonably prudent practitioner in similar practice in Virginia would tell a patient.

a. In the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder, the legally authorized person available to give consent shall be informed and the consent documented.

b. An exception to the requirement for consent prior to performance of surgery or an invasive procedure may be made in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient.

c. For the purposes of this provision, "invasive procedure" shall mean any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for

which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decision-maker prior to proceeding.

4. Practitioners shall adhere to requirements of § 32.1-162.18 of the Code of Virginia for obtaining informed consent from patients prior to involving them as subjects in human research, with the exception of retrospective chart reviews.

B. Termination of the practitioner/patient relationship.

1. The practitioner or the patient may terminate the relationship. In either case, the practitioner shall make a copy of the patient record available, except in situations where denial of access is allowed by law.

2. Except as provided in § 54.1-2962.2 of the Code of Virginia, a practitioner shall not terminate the relationship or make his services unavailable without documented notice to the patient that allows for a reasonable time to obtain the services of another practitioner.

18VAC85-20-29. Practitioner responsibility.

A. A practitioner shall not:

1. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised;

2. Engage in an egregious pattern of disruptive behavior or interaction in a health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

3. Exploit the practitioner/patient relationship for personal gain.

B. Advocating for patient safety or improvement in patient care within a health care entity shall not constitute disruptive behavior provided the practitioner does not engage in behavior prohibited in A 2 of this section.

18VAC85-20-30. Advertising ethics.

A. Any statement specifying a fee, whether standard, discounted or free, for professional services which does not include the cost of all related procedures, services and products which, to a substantial likelihood, will be necessary for the completion of the advertised service as it would be understood by an ordinarily prudent person shall be deemed to be deceptive or misleading, or both. Where reasonable disclosure of all relevant variables and considerations is made, a statement of a range of prices for specifically described services shall not be deemed to be deceptive or misleading.

B. Advertising a discounted or free service, examination, or treatment and charging for any additional service, examination, or treatment which is performed as a result of and within 72

hours of the initial office visit in response to such advertisement is unprofessional conduct unless such professional services rendered are as a result of a bona fide emergency. This provision may not be waived by agreement of the patient and the practitioner.

C. Advertisements of discounts shall disclose the full fee that has been discounted. The practitioner shall maintain documented evidence to substantiate the discounted fees and shall make such information available to a consumer upon request.

D. A licensee shall disclose the complete name of the specialty board which conferred the certification when using or authorizing the use of the term "board certified" or any similar words or phrase calculated to convey the same meaning in any advertising for his practice.

E. A licensee of the board shall not advertise information which is false, misleading, or deceptive. For an advertisement for a single practitioner, it shall be presumed that the practitioner is responsible and accountable for the validity and truthfulness of its content. For an advertisement for a practice in which there is more than one practitioner, the name of the practitioner or practitioners responsible and accountable for the content of the advertisement shall be documented and maintained by the practice for at least two years.

F. Documentation, scientific and otherwise, supporting claims made in an advertisement shall be maintained and available for the board's review for at least two years.

18VAC85-20-40. Vitamins, minerals and food supplements.

A. The recommendation or direction for the use of vitamins, minerals or food supplements and the rationale for that recommendation shall be documented by the practitioner. The recommendation or direction shall be based upon a reasonable expectation that such use will result in a favorable patient outcome, including preventive practices, and that a greater benefit will be achieved than that which can be expected without such use.

B. Vitamins, minerals, or food supplements, or a combination of the three, shall not be sold, dispensed, recommended, prescribed, or suggested in doses that would be contraindicated based on the individual patient's overall medical condition and medications.

C. The practitioner shall conform to the standards of his particular branch of the healing arts in the therapeutic application of vitamins, minerals or food supplement therapy.

18VAC85-20-50. Anabolic steroids.

A practitioner shall not sell, prescribe, or administer anabolic steroids to any patient for other than accepted therapeutic purposes.

18VAC85-20-60 to 18VAC85-20-70. [Repealed]

18VAC85-20-80. Solicitation or remuneration in exchange for referral.

A practitioner shall not knowingly and willfully solicit or receive any remuneration, directly or indirectly, in return for referring an individual to a facility or institution as defined in §37.2-100 of the Code of Virginia, or hospital as defined in §32.1-123 of the Code of Virginia. Remuneration shall be defined as compensation, received in cash or in kind, but shall not include any payments, business arrangements, or payment practices allowed by Title 42, §1320a-7b(b) of the United States Code, as amended, or any regulations promulgated thereto.

18VAC85-20-90. Pharmacotherapy for weight loss.

A. A practitioner shall not prescribe amphetamine, Schedule II, for the purpose of weight reduction or control.

B. A practitioner shall not prescribe controlled substances, Schedules III through VI, for the purpose of weight reduction or control in the treatment of obesity, unless the following conditions are met:

1. An appropriate history and physical examination are performed and recorded at the time of initiation of pharmacotherapy for obesity by the prescribing physician, and the physician reviews the results of laboratory work, as indicated, including testing for thyroid function;

2. If the drug to be prescribed could adversely affect cardiac function, the physician shall review the results of an electrocardiogram performed and interpreted within 90 days of initial prescribing for treatment of obesity;

3. A diet and exercise program for weight loss is prescribed and recorded;

4. The patient is seen within the first 30 days following initiation of pharmacotherapy for weight loss, by the prescribing physician or a licensed practitioner with prescriptive authority working under the supervision of the prescribing physician, at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy;

5. The treating physician shall direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy. Continuation of prescribing for treatment of obesity shall occur only if the patient has continued progress toward achieving or maintaining a target weight and has no significant adverse effects from the prescribed program.

18VAC85-20-100. Sexual contact.

A. For purposes of § 54.1-2915 A 12 and A 19 of the Code of Virginia and this section, sexual contact includes, but is not limited to, sexual behavior or verbal or physical behavior which:

1. May reasonably be interpreted as intended for the sexual arousal or gratification of the practitioner, the patient, or both; or

2. May reasonably be interpreted as romantic involvement with a patient regardless of whether such involvement occurs in the professional setting or outside of it.

B. Sexual contact with a patient.

1. The determination of when a person is a patient for purposes of § 54.1-2915 A 19 of the Code of Virginia is made on a case-by-case basis with consideration given to the nature, extent, and context of the professional relationship between the practitioner and the person. The fact that a person is not actively receiving treatment or professional services from a practitioner is not determinative of this issue. A person is presumed to remain a patient until the patient-practitioner relationship is terminated.

2. The consent to, initiation of, or participation in sexual behavior or involvement with a practitioner by a patient does not change the nature of the conduct nor negate the statutory prohibition.

C. Sexual contact between a practitioner and a former patient.

Sexual contact between a practitioner and a former patient after termination of the practitioner-patient relationship may still constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge, or influence of emotions derived from the professional relationship.

D. Sexual contact between a practitioner and a key third party shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. For purposes of this section, key third party of a patient shall mean: spouse or partner, parent or child, guardian, or legal representative of the patient.

E. Sexual contact between a medical supervisor and a medical trainee shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care.

18VAC85-20-105. Refusal to provide information.

A practitioner shall not willfully refuse to provide information or records as requested or required by the board or its representative pursuant to an investigation or to the enforcement of a statute or regulation.

DENTISTRY

Part V. Unprofessional Conduct.

18VAC60-20-150 to 18VAC60-20-160. [Repealed]

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18VAC60-20-170. Acts constituting unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of §54.1-2706 of the Code of Virginia:

1. Fraudulently obtaining, attempting to obtain or cooperating with others in obtaining payment for services;
2. Performing services for a patient under terms or conditions which are unconscionable. The board shall not consider terms unconscionable where there has been a full and fair disclosure of all terms and where the patient entered the agreement without fraud or duress;
3. Misrepresenting to a patient and the public the materials or methods and techniques the licensee uses or intends to use;
4. Committing any act in violation of the Code of Virginia reasonably related to the practice of dentistry and dental hygiene;
5. Delegating any service or operation which requires the professional competence of a dentist or dental hygienist to any person who is not a dentist or dental hygienist as authorized by this chapter;
6. Certifying completion of a dental procedure that has not actually been completed;
7. Knowingly or negligently violating any applicable statute or regulation governing ionizing radiation in the Commonwealth of Virginia, including, but not limited to, current regulations promulgated by the Virginia Department of Health; and
8. Permitting or condoning the placement or exposure of dental x-ray film by an unlicensed person, except where the unlicensed person has complied with 18VAC60-20-195.

NURSING

Part V. Disciplinary Provisions.

18VAC90-20-300. Disciplinary provisions.

A. The board has the authority to deny, revoke or suspend a license or multistate licensure privilege issued, or to otherwise discipline a licensee or holder of a multistate licensure privilege upon proof that the licensee or holder of a multistate licensure privilege has violated any of the provisions of § 54.1-3007 of the Code of Virginia. For the purpose of establishing allegations to be included in the notice of hearing, the board has adopted the following definitions:

1. Fraud or deceit in procuring or maintaining a license means, but shall not be limited to:
 - a. Filing false credentials;

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b. Falsely representing facts on an application for initial license, reinstatement or renewal of a license; or

c. Giving or receiving assistance in the taking of the licensing examination.

2. Unprofessional conduct means, but shall not be limited to:

a. Performing acts beyond the limits of the practice of professional or practical nursing as defined in Chapter 30 (§54.1-3000 et seq.) of Title 54.1 of the Code of Virginia, or as provided by §§54.1-2901 and 54.1-2957 of the Code of Virginia;

b. Assuming duties and responsibilities within the practice of nursing without adequate training or when competency has not been maintained;

c. Obtaining supplies, equipment or drugs for personal or other unauthorized use;

d. Employing or assigning unqualified persons to perform functions that require a licensed practitioner of nursing;

e. Falsifying or otherwise altering patient, employer, student, or educational program records, including falsely representing facts on a job application or other employment-related documents;

f. Abusing, neglecting or abandoning patients or clients;

g. Practice of a clinical nurse specialist beyond that defined in 18VAC90-20-290;

h. Representing oneself as or performing acts constituting the practice of a clinical nurse specialist unless so registered by the board;

i. Delegating nursing tasks to an unlicensed person in violation of the provisions of Part VIII (18VAC90-20-420 et seq.) of this chapter;

j. Giving to or accepting from a patient or client property or money for any reason other than fee for service or a nominal token of appreciation;

k. Obtaining money or property of a patient or client by fraud, misrepresentation or duress;

l. Entering into a relationship with a patient or client that constitutes a professional boundary violation in which the nurse uses his professional position to take advantage of a patient or client's vulnerability, to include but not limited to actions that result in personal gain at the expense of the patient or client, a nontherapeutic personal involvement or sexual conduct with a patient or client; or

m. Violating state laws relating to the privacy of patient information, including but not limited to §32.1-127.1:03 of the Code of Virginia.

n. Violating any provision of this chapter.

B. Any sanction imposed on the registered nurse license of a clinical nurse specialist shall have the same effect on the clinical nurse specialist registration.

315.121 Grounds for acting against licensee -- Notification to board of conviction required -- Petition for reinstatement -- Expungement.

- (1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
 - (a) Unprofessional or unethical conduct;
 - (b) Mental or physical incapacity that prevents the licensee, permit holder, or certificate holder from engaging in the practice of pharmacy or the wholesale distribution or manufacturing of drugs with reasonable skill, competence, and safety to the public;
 - (c) Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea, one (1) or more of the following:
 1. A felony;
 2. An act involving moral turpitude or gross immorality; or
 3. A violation of the pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government;
 - (d) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician is incapable of engaging or assisting in the practice of pharmacy with reasonable skill, competence, and safety to the public and failing to report any relevant information to the board;
 - (e) Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate;
 - (f) Engaging in fraud in connection with the practice of pharmacy or the wholesale distribution or manufacturing of drugs;
 - (g) Engaging in or aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of "pharmacist," "pharmacist intern," or other term which might imply that the individual is a pharmacist or pharmacist intern;
 - (h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;
 - (i) Violation of any order issued by the board to comply with any applicable law or administrative regulation; or
 - (j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the board.

- (2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist or pharmacist intern:
- (a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;
 - (b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:
 - 1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
 - 2. Certified or licensed health-care personnel who are responsible for care of the patient;
 - 3. Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A;
 - 4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
 - 5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;
 - (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist or pharmacy intern knows or should have known of their intended use in illegal activities;
 - (d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;
 - (e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;
 - (f) Selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;
 - (g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;
 - (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
 - (i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care; or

- (j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.
- (3) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.
- (4) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.
- (5) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.
- (6) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.
 - (a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.
 - (b) No person may have his or her record expunged under this section more than once.

The board shall promulgate administrative regulations under KRS Chapter 13A to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person, or create a significant threat of such harm.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 99, sec. 598, effective June 20, 2005. -- Amended 2003 Ky. Acts ch. 51, sec. 4, effective June 24, 2003. -- Amended 2002 Ky. Acts ch. 335, sec. 1, effective July 15, 2002. -- Amended 1998 Ky. Acts ch. 426, sec. 549, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 14, effective July 15, 1996. --Created 1982 Ky. Acts ch. 191, sec. 11, effective July 15, 1982.

(Rule 1140-2-.01, continued)

- (b) without discriminating in any manner between patients or groups of patients; and
 - (c) without compromising the kind or extent of services or facilities made available.
- (12) A pharmacist shall recognize the Tennessee Board of Pharmacy as the governing body of the practice of pharmacy in the State of Tennessee, and report to the board any violations of pharmacy laws or rules which may come to the pharmacist's attention. The pharmacist at all times shall refrain from discussing these matters with nonmembers of the profession.
- (13) The following functions must be performed personally by a pharmacist or by a pharmacy intern under the personal supervision and in the presence of a pharmacist:
- (a) Certification of medical and prescription orders;
 - (b) Performance of final verification of the product prior to dispensing;
 - (c) Initialing of medical and prescription orders noting appropriate comments;
 - (d) Providing patient counseling;
 - (e) Providing direct patient care services;
 - (f) Providing drug information to patients, care givers, and health care providers;
 - (g) Supervision of compounding;
 - (h) Evaluation and establishment of criteria for selection of drug product(s) and supplier(s); and
 - (i) Daily opening and closing of a pharmacy practice site.
- (14) A pharmacist and pharmacy intern shall wear appropriate identification showing name and appropriate title.
- (15) A pharmacist shall immediately notify the board office in writing of a change in location of primary practice site and permanent residence.
- (16) A pharmacist shall conspicuously display the pharmacist's license and certificate of registration at the primary pharmacy practice site. Pharmacists shall possess at all times, while engaged in the practice of pharmacy, proof of a license.
- (17) A pharmacist convicted of any crime, including driving under the influence of alcohol or controlled substances, shall report such conviction to the board within ten (10) days of the conviction becoming final. For purposes of this reporting requirement, a conviction includes pretrial or judicial diversion.
- (18) A pharmacist shall comply with lawful order(s) of the board.

Authority: T.C.A. §§63-10-404(26),(27), and (29), 63-10-504(b)(1), and 63-10-504(b)(1)(C). *Administrative*

History: Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-2-.02 PHARMACY TECHNICIANS.

- (1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:
 - (a) Provide a statement of good moral character;
 - (b) Submit an affidavit from his employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment.)
 - (c) Submit the appropriate application fee as set in Rule 1140-1-.10 of the Rules of the Board of Pharmacy.
- (2) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.
- (3) A pharmacy technician may perform the following functions, but only in the presence of and under the supervision of a pharmacist:
 - (a) Accept a request from a patient to refill a medical or prescription order;
 - (b) Accept or request authorization for a refill of a medical or prescription order from a practitioner or a practitioner's agent;
 - (c) Prepare a label to be placed on the dispensing container;
 - (d) Obtain and enter patient or medical or prescription order data into the patient information system;
 - (e) Retrieve prescription drugs and devices and related materials from stock, count or measure prescription drugs and devices and related materials, and place the prescription drugs and devices and related materials in the dispensing container;
 - (f) Affix a label to a dispensing container;
 - (g) Assist in reconstituting of prescription drugs;
 - (h) Assist in compounding;
 - (i) Transmit pharmacist approved orders to suppliers;
 - (j) Place ancillary information on the dispensing container;
 - (k) Prepackage and label drugs and devices and related materials for future dispensing;
 - (l) Deliver drugs and devices and related materials provided an established procedure is followed to ensure proper and safe delivery;
 - (m) Issue drugs and devices and related materials to authorized persons when such are to be used for administration to an inpatient;
 - (n) Prepare unit dose carts for final review by a pharmacist;
 - (o) Order drugs and devices and related materials from suppliers according to established criteria; and

(Rule 1140-2-.02, continued)

- (p) Retrieve and transport drugs and devices and related materials to and from approved areas.
- (4) In addition to the functions contained in paragraph (2) above, certified pharmacy technicians may receive new, or transferred oral medical and prescription orders.
- (5) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by the pharmacy technician.
- (6) The actual working ratio of pharmacy technicians to pharmacists shall not be more than 2:1 in any pharmacy practice site; provided, however, that the ratio may be increased to a maximum of 3:1 if at least one (1) of the pharmacy technicians is a certified pharmacy technician. For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.
- (7) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g., pharmacy technician, certified pharmacy technician).
- (8) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions. Supervision requires the physical presence of the pharmacist making appropriate in-process and end-process verifications of the pharmacy technician's activities.
- (9) All registered technicians shall conspicuously display the technician's registration certificate at the primary practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.
- (10) All registered technicians shall immediately notify the board in writing of any change of address or employer.

Authority: T.C.A. §§63-10-404(30), 63-10504(b)(1), 63-10-504(b)(1)(C), 63-10-506, and 63-10-508.
Administrative History: Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-3
STANDARDS OF PRACTICE**

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1140-3-.01 RESPONSIBILITIES FOR PHARMACEUTICAL CARE.

- (1) Patient counseling
- (a) Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to-face" if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means.
 - (b) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.
 - (c) Patient counseling, as described herein, shall also be required for outpatients of hospitals or other institutional facilities dispensing medical and prescription orders and for patients when medications are dispensed on discharge from the hospital or other institutional facility.
 - (d) Patient counseling as described in this rule shall not be required for inpatients of an institutional facility.
 - (e) Patient counseling shall cover matters, which in the exercise of the pharmacist's professional judgement, the pharmacist deems significant including:
 - 1. the name and description of the medication;
 - 2. the dosage form, dose, route of administration, and duration of drug therapy;
 - 3. special directions and precautions for preparation, administration, and use by the patient;
 - 4. common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - 5. techniques for self-monitoring drug therapy;
 - 6. proper storage;
 - 7. prescription refill information; and
 - 8. action to be taken in the event of a missed dose.

(Rule 1140-3-.01, continued)

- (f) Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver. Counseling as described in (e) above is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist.
 - (g) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling.
- (2) Patient Profiling.
- (a) A patient's record system shall be maintained by all pharmacy practice sites for patients for whom medical and prescription orders are dispensed. The patient's record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed medical and prescription orders at the time a medical or prescription order is presented.
 - (b) In order to effectively counsel patients, the pharmacist or a person designated by the pharmacist shall, through communication with the patient, caregiver, or agent make a reasonable effort to obtain, record, and maintain the following information for each patient of the individual pharmacy practice site.
 - 1. Name, address, telephone number.
 - 2. Date of birth (age), gender.
 - 3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
 - 4. Pharmacist's comments as deemed relevant. This may be done manually or by computer.
- (3) Drug Regimen Review.
- (a) A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for:
 - 1. over-utilization or under-utilization;
 - 2. therapeutic duplication;
 - 3. drug-disease contraindication;
 - 4. drug-drug interactions;
 - 5. incorrect drug dosage or duration of drug treatment;
 - 6. drug-allergy interactions;
 - 7. clinical abuse/misuse.
 - (b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem.
- (4) Implementation of Pharmaceutical Care.

(Rule 1140-3-.01, continued)

- (a) As a necessary health care provider, pharmacists shall carry out, in addition to the responsibilities in paragraphs (1) through (3) of this rule, those professional acts, professional decisions and professional services necessary to maintain a patient's pharmacy-related care and to implement and accomplish the medical and prescription orders of licensed practitioners, including but not limited to:
1. Developing relationships with licensed practitioners to enable the pharmacist to accomplish comprehensive management of a patient's pharmacy related care and to enhance a patient's wellness, quality of life and optimize outcomes; and
 2. Communicating to the health care provider any knowledge of unexpected or adverse response to drug therapy, or resolving unexpected or adverse response; and
 3. Having a pharmacist accessible at all times to patients and healthcare providers to respond to their questions and needs.

Authority: T.C.A. §§63-10-404(19),(22),(23),(26), and (34), 63-10-504(b)(1) and (2), 63-10-504(j), and 63-10-504(c). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.02 LOCATION OF PRACTICE.

A pharmacist may compound and dispense prescription drugs and devices and related materials only in a pharmacy practice site which is duly licensed by the board and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy. The practice of the knowledge skills of pharmacy is not pharmacy practice site dependent. However, any person practicing any aspect of the art and science of pharmacy must be licensed by the board.

Authority: T.C.A. §§63-10-404(4),(8),(11),(14),(26), and (28), 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.03 MEDICAL AND PRESCRIPTION ORDERS.

- (1) To the extent that a medical order contains an order for the compounding, dispensing or administration of a prescription drug or device or related material, the medical order shall be treated as a prescription order. Written medical and prescription orders must be signed by the prescriber. Verbal medical and prescription orders must be immediately reduced to writing (by hand or other means), dated, and initialed by the authorized individual accepting the medical and prescription orders.
- (2) Each medical and prescription order when dispensed shall be serially numbered, filed numerically and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date the medical and prescription order was last dispensed. Institutional pharmacies shall not be required to serially number medical and prescription orders dispensed for administration to inpatients of that institution.
- (3) A pharmacist upon initial dispensing of a medical or prescription order shall record on that medical or prescription order: the date such medical or prescription order was dispensed, the pharmacist's initials, and the amount of any product dispensed. If the pharmacist merely initials and dates a medical or prescription order the pharmacist shall be deemed to have dispensed the full face amount of the medical or prescription order.
- (4) A pharmacist upon refilling a medical or prescription order shall enter on the back of that medical or prescription order: the date such medical or prescription order was refilled, the pharmacist's initials,



(Rule 1140-3-.03, continued)

and the amount of any product dispensed on such refill. If the pharmacist merely initials and dates the back of the medical or prescription order the pharmacist shall be deemed to have dispensed a refill for the full face amount of the medical or prescription order. As an alternative to recording refill information on the back of medical and prescription orders, an automated data processing system may be used for the storage and retrieval of refill information for medical and prescription orders, subject to the following conditions:

- (a) Any such computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of the original medical or prescription order information and the complete refill history of all medical and prescription orders which are currently authorized for refilling. This shall include all the information contained in and required to be entered on each such medical or prescription order. This data must include at least the medical or prescription order serial number; date of issuance of the medical or prescription order; patient's name (and address on controlled substance medical and prescription orders); prescriber's name (and address and DEA registration number on controlled substance medical and prescription orders); product name, strength, dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and identity (name, initials, or identification code) of the dispensing pharmacist for the original dispensing and each refill.
- (b) Each individual pharmacist using a computerized system in the refilling of a medical or prescription order shall certify that the information entered into the computer for such a refill is correct by verifying, dating, and signing a hard-copy printout of each day's medical or prescription order refill data, or in lieu of such a printout, by signing a statement in a book or file each day attesting that the refill information entered that day has been reviewed by the pharmacist and is correct as shown. Such documentation shall be separately maintained at the pharmacy practice site for at least two (2) years from the date of the last dispensing.
- (c) Any such computerized system shall have the capability of producing a hard-copy printout of any medical or prescription order refill data which the pharmacy practice site is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. (This would, for example, furnish a medical or prescription order-by-medical or prescription order, refill-by-refill audit trail for any specified strength and dosage form of any prescription drug and device, by either brand or generic name or both.) Such a printout must include: the medical or prescription order serial number; patient's name (and address on controlled substance medical and prescription orders); name of prescriber; name, strength, and dosage form of the product; and the date of each refill, quantity dispensed on each refill, and the name or identification code of the dispensing pharmacist. Controlled substance data contained on such a printout must be separated, asterisked, or in some other manner visually identifiable apart from other items appearing on the printout. Any computerized system employed by a pharmacy practice site must, upon the request of an authorized representative of the board, send or provide such a printout to the pharmacy practice site within forty eight (48) hours excluding weekends (Saturdays and Sundays) and legal holidays.
- (d) In the event that a pharmacy practice site which utilizes such a computerized system experiences system down-time, the pharmacy practice site must have a written or readily retrievable auxiliary policy and procedure which will be used for documentation of refills of all medical and prescription orders. This auxiliary procedure must ensure that each refill is authorized, and that all appropriate data is retained for on-line data entry as soon as the computer system is available for use again.
- (e) Each pharmacy practice site and pharmacist using such a computerized system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall apply, unless this initial dispensing data is included on the printout required by subparagraph four (4)(b) of this rule, and is identified as pertaining to the initial dispensing.

(Rule 1140-3-.03, continued)

- (5) A pharmacist may dispense an appropriately authorized refill of a medical or prescription order by referral to a patient profile (medication record) instead of the original medical or prescription order on file at that pharmacy practice site, subject to the following conditions:
- (a) The patient profile must contain all the information contained in and required to be entered on the original medical or prescription order, including the complete refill history of that medical or prescription order. This data includes the medical or prescription order serial number; date of issuance of the medical or prescription order; name of patient; name of the prescriber; product name; strength; dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and initials of the dispensing pharmacist for the original dispensing and each refill. Dispensing data must be identified as to whether it pertains to the original dispensing or to a refill.
 - (b) Controlled substance data contained on the patient profile must be asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the profile.
 - (c) The patient profile system must contain a complete and accurate record of the refill history of all medical and prescription orders dispensed at the pharmacy practice site. (This record will constitute compliance with the provisions of paragraph four (4) of this rule.)
 - (d) Each such profile must be maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date of the last dispensing recorded on the profile.
 - (e) A pharmacist dispensing a medical or prescription order by referral to a patient profile in so doing certifies as to the accuracy and validity of the information contained on the patient profile.
 - (f) Each pharmacy practice site and pharmacist using such a patient profile system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall obtain, unless the patient profile system contains a record of this initial dispensing information for all medical and prescription orders dispensed at the pharmacy practice site.
- (6) No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions:
- (a) All medical and prescription orders shall be compounded and dispensed in strict conformity with any directions of the prescriber. Nothing in this rule shall prohibit a pharmacist from substituting a therapeutically equivalent prescription drug or device or related material containing the same active ingredient or ingredients, dosage form and strength;
 - (b) No medical or prescription order shall be refilled if it contains a statement over the signature of the prescriber that it is not to be refilled, and a medical or prescription order shall not be refilled unless so authorized by the prescriber;
 - (c) If any medical or prescription order contains a statement that it may be refilled a specified number of times within or during any particular period, such order shall be refilled in strict conformity with such statement; and
 - (d) If a prescription contains a statement that during any particular time it may be refilled at will, the order shall be refilled in strict conformity to dosage directions, with the exception that it may not be refilled after the expiration of the time specified or one (1) year from the date the order was originally issued or dispensed, whichever comes first.

(Rule 1140-3-.03, continued)

- (e) At a rate, based on the actual number of medical and prescription orders compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare.
- (7) Copies of Medical and Prescription Orders.
- (a) Copies of medical and prescription orders issued directly to the patient by the pharmacy practice site where the order was originally compounded and dispensed pursuant to the receipt of the order shall bear on the face thereof, in letters red in color and equal in size to those describing the prescription drug or device or related material, the statement: "Copy for Information Only." Presentation of an informational written copy or label of a dispensing container shall be for information purposes only and have no legal status as a valid medical or prescription order. The recipient pharmacist of such copy or label shall contact the prescriber or transferor pharmacy practice site and obtain all information required by this rule, which is the same as obtaining an original medical or prescription order;
 - (b) Medical and prescription orders shall be transferred between pharmacy practice sites for the purpose of compounding and dispensing provided that the transferee, upon receiving such order directly from the transferor, records the following:
 - 1. The name, address and original medical or prescription order serial number at the pharmacy practice site from which the order was transferred;
 - 2. The name of the transferor; and
 - 3. All information constituting a medical or prescription order including the following:
 - (i) Date of original dispensing;
 - (ii) Original number of refills authorized on the original order;
 - (iii) Date of last dispensing; and
 - (iv) Number of valid refills remaining.
 - (c) The transferee informs the patient that the original medical or prescription order has been canceled at the pharmacy practice site from which it was obtained.
 - (d) Computerized systems must satisfy all information requirements.
 - (e) The transfer of schedule III, IV, V, controlled substances are subject to the conditions set forth in C.F.R. 1306.26.
- (8) It is unlawful for any pharmacy practice site, pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, or any other place of business engaged in compounding and dispensing prescription drugs and devices and related materials for human consumption to receive from any patient or other person the return of any portion of an order that has been taken from the premises of the pharmacy practice site or other place of business, except pursuant to 1140-4-.10.
- (9) Medical and prescription orders cannot be accepted, solicited, collected or advertised at a location other than a pharmacy practice site for which a license has been issued by the board, and such pharmacy practice site shall be actively engaged in compounding and dispensing medical and prescription orders.
- (10) Medical and prescription orders typed or printed must be signed by the prescriber. Oral medical and prescription orders shall be initialed by the authorized individual accepting the order.

(Rule 1140-3-.03, continued)

Authority: T.C.A. §§63-10-404(4),(11),(14),(19),(26),(29),(30), and (34), 63-10-504(b)(1), 63-10-504(j), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.04 FACSIMILE AND ELECTRONIC MEDICAL AND PRESCRIPTION ORDERS.

(1) Facsimile Orders

- (a) The transmission of a facsimile medical or prescription order shall be to a pharmacy practice site of the patient's choice and shall occur only at the option of the patient.
- (b) Medical and prescription orders may be transmitted to a pharmacy practice site by a facsimile device. Medical and prescription orders for controlled substances may be transmitted by facsimile devices in compliance with 21 C.F.R. 21306.11, 1306.21 and 1306.31.
- (c) A pharmacist may dispense medical and prescription orders transmitted by facsimile devices only when transmitted by an authorized prescriber or the prescriber's designated agent.
- (d) A facsimile medical or prescription order which meets the requirements of this rule shall be deemed the original medical or prescription order for purposes of filing. The facsimile medical or prescription order must either be photocopied or the original medical or prescription order should be of such quality to not fade within the legal requirements of medical or prescription order record keeping.
- (e) Wholesalers, manufacturers, pharmacists and pharmacy practice sites are prohibited from supplying facsimile devices or supplies to any authorized prescriber under any conditions.
- (f) An original medical or prescription order that indicates that it has been faxed to a pharmacy practice site, consistent with the provisions of this rule, may only be dispensed as an original medical or prescription order by the pharmacy practice site to which it was faxed, consistent with the notation on the medical or prescription order to be made in accordance with the requirements contained in this rule.

(2) Electronic Orders.

- (a) Prescription or medical orders transmitted electronically shall meet the following criteria:
 1. All prescription or medical orders shall be transmitted directly from an authorized prescriber or prescriber's agent to a licensed pharmacist or to an area in a licensed pharmacy of the patient's choice that is under the direct supervision of a licensed pharmacist, with no intervening person or entity having access to the order for purposes other than transmission of the order. Subject to the provisions of this rule, a prescriber or prescriber's agent may electronically transmit medical or prescription orders to a pharmacist within an institutional facility for inpatients and/or outpatients currently under treatment at that facility. Nothing in this subsection shall apply to distributors of medical gases.
 2. The transmission shall include:
 - (i) The telephone number of the authorized prescriber to allow verbal confirmation of the validity and accuracy of the order;
 - (ii) The correct time and date of the transmission;

(Rule 1140-3-.04, continued)

- (iii) The name of the pharmacy to which the order is being transmitted; and
 - (iv) The prescribing practitioner's electronic signature or other secure method of validation. "Electronic Signature" is defined as the process that secures the user authentication (proof of claimed identify, such as by biometrics, fingerprints, retinal scans, hand written signature verification, etc.) at the time the signature is generated and creates the logical manifestation of a signature.
 - (v) If the transmission is delegated by the prescriber to an agent of the prescriber, the identity of the agent shall be included in the transmission.
- (b) A hard copy or exact image of the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-3-.03 of the rules of the board.
 - (c) The Pharmacist receiving any transmitted order shall not knowingly participate in any system that restricts the patient's choice of pharmacy.
 - (d) The pharmacist may not provide financial or other remuneration to the prescriber for any prescription transmitted to the dispensing pharmacy. No person or entity, including but not limited to wholesalers, distributors, manufacturers, pharmacists, and pharmacies, shall supply electronic equipment, software, devices, or modems to any prescriber in exchange for transmitting orders.
 - (e) The pharmacist shall not use the electronic transmission of orders to circumvent or violate any provision of state or federal drug laws, or the Tennessee Pharmacy Practice Act, or the regulations of the board.
 - (f) This rule shall not apply to medical or prescription orders electronically transmitted between pharmacies or medical or prescription orders transmitted by facsimile.

Authority: T.C.A. §§63-10-404(19),(26),(29),(30), and (34), 63-10-504, 63-10-504(b)(1) and (2), and 63-10-504(j).
Administrative History: Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.

1140-3-.05 AREAS OF RECEIPT AND DISPENSING.

All medical and prescription orders shall be received or accepted and compounded and dispensed from a pharmacy practice site which is in a building permanently located and non-mobile in nature. In case of emergency, the board may waive this rule upon request.

Authority: T.C.A. §§63-10-404(4),(11),(19),(28), and (34), and 63-10-504(b)(1) and (2)(j). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.06 LABELING REQUIREMENTS.

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; "poison", "shake", "caution", or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy for administration to inpatients of that institution.

(Rule 1140-3-.06, continued)

Authority: T.C.A. §§63-10-404(11),(15), and (19), and 63-10-504(b)(1) and (2)(j). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.07 TEMPORARY ABSENCE OF PHARMACIST.

A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words "pharmacist not on duty" must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling.

Authority: T.C.A. §§63-10-404(4),(11),(19),(26),(28), and (34), and 63-10-504(b)(1) and (2)(j). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.08 REPACKAGING.

- (1) Any repackaging of prescription drugs and devices and related materials must be supervised and controlled by a pharmacist with in-process and end-process verification and documentation.
- (2) Prescription drugs and devices and related materials which are repackaged by an institutional pharmacy practice site for subsequent dispensing and use within the institution shall be labeled to include:
 - (a) the name, strength, and quantity of prescription drug or device or related material, if larger than one (1), in the container;
 - (b) the manufacturer's name, and lot or control number;
 - (c) the expiration date of the prescription drug or device or related material being repackaged; and
 - (d) cautionary notations (e.g., refrigerate, shake well, not for injection), if applicable.
- (3) A batch number assigned by the pharmacy practice site may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy practice site maintains a readily retrievable record which identifies, by batch number, the manufacturer and lot number of the prescription drug or device or related material.
- (4) The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such repackaging. All repackaging must be performed by a pharmacist or by a pharmacy intern or pharmacy technician under the supervision of a pharmacist.

Authority: T.C.A. §§63-10-404(8),(14),(26), and (28), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.09 LOSS OF PRESCRIPTION DRUGS, DEVICES AND RELATED MATERIALS.

The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.

Authority: T.C.A. §§63-10-404(6),(8),(14), and (27), 63-10-504(b)(1) and (2). *Administrative History:* Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.10 CONDITIONS FOR DELIVERY OR SALE.

- (1) No package containing any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes shall be placed in stock, offered for sale or dispensed or otherwise sold. Any repossession proceedings must be performed with the approval of the board.
- (2) Under no circumstances shall any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes be delivered or handed over to any insurance company, adjustor, salvage company, or other person unless approved by the board prior to delivery.

Authority: T.C.A. §§63-10-404(8),(11), and (14), and 63-10-504(b)(1) and (2). *Administrative History:* Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.11 OUTDATED AND DETERIORATED DRUGS.

The owner or pharmacist in charge of a pharmacy practice site shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be performed by a board approved agent or vendor.

Authority: T.C.A. §§63-10-404(6),(8),(14),(27), and (28), and 63-10-504(b)(1) and (2). *Administrative History:* Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 25, 1985; effective February 12, 1986. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.12 STORAGE, SALE AND DELIVERY.

- (1) All prescription drugs and controlled substances and devices and related materials shall be stored in an area not accessible to the public.
- (2) A controlled substance which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act may be dispensed by a pharmacist without a prescription to a patient provided the pharmacist complies with the provisions of 21 CFR §1306.32 and any other applicable law.
- (3) Instruments and/or devices intended for the injection of any substance through the skin shall be stored in an area not accessible to the public, and shall be sold only on proof of medical need by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.
- (4) All insulin preparations must be stored in an area not accessible to the public, and shall be sold only by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.
- (5) Nothing in this section prohibits delivery of a prescription to a patient's home or business by an agent of the pharmacy practice site.

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(Rule 1140-3-.12, continued)

Authority: T.C.A. §§63-10-404(6),(8),(14),(26), and (28), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.13 AUTOMATED DISPENSING DEVICES FOR AMBULATORY PHARMACY PRACTICE.

The following procedures shall be observed in the use and operation of automated dispensing devices used for storing and dispensing capsules or tablets:

- (1) The lot number of each drug contained therein must be listed or posted on the device.
- (2) After each lot number is used, the portion of the device where the drug was contained must be thoroughly cleaned to remove all residue before refilling.
- (3) Lot numbers may not be mixed.
- (4) The device may be loaded by a pharmacist; or a pharmacy intern or a pharmacy technician under the supervision of a pharmacist.

Authority: T.C.A. § 63-10-404(8),(14),(26),(29), and (30), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-3-.14 PHARMACIST IN CHARGE.

- (1) The board shall maintain a current record of all pharmacists who have been designated "pharmacist in charge" of a pharmacy practice site in the state of Tennessee.
- (2) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy practice site license issued pursuant to T.C.A. § 63-10-506 to notify the board immediately of:
 - (a) the resignation, removal, or death of the pharmacist in charge named in the application for license (or successor pharmacist in charge); or
 - (b) the disability for a period exceeding thirty (30) days of the pharmacist in charge named in the application for license (or successor pharmacist in charge).
- (3) The notice required by paragraph two (2) of this rule shall contain:
 - (a) the name and (except in the case of death or disability) signature of the outgoing pharmacist in charge;
 - (b) the effective date of the appointment (whether temporary or permanent) of the new pharmacist in charge;
 - (c) the name and signature of the new pharmacist in charge; and
 - (d) the name and address of the pharmacy practice site.
- (4) Except in case of death or incapacity, the outgoing pharmacist in charge shall, prior to departure, conduct with the successor pharmacist in charge a joint inventory of all controlled substances. In case of failure of the outgoing pharmacist in charge to comply with this requirement, the successor pharmacist in charge shall conduct such inventory alone.

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(Rule 1140-3-.14, continued)

- (5) In the event of death of a pharmacist in charge, the successor pharmacist in charge shall, immediately upon assuming the appointment as pharmacist in charge, conduct an inventory of all controlled substances.
- (6) In the event of disability for a period exceeding thirty (30) days of a pharmacist in charge, the successor pharmacist in charge (temporary or permanent) shall conduct an inventory of all controlled substances. Should the disabled pharmacist in charge return, the disabled pharmacist in charge and successor pharmacist in charge shall immediately conduct a joint inventory of all controlled substances.
- (7) A record of any inventory required by this rule shall be signed by the pharmacist(s) in charge conducting it and maintained at the pharmacy practice site with other controlled substance records for at least two (2) years. The inventory record shall indicate:
 - (a) the name and address of the pharmacy practice site;
 - (b) the name, strength, dosage form, and quantity of each controlled substance on hand;
 - (c) the date of inventory; and
 - (d) whether the inventory was taken as of the opening or close of business on that date.
- (8) The pharmacist in charge shall immediately notify the board in writing in the event of termination of business by the pharmacy practice site at which the pharmacist in charge practices. Such notice shall include a complete statement concerning the disposition by the pharmacy practice site of controlled substances and all prescription drugs and devices and related materials, invoices, records, and files.
- (9) In a transaction involving the purchase of a pharmacy practice site or its stock of prescription drugs and devices and related materials, both the pharmacist in charge, except in case of death or incapacity, of the pharmacy practice site selling and the pharmacist in charge of the pharmacy practice site buying the stock, or the new owner of the pharmacy practice site if no pharmacist in charge has been appointed, shall jointly inventory all controlled substances and both shall sign and date that inventory and mail a copy of that inventory to the board within thirty (30) days of the completion of the sale.
- (10) The pharmacist in charge shall maintain a current registry of individuals employed at the pharmacy practice site performing the functions of a pharmacy technician.
- (11) This rule does not relieve other pharmacists or persons from their responsibility to comply with state laws and regulations.
- (12) No pharmacist shall be designated pharmacist in charge of more than one (1) pharmacy practice site except where the board determines that such is in the best interest of the public health.
- (13) The designated pharmacist in charge at a particular pharmacy practice site shall be on duty a minimum of fifty percent (50%) of the hours that the pharmacy is in operation. Except, in any event, the pharmacist in charge shall not be required to be on duty more than an average of forty (40) hours per week.
- (14) The designated pharmacist in charge shall report to the board any situation in which a medical or prescription order has caused serious personal injury or death.

Authority: T.C.A. §§63-10-404(2),(25),(26),(27), and (28), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.

1140-3-.15 REFERENCE BOOKS.

Each pharmacy practice site shall maintain in its library at least one (1) reference book (printed or electronic) from either of the last two (2) editions that address each category listed below:

- (1) drug monographs;
- (2) patient counseling;
- (3) pharmacology and therapeutics;
- (4) pharmaceutical technology;
- (5) product availability and identification;
- (6) drug interactions (e.g., drug-drug, drug-food, drug-lab tests);
- (7) health related periodicals
- (8) toxicology, poisoning and antidote information;
- (9) stability and compatibility information;
- (10) laboratory tests and/or microbiology; and
- (11) current Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and updates.

A single reference may fulfill the requirements of more than one (1) category. References should be pertinent for the services provided from that pharmacy practice site.

Authority: T.C.A. §§63-10-404(28), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.