

TABLE OF CONTENTS

CHAPTER 6

ISSUING, FILING AND FILLING OF PRESCRIPTIONS

Section 1. Scope of Chapter 6.....1

Section 2. Definitions.....1

Section 3. Persons Entitled to Issue Prescriptions.....2

Section 4. Purpose of Issue of Prescription.....2

Section 5. Manner of Issuance of Written, Typed or Computer Generated Prescriptions...2

Section 6. Persons Entitled to Fill Prescriptions.....4

Section 7. Identification of a Patient.....5

Section 8. Dispensing of Narcotic Drugs for Maintenance Purposes.....5

Section 9. Electronic Prescription Transmission.....5

Section 10. Requirement of Prescription for Schedule II Substances.....6

Section 11. Refilling Prescriptions-Schedule II; Issuance of Multiple Prescriptions.....8

Section 12. Partial Filling of a Prescription-Schedule II.....9

Section 13. Labeling of Substances-Schedule II.....9

Section 14. Filing of Prescription-Schedule II.....9

Section 15. Requirement of Prescription for Schedule III and IV Substances.....10

Section 16. Refilling of Prescription-Schedules III and IV.....10

Section 17. Partial Filling of Prescriptions-Schedules III and IV.....10

Section 18. Labeling of Substances-Schedule III and IV.....11

Section 19. Filing Prescription-Schedules III and IV.....11

Section 20. Requirements of Prescription for Schedule V Substances.....11

CHAPTER 6

ISSUING, FILING AND FILLING OF PRESCRIPTIONS

Section 1. Scope of Chapter 6.

Rules governing the issuance, filling and filing of prescriptions pursuant to The Wyoming Controlled Substances Act WYO.STAT. § 35-7-1001 through 35-7-1062.

Section 2. Definitions.

(a) “Audit Trail” means a record showing who has accessed an information technology application and what operations the user performed during a given period.

(b) “Authentication” means verifying the identity of the user as a prerequisite to allowing access to the information application.

(c) “Digital signature” means an electronic identifier that”

(i) Is intended by the party using it to have the same force and effect as a manual signature;

(ii) Is unique to the authorized signer;

(iii) Is capable of verification;

(iv) Is under the sole control of the authorized signer;

(v) Is linked to the prescription in such a manner that, if the prescription information is changed, the signature is invalidated; and

(vi) Conforms to Wyoming State Statute and Board Rules and Regulations.

(d) “Drug order” means a written or electronic order issued by an authorized practitioner, or a verbal order promptly reduced to writing, for the compounding and dispensing of a drug to be administered to patients within a facility.

(e) “Electronic prescription” means a prescription that is generated on an electronic application and transmitted as an electronic data file.

(f) “Electronic signature” means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person’s approval of the information contained in the message.

(g) “Electronic transmission” means transmission of the digital representation of information from one computer or other similar electronic device to another computer, which is authenticated by a digital signature, or transmission of the electronic representation of information from one computer or other similar electronic device to a fax machine, which is authenticated by an electronic signature.

(h) “Paper prescription” means a prescription created on paper or computer generated to be printed or transmitted via facsimile that includes a manual signature.

(i) “Readily retrievable” means that certain records are kept in such a manner that they can be separated out from all other records and produced for review within forty-eight hours (48 hr.).

(j) “Security” or “secure system” means a system to maintain the confidentiality and integrity of patient records which are being transmitted electronically.

Section 3. Persons Entitled to Issue Prescriptions.

A prescription for a controlled substance may be issued only by a practitioner who is either registered or exempted from registration under the Act.

Section 4. Purpose of Issue of Prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Section 5. Manner of Issuance of Written, Typed or Computer Generated Prescriptions.

(a) Effective January 1, 2007, all controlled substance prescriptions written by a Wyoming practitioner shall be issued on security paper, unless exempted under this Chapter for electronic transmission. Any controlled substance prescription written by a Wyoming practitioner issued on non-security paper may not be dispensed by a pharmacist.

(b) Any written, typed or computer generated prescription issued by a Wyoming practitioner for a Schedule II-V controlled substance except those issued as a

medication order for administration in a long-term care facility or institutional facility shall meet the following requirements:

(i) Shall be printed on security paper, which includes the following features:

(A) If scanned or copied, "void" is displayed prominently throughout the front side of the document;

(B) Erasure protection on green or blue background is utilized on the front side;

(C) Clear instructions printed on the paper indicating the front and back sides;

(D) Security warning list on the front or back of the blank;

(E) Quantity check-off boxes plus numeric forms of quantity values or alpha and numeric forms of quantity value;

(F) Refill indicator (circle or check number of refills or "NR") plus numeric form of refill values or alpha and numeric form of refill values.

(ii) All suppliers of security paper must be approved by the Board. Approval will be based on the suppliers' product meeting the requirements of this chapter. The Board shall make available a listing of all approved suppliers, which is updated at least annually.

(iii) All Board approved suppliers of security paper shall provide the Board written assurance that they will distribute prescription pads or paper only to practitioners duly authorized to prescribe controlled substances in Wyoming.

(iv) All controlled substance prescriptions written by a Wyoming practitioner shall be manually signed in the same manner as the practitioner would sign a check or legal document. The use of electronic or digital signatures or signature stamps are not allowed, unless electronic prescriptions are used according to this chapter.

(v) Prescriptions may be prepared for dating and signature of the practitioner by an authorized agent of the practitioner and the use of preprinted prescriptions is allowed. Under no circumstances may stickers be utilized for information relating to patient name, drug, strength, quantity or directions.

(vi) Prescriptions shall be dated as of, and signed on, the day when issued and shall bear the full name, address, telephone number and DEA registration

number of the issuing practitioner. No post dating of controlled substance prescriptions are allowed.

(vii) Prescriptions shall be written in ink, typed or electronically generated.

(viii) The prescribing practitioner and dispensing pharmacist share the responsibility to assure compliance with this section.

(c) A refill request for a Schedule III-V controlled substance generated and faxed by the pharmacy to a practitioner for refill authorization need not be printed on security paper.

(d) A refill request for a Schedule III-V controlled substance generated electronically and transmitted electronically by the pharmacy to a practitioner need not be printed on security paper.

(e) The information sent by the practitioner to the pharmacy shall indicate who authorized the refill.

(f) A Schedule III-V controlled substance prescription faxed by the practitioner to the pharmacy need not be printed on security paper.

(g) An intern, resident, or foreign physician exempted from registration under Chapter 3, shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in Chapter 3, in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign physician stamped or printed on it, as well as the signature of the physician.

(h) An official exempted from registration under Chapter 3 shall include on all prescriptions issued by him, his branch of service or agency (e.g. "U. S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

Section 6. Persons Entitled to Fill Prescriptions.

A prescription for controlled substance may only be filled by a pharmacist or intern or pharmacy technician or technician-in-training under direct supervision by a pharmacist, acting in the usual course of his/her professional practice or by a registered practitioner.

Section 7. Identification of a Patient.

(a) The pharmacist or employee under supervision must verify the identity of the person presenting a controlled substance prescription to the pharmacy for dispensing. This may be done by visual recognition. If identity is not established by visual recognition, a driver's license or similar photo identification form is considered acceptable documentation. The following information must be recorded on the reverse of the prescription, if identification is utilized: name, type of identification, and identification number.

(b) The name of the person receiving the dispensed drug is to be recorded on the prescription document, patient profile, or signature log, if an agent and not the patient receives the drug.

(c) This Section shall not apply to pharmacies that mail prescriptions to their patients. A note shall be entered on the prescription or patient's profile with the name and address of where the medication was mailed. Additionally, the date of such mailing shall be entered.

Section 8. Dispensing of Narcotic Drugs for Maintenance Purposes.

The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting a federally authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research"

Section 9. Electronic Prescription Transmission.

(a) A pharmacist may dispense directly any legend drug which requires a prescription to dispense only pursuant to the following:

(i) A written prescription signed by a practitioner or their agent; or

(ii) A prescription transmitted by the practitioner or their agent to the pharmacy by electronic means; or

(iii) An oral prescription made by an individual practitioner or their agent and promptly reduced to hard copy by the pharmacist or pharmacy intern containing all information required.

(b) Electronic prescriptions for controlled substances shall include the requirements listed in 21 CFR § 1311 including:

(i) The practitioner may issue a prescription for a Schedule II, III, IV or V controlled substance electronically if an electronic prescription application is used

that has been certified by a third party auditor to ensure that the electronic prescription application records, stores, and transmits the prescription accurately and consistently and that the individual practitioner has obtained a two-factor authentication credential for signing.

(ii) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner and the contents of the prescription must not be altered during transmission between the practitioner and pharmacy.

(iii) The pharmacy receiving the electronic prescription must determine that third-party certification has found that the pharmacy application accurately and consistently imports, stores and displays the information required for the prescription including the number of refills and the practitioner's digital signature.

(c) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice.

(d) The pharmacist is responsible for assuring the validity of the electronically transmitted prescription.

(e) A pharmacist or pharmacy shall not enter into any agreement to provide or receive a computer or computer modem, personal digital assistant, facsimile machine, or any other electronic device which would adversely affect a patient's freedom to select the pharmacy of the patient's choice.

(f) A pharmacist or pharmacy shall not provide a computer or computer modem, personal digital assistant, facsimile machine or any other electronic device to a prescriber or health care facility for the purpose of proving an incentive to refer a patient to a particular pharmacy.

Section 10. Requirement of Prescription for Schedule II Substances.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written or electronic prescription signed by the prescribing individual practitioner, except as provided in this section.

(b) A practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription.

(c) In the case of an emergency situation, as defined in this section, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

(i) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written or electronic prescription signed by the prescribing practitioner);

(ii) The emergency oral prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in this chapter except for the signature of the prescribing practitioner;

(iii) If the prescribing practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call back to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to ensure his identity; and

(iv) Within 7 days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this chapter, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Board if the prescribing individual fails to deliver a written prescription to him, failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing practitioner.

(d) A prescription for a Schedule II controlled substance shall be valid up to six months from the date issued by the practitioner.

(e) A pharmacist shall cancel all written Schedule II controlled substance prescriptions when dispensed by dating and signing the face of the prescription. All electronic Schedule II controlled substance prescriptions shall be cancelled once dispensed.

(f) Information that can be changed on a Schedule II prescription shall meet the following requirements:

(i) After consultation/approval of the prescribing practitioner, the pharmacist is permitted to change the following:

(A) Drug strength

(B) Drug quantity

(C) Directions for use

(D) Dosage form

(ii) The pharmacist is permitted to add or change the patient's address with proper verification without consulting the prescribing practitioner.

(iii) The prescribing practitioner's DEA registration number may be added to a prescription drug order after consulting the prescribing practitioner or verifying the number from another reliable source.

(iv) Required information may appear on the front or back of the prescription drug order and computer generated data on the prescription drug order satisfies these requirements.

(v) Any change made by the pharmacist shall be documented and shall include the date, name of person consulted, and initials of the pharmacist.

(vi) A pharmacist is not permitted to change the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), date issued, or the prescriber's signature.

(g) For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Controlled Substance Act, the term "emergency situation" means those situations in which the prescribing practitioner determines:

(i) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;

(ii) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and

(iii) That it is not reasonably possible for the prescribing practitioner to provide a written or electronic prescription to be presented to the person dispensing the substance, prior to dispensing.

(h) A Schedule II controlled substance prescription may be faxed if it meets the criteria as specified in Chapter 2, General Practice of Pharmacy Regulations.

Section 11. Refilling Prescriptions-Schedule II; Issuance of Multiple Prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(ii) Each individual prescription is dated with the date it was prescribed and contains all other information required by this Chapter.

(iii) The practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iv) The practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

Section 12. Partial Filling of a Prescription-Schedule II.

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written, electronic or emergency oral prescription and he makes a notation of the quantity supplied on the prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Section 13. Labeling of Substances-Schedule II.

The pharmacist filling a written, electronic, or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of the filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Section 14. Filing of Prescription-Schedule II.

All written or electronic prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of Chapter 4 of these regulations.

Section 15. Requirement of Prescription for Schedule III and IV Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule III or IV, which is a prescription drug as determined under Federal Food, Drug and Cosmetic Act, only pursuant to either a written or electronic prescription signed by a prescribing practitioner or an oral prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist containing all information required in this chapter, except for the signature of the prescribing practitioner, or an electronically transmitted prescription provided it meets all requirements in Chapter 2 of the Board's Rules and federal law, or a faxed prescription provided it meets all requirements in Chapter 2 of the Board's Rules.

(b) A practitioner may administer or dispense a controlled substance listed in Schedules III or IV in the course of his professional practice without a prescription.

(c) A practitioner may administer or dispense directly (but not prescribe) controlled substances listed in Schedules III or IV pursuant to a written prescription signed by a prescribing practitioner, or pursuant to an oral prescription made by a prescribing practitioner and promptly reduced to writing by the pharmacist (containing all information required in Chapter 6, except for the signature of the prescribing practitioner, or pursuant to an order for medication made by a practitioner which is dispensed for immediate administration to the ultimate user.)

Section 16. Refilling of Prescription-Schedules III and IV.

No prescription for a controlled substance listed in Schedules III or IV shall be filled or refilled more than six (6) months after the date on which such prescription was issued. No such prescription authorized to be refilled may be refilled more than five (5) times. Each refilling of a prescription shall be documented on a readily retrievable record, such as medication record, which indicates the date, quantity, and name of the dispensing pharmacist for each prescription initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription.

Section 17. Partial Filling of Prescriptions-Schedules III and IV.

The partial filling of a prescription for a controlled substance listed in Schedules III or IV is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling;

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(c) No dispensing occurs after six (6) months after the date on which the prescription was issued.

Section 18. Labeling of Substances-Schedule III and IV.

The pharmacist filling a prescription for a controlled substance listed in Schedules III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of the initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use, and cautionary statements, if any, contained in such prescription as required by law.

Section 19. Filing Prescription-Schedules III and IV.

All prescriptions for controlled substances listed in Schedules III and IV shall be kept in accordance with Chapter 4 of these regulations.

Section 20. Requirements of Prescription for Schedule V Substances.

(a) A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedules III and IV in this chapter. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing practitioner on the prescription; if no authorization is given, the prescription may not be filled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with this chapter and file the prescription in accordance with this chapter.

(b) A practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription subject to this chapter.