

Title 20. Public Health and Welfare
Chapter I. Generally, Department of Health
Subchapter H. Drugs
Part 203. Rules Pertaining to Controlled Substances

Codification Notes. This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"Effective Date: June 30, 2025"

"Section I Authority

The following Rules have been hereby promulgated pursuant, to Arkansas Code Annotated §5-64-702, §20-7-109, §20-64-219, and §20-64-317."

"Section III General Requirements

(Attached copy of Proposed Rules of the Arkansas Department of Health Pertaining to Controlled Substances.)"

"Section IV Repeal

All Rules and parts thereof in conflict herewith are hereby repealed.

If any provision of these Rules, or the application thereof, to any person or circumstances is held

invalid, such invalidity shall not affect other provisions or applications of these Rules which can

give effect without the invalid provisions or applications, and to this end the provisions hereto

are declared to be severable."

"CERTIFICATION

This will certify the Amendments to the Rules Pertaining to Controlled Substances were adopted by the Arkansas State Board of Health at a regular session of the Board held in Little Rock, Arkansas, at the Department of Health Building, on the 24th day of October, 2024.

Jennifer Dillaha, M.D.
Secretary of the State Board of Health"

Subpart 1. Generally

20 CAR § 203-101. Purpose.

- (a) Drug abuse in Arkansas is a widespread problem.
- (b) This part has been prepared for the purpose of establishing a criterion for minimum standards of compliance in the prescribing, ordering, administration, dispensing, sale, and other means of legitimate handling of controlled substances.
- (c) By necessity they are of a regulatory nature, but are considered to be practical minimum design and operational standards.
- (d) This part conforms, insofar as practicable, with those regulations promulgated at the federal level.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-102. Registration.

- (a) Every practitioner defined as follows shall obtain a registration from the Drug Enforcement Administration, Department of Justice, unless exempted by law:
 - (1) A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense,

distribute, administer, or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas;

(2) A pharmacy, hospital or related institution, manufacturer, wholesaler, distributor, or other institution or facility licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Arkansas; or

(3) Persons authorized and registered by the Secretary of the Department of Health or designee to engage in research on the use and effects of controlled substances, including persons conducting instructional activities, conducting chemical analysis, or conducting animal training and animal euthanasia with controlled substances in the course of practice approved and registered by the secretary.

(b) A separate registration is required for each principal place of business or professional practice at one (1) general physical location where controlled substances are:

- (1) Maintained;
- (2) Manufactured;
- (3) Distributed;
- (4) Imported;
- (5) Exported; or
- (6) Dispensed.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-103. Exempt preparations.

(a) **Schedule V exempt narcotics.** A controlled substance listed in Schedule V that is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., may be dispensed by a pharmacist without a prescription to a purchaser at retail provided that:

(1) Such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist, although after the pharmacist

has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash or credit transaction or delivery may be completed by a nonpharmacist;

(2) Not more than two hundred forty cubic centimeters (240 cc) or eight ounces (8 oz.) of any such controlled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) or four ounces (4 oz.) of any other such controlled substance, nor more than forty-eight (48) dosage units of any such controlled substance containing opium, nor more than twenty-four (24) dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given forty-eight-hour period;

(3) The purchaser is at least eighteen (18) years of age;

(4) The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification, including proof of age where appropriate;

(5)(A) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which shall contain the:

(i) Name and address of the purchaser;

(ii) Name and quantity of the controlled substance purchased;

(iii) Date of each purchase; and

(iv) Name or initials of the pharmacist who dispensed the substance to the purchaser.

(B) The book shall be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04; and

(6) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state, or local law.

(b) Ephedrine, pseudoephedrine, or phenylpropanolamine.

(1) As provided in Arkansas Code § 5-64-1101 et seq., unless dispensed under a valid prescription, all sales or transfers of ephedrine, pseudoephedrine, or phenylpropanolamine are subject to the following quantity limits and restrictions:

(A) In a single transaction, no more than three (3) packages of one (1) or more products that contain:

- (i) Ephedrine, pseudoephedrine, or phenylpropanolamine; or
- (ii) Their salts, isomers, or salts of isomers;

(B) In a single transaction, no more than a single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, isomers, or salts of isomers or a combination of any of these substances, whichever is smaller;

(C) In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:

(i) The product is:

(a) Sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; and

(b) Packaged in a blister pack, each blister containing not more than two (2) dosage units;

(ii) When the use of a blister pack is technically infeasible, the product is packaged in a unit dose packet or pouch; or

(iii) In the case of a liquid, the drug is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(D) No product containing ephedrine, pseudoephedrine, or phenylpropanolamine may be sold or transferred to any person under eighteen (18) years of age unless the person is purchasing an exempt product under Arkansas Code § 5-64-1103(b).

(2) No more than five grams (5g) of any product containing ephedrine or nine grams (9g) of any product containing pseudoephedrine or phenylpropanolamine may be sold or transferred to a single patient in any thirty-day period.

(3) A pharmacist, pharmacy, or pharmacy employee must also comply with federal law prohibiting the sale of more than three and six-tenths grams (3.6g) of

ephedrine, pseudoephedrine, or phenylpropanolamine to a patient in any twenty-four-hour period.

(4) The sale of such products shall:

(A) Be recorded in written or electronic format; and

(B) Document the:

(i) Signature and address of the purchaser, printed name if illegible;

(ii) Name of the product and the quantity of the product purchased;

(iii) Date of the purchase; and

(iv) Signature of the licensed pharmacist or registered technician who issued the controlled substance to the purchaser.

(5) All such records shall be maintained for a period of two (2) years from the last date of entry.

(c)(1) A pharmacist may not dispense and a pharmacy technician or intern may not sell or transfer ephedrine, pseudoephedrine, or phenylpropanolamine unless the patient has provided:

(A) A driver's license or non-driver's identification card issued by the Department of Finance and Administration that contains:

(i) A photograph of the person;

(ii) The person's date of birth; and

(iii) A functioning magnetic stripe or barcode; or

(B) An identification card issued by the Department of Defense to active duty military personnel that contains:

(i) A photograph of the person; and

(ii) The person's date of birth.

(2) In addition to documenting the professional determination required by Arkansas Code § 5-64-1103(c) and (d), a sale of ephedrine, pseudoephedrine, or phenylpropanolamine must also be approved by:

(A) Scanning the license or identification card issued by the Department of Finance and Administration using the magnetic stripe or barcode; or

(B) Entering required information from the identification card issued by the Department of Defense into the real-time electronic logbook.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-104. Security requirements.

(a) All practitioners shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

(b) Controlled substances listed in Schedules I, II, III, IV, V, and VI shall be stored under double-lock security in a substantially constructed, permanently mounted cabinet.

(c) However, pharmacies may disperse controlled substances in Schedules II – V throughout the prescription area stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-105. Procedure in case of loss.

(a)(1) Each practitioner who discovers any suspected loss, theft, or other diversion, or any combination thereof, of any controlled substance shall immediately notify by phone or fax the:

(A) Pharmacy Services and Drug Control Section of the Department of Health; and

(B) Arkansas State Board of Pharmacy.

(2) The nearest Drug Enforcement Administration Diversion Field Office must be notified in writing within one (1) business day of the discovery of any suspected loss, theft, or diversion.

(3) In addition, practitioners shall file theft and loss reports, Drug Enforcement Administration Form 106, with Pharmacy Services and Drug Control Section, the Drug Enforcement Administration, and the board within seven (7) days of the occurrence of said loss or the discovery of said loss.

(b)(1) Long-term care facilities (LTCFs) that discover any suspected loss, theft, or other diversion, or any combination thereof, of any controlled substance shall immediately notify Pharmacy Services and Drug Control Section by phone or fax.

(2) In addition, LTCFs shall file Department of Health theft and loss report form PHA-21 with Pharmacy Services and Drug Control Section.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-106. Classification of controlled substances.

(a) Pursuant to Arkansas Code § 5-64-201 et seq., the Secretary of the Department of Health or designee may add substances to or delete or reschedule all substances enumerated in the schedules pursuant to the procedures of the Arkansas Administrative Procedure Act, Arkansas Code § 25-15-201 et seq., with prior approval by the Legislative Council.

(b) The controlled substances listed in the schedules shall be:

(1) Included by whatever official, common, usual chemical or trade name designated; and

(2) Revised and republished annually, pursuant to Arkansas Code § 5-64-216.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 20-107. Records of controlled substances.

(a)(1) Every practitioner and LTCF shall keep a record of such controlled substances received, administered, dispensed, or professionally used otherwise than by prescription in order to maintain complete accountability.

(2) The record shall in every case show the:

(A) Date of receipt;

(B) Name and address of the person or business from whom received;

and

(C) Kind and quantity of such controlled substances received.

(b)(1) The record shall show the:

(A) Controlled substances:

(i) Sold;

(ii) Administered;

(iii) Dispensed; or

(iv) Otherwise disposed of;

(B) Date of selling, administering, or dispensing;

(C) Name and address of the person to whom or for whose use the controlled substances were sold, administered, or dispensed or the owner and species of animal for which the controlled substances were sold, administered, or dispensed; and

(D) Name, strength, and quantity of controlled substances.

(2) Persons engaged in research on the use of controlled substances may withhold the name and other identifying characteristics of individuals who are the subjects of the research.

(c)(1) Institutional practitioner and LTCF records shall be designed so that all clinical personnel are using the same records in caring for patients, and if diversion does occur, the chance of discovery is increased.

(2) The basic records of receipt and disposition of controlled substances within the institution are the:

(A) Patient medication records; and

(B) Controlled substances procurement and disposition records.

(3) Patient medication records shall consist of at least the:

(A) Practitioners' orders authorizing the dispensing and administration of medications;

(B) Medication administration record indicating the date, time, and signature of licensed person administering controlled substances to the patient; and

(C) Nurses' notes indicating the date, time, and condition of the patient before and after the as-needed controlled substance was administered and signature of the licensed person administering the controlled substance.

(4) In addition to patient medication records, a record of the procurement and disposition of a controlled substance shall be maintained.

(5)(A) The disposition record shall reflect the:

- (i) Actual dosage administered to the patient;
- (ii) Patient's name; and
- (iii) Date, time, and signature of the licensed person administering the controlled substance.

(B) Any error of entry on the disposition and procurement record shall follow a policy for correction of errors and accurate accountability.

(C) If the licensed person who procures the controlled substance is not the licensed person who administers the controlled substance, then both licensed persons shall sign the disposition record.

(6)(A) When breakage or wastage of all or a partial dose of a controlled substance not in its original sealed package or not administered to a patient occurs, the amount administered and the amount wasted shall be:

- (i) Recorded by the licensed person who wasted the controlled substance; and
- (ii) Verified by the signature of another licensed person who observed the wastage and how it was wasted.

(B) Controlled substances shall be wasted in such a manner that such substances are rendered unusable.

(C) Licensed persons in this paragraph are those who are authorized by their current practice act to administer controlled substances, to include those licensed by the:

- (i) Arkansas State Medical Board;
- (ii) Arkansas State Board of Nursing;
- (iii) Arkansas State Board of Dental Examiners;
- (iv) Arkansas Board of Podiatric Medicine; and
- (v) State Board of Optometry.

(D) Licensed pharmacists and paramedics shall also be allowed to witness wastage of controlled substances.

(7)(A) Records to include electronic signatures in a closed system, i.e., hospital, generated by automatic medication distribution devices shall comply with this part unless specifically exempted by Pharmacy Services and Drug Control Section.

(B) Policies and procedures shall be:

(i) Developed to ensure security and accountability of controlled substances; and

(ii) Approved administratively by Pharmacy Services and Drug Control Section prior to usage of such automatic medication distribution devices.

(d) Each practitioner shall maintain inventory records in one (1) consolidated record system of all controlled substances under the licensed practitioner's control and inventory shall be taken every two (2) years as required by the Drug Enforcement Administration.

(e)(1) Records of Schedules I and II substances shall be maintained separately from all other records.

(2) Records of Schedules III, IV, and V substances shall be maintained either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records for inspection and copying by authorized agents of Pharmacy Services and Drug Control Section.

(3) Every record shall be maintained by the registrant for at least two (2) years.

(f)(1) Adequate accountability does not require the use of a specific system or form.

(2) However, the system employed shall be designed so that all recordkeeping requirements are met.

(g) When an automated data processing system is used for the storage and retrieval of prescription orders for controlled substances, the system shall have the capability of generating a printout of all data that the user practitioner is responsible for maintaining under this part.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

Codification Notes. “LTCF” means long-term care facility.

20 CAR § 203-108. Surrender of unwanted controlled substances.

(a) All controlled substances no longer usable because of deterioration or expired dating or that are unwanted:

(1) Shall be delivered in person, by registered mail, or by another means of shipment to allow for tracking from shipping point to destination with return receipt to Pharmacy Services and Drug Control Section, Department of Health, 4815 West Markham, Slot 25, Little Rock, Arkansas 72205-3867, accompanied by all completed copies of Report of Drugs Surrendered, Form PhA:DC-1, furnished by the Department of Health; or

(2) May be destroyed onsite only by authorized agents of the department.

(b) Each controlled substance item submitted for destruction by LTCFs or related facilities shall be submitted at least quarterly and each time there is a change in the licensed person responsible for discontinued or unwanted controlled substances and identified in such a manner to determine the exact location in the facility where it was last recorded in an accountability record to determine what person or persons had access to or administered such controlled substances during the time they were in inventory in the facility.

(c)(1) In LTCFs, all unwanted or discontinued controlled substances shall be entered on the Report of Drugs Surrendered, Form PhA:DC-1, at the time of transfer to the secured storage area.

(2) Form PhA:DC-1 requires the signature of two (2) licensed persons verifying this transfer.

(3) Form PhA:DC-1 shall be securely and separately stored apart from all unwanted or discontinued controlled substances.

(4) Accountability of discontinued controlled substances rests with the licensed person receiving the discontinued controlled substances until they are submitted to Pharmacy Services and Drug Control Section for destruction.

(d)(1) Non-Drug Enforcement Administration-registered licensed healthcare facilities shall develop policies and procedures to ensure that complete accountability is maintained on all controlled substances.

(2) Policies and procedures shall include specific licensed personnel responsible for unwanted or out-of-date controlled substances removed from use in the facility.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

Codification Notes. "LTCF" means long-term care facility.

20 CAR § 203-109. Controlled drug prescription or orders.

(a) Issue of prescriptions or orders.

(1)(A) "Prescription" means an order for medication that is dispensed to or for an ultimate user but does not include an order for medication that is dispensed for immediate administration to the ultimate user.

(B) For example, an order to dispense a medication to a resident or patient for immediate administration in a licensed facility is not a prescription.

(C) However, the recordkeeping requirements of 20 CAR § 203-107 do apply to such orders.

(2) A prescription or an order for controlled substances may be issued only by an individual practitioner who:

(A) Is legally authorized to prescribe or order controlled substances in the State of Arkansas; and

(B) Holds a current Drug Enforcement Administration registration.

(3)(A) In settings where non-Drug Enforcement Administration-registered nurse practitioners, advanced practice nurses, and physician's assistants are employed,

a Drug Enforcement Administration-registered licensed practitioner must determine the need for a controlled substance to be issued to a patient.

(B) Only the Drug Enforcement Administration-registered licensed practitioner may then communicate the order to the pharmacist, either by written, oral, fax, or electronic prescription, if issued in compliance with federal law and regulations.

(C) No standing orders or protocol for controlled substances shall be valid.

(b) Purpose of issue.

(1)(A) A prescription, in order to be effective, must be issued for legitimate medical purposes.

(B) The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(2) An order purporting to be a prescription issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with controlled substances sufficient to keep him or her comfortable by maintaining his or her customary use, is not a prescription within the meaning and interest of Arkansas Code § 20-64-206, and the person knowingly dispensing such an order, as well as the person knowingly issuing it, shall be subject to penalties by Arkansas Code § 20-64-220.

(3)(A) All prescriptions for controlled substances shall:

(i) Be dated as of, and signed on, the day when issued; and

(ii) Bear the:

(a) Full name and address of the patient;

(b) Drug name;

(c) Strength;

(d) Dosage form;

(e) Quantity prescribed;

(f) Directions for use; and

(g) Name, address, and registration number of the individual prescribing practitioner.

(B) A practitioner shall sign a prescription in the same manner as he or she would sign a check or legal document.

(C) When an oral order is not permitted, prescriptions shall be:

- (i) Written with ink, indelible pencil, or typewriter; and
- (ii) Manually signed by the practitioner.

(D) The prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential aspects to the law and rules.

(E) A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed in this part.

(4)(A) An intern, resident, foreign-trained physician, or physician on the staff of a Veterans' Administration facility exempted from registration under 21 C.F.R. § 1301.24(c) shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in lieu of the registration number of the practitioner as required by this section.

(B) Each written prescription shall have the name of the practitioner stamped, typed, or printed on it as well as the signature in ink of the practitioner.

(C) In lieu of the registration number of the practitioner required by this section, all prescriptions issued shall include the branch of service or agency and service identification number.

(c) Refilling of prescriptions.

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

(2)(A) No prescription for a controlled substance listed in Schedules III, IV, or V shall be:

- (i) Dispensed or refilled more than six (6) months after the date on which the prescription was issued; and
- (ii) Authorized to be refilled more than five (5) times.

(B) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document.

(C) If entered on another document, such as a medication record, the document shall be uniformly maintained and readily retrievable.

(D) The following information shall be retrievable by the prescription number, consisting of the:

- (i) Name and dosage form of the controlled substance;
- (ii) Date dispensed or refilled;
- (iii) Quantity dispensed;
- (iv) Initials of the dispensing pharmacist for each refill; and
- (v) Total number of refills for that prescription.

(E) If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed.

(F) The prescribing practitioner may authorize additional refills of Schedules III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(i) The total quantity authorized, including the amount of the original prescription, does not exceed five (5) refills nor extend beyond six (6) months from the date of issue of the original prescription;

(ii) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the:

- (a)* Date;
- (b)* Quantity of refill;
- (c)* Number of additional refills authorized; and
- (d)* Initials the prescription showing who received the

authorization from the prescribing practitioner who issued the original prescription;

(iii) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription; and

(iv) The prescribing practitioner shall execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(3) As an alternative to the procedures provided by subdivision (c)(2) of this section, an electronic data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V subject to the following conditions:

(A)(i) Any such proposed electronic data processing system shall provide online retrieval (electronic record of hard-copy printout) of original prescription order information.

(ii) This shall include, but is not limited to, data such as the:

(a) Original prescription number;

(b) Date of issuance of the original prescription order by the practitioner;

(c) Full name and address of the patient;

(d) Name, address, and Drug Enforcement Administration registration number of the practitioner;

(e) Name, strength, dosage form, and quantity of the controlled substance prescribed, and quantity dispensed if different from the quantity prescribed; and

(f) Total number of refills authorized by the prescribing practitioner;

(B)(i) Any such electronic data processing system must also provide online retrieval (electronic record of hard-copy printout) of the current refill history for Schedules III, IV, or V controlled substance prescription orders, those authorized for refill during the past six (6) months.

(ii) This refill history shall include but is not limited to the:

(a) Name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or the name or initials of the dispensing pharmacist for each refill; and

(b) Total number of refills dispensed to date for the prescription order;

(C)(i) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedules III, IV, or V controlled substance is correct shall be provided by the individual pharmacist who makes use of the system.

(ii) If such a system provides a hard-copy printout of controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order.

(iii) The individual pharmacist shall verify that the data indicated is correct and then sign this document in the same manner in which he or she would sign a check or legal document, for example, J. H. Smith or John H. Smith.

(iv) This document shall be maintained in a separate file at the pharmacy for a period of two (2) years from the dispensing date.

(v) This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such an electronic data processing system within seventy-two (72) hours of the date on which the refill was dispensed.

(vi) It shall be verified and signed by each pharmacist who is involved with such dispensing.

(vii) All required information shall be:

(a) Entered on the records of all prescription orders dispensed at the pharmacy including nonrefillable prescriptions; and

(b) Maintained for a period of no less than two (2) years.

(viii) In lieu of such a printout, the pharmacy shall maintain a bound log book or separate file in which each individual pharmacist involved in such dispensing shall sign a statement, in the manner previously described, each day attesting to the fact that the refill information entered into the computer that day:

(a) Has been reviewed by him or her; and

(b) Is correct as shown.

(ix) Such a book or file shall be maintained at the pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized refill;

(D)(i) Any such electronic data processing system shall have the capability of generating a printout of any refill data that the user pharmacy is responsible for maintaining under this part.

(ii) For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance by brand, generic name, or both.

(iii) Such a printout shall include the:

(a) Name of the prescribing practitioner;

(b) Name and address of the patient;

(c) Quantity dispensed on each refill;

(d) Date of dispensing for each refill;

(e) Name or identification code of the dispensing pharmacist;

and

(f) Number of the original prescription order.

(iv) In any electronic data processing system employed by a user pharmacy the central recordkeeping location shall be capable of sending the printout to the pharmacy within forty-eight (48) hours, and if the agent or investigator requests a copy of such printout from the user pharmacy, it shall, if requested to do so by the agent or investigator, verify the printout transmittal capability of its system by documentation, for example, postmark;

(E)(i) In the event a pharmacy that employs such an electronic data processing system experiences downtime, the pharmacy shall have an approved auxiliary procedure that will be used for documentation of refills of Schedules III, IV, and V controlled substance prescription orders.

(ii) This auxiliary procedure shall ensure that:

(a) Refills are authorized by the original prescription order;

(b) The maximum number of refills has not been exceeded; and

(c) All the appropriate data is retained for online data entry as soon as the computer system is available for use again; and

(F) When filing refill information for original prescription orders for Schedules III, IV, or V controlled substances, a pharmacy may use only one (1) of the two (2) systems described in this section.

(d) Partial dispensing of prescriptions.

(1) The partial dispensing of a prescription for a controlled substance listed in Schedules III, IV, or V is permissible provided that:

(A) Each partial dispensing is recorded in the same manner as the refilling;

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

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

(2)(A) The partial dispensing of a prescription for controlled substances listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of a written prescription, or written record of the emergency oral prescription, on the first partial dispensing.

(B) However, if the remaining portion is not or cannot be dispensed within a seventy-two-hour period, the pharmacist shall so notify the prescribing individual practitioner.

(C) No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(3)(A) A prescription for a Schedule II controlled substance written for a patient in an LTCF or for a patient with a medical diagnosis documenting a terminal illness may be dispensed in partial quantities to include individual dosage units.

(B) If there is any question as to whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially dispensing the prescription.

(C) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

(D) The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient".

(E) Prior to any subsequent partial dispensing, the pharmacist shall determine the necessity of additional medication.

(F) For each partial dispensing, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate record, uniformly maintained and readily retrievable, the:

- (i) Date of the partial dispensing;
- (ii) Quantity dispensed;
- (iii) Remaining quantity authorized to be dispensed; and
- (iv) Identification of the dispensing pharmacist.

(G) The total quantity of Schedule II controlled substances dispensed in all partial dispensings shall not exceed the total quantity prescribed.

(H) Schedule II prescriptions for patients in an LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by discontinuance of medication.

(4) Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(A) Output, display or print, of the:

- (i) Original prescription number;
- (ii) Date of issue;
- (iii) Identification of prescribing individual practitioner;
- (iv) Identification of patient;
- (v) Address of the LTCF or address of the hospital or residence of the

patient;

(vi) Identification of medication authorized, to include dosage, form, strength, and quantity;

(vii) Listing of the partial dispensings that have been dispensed under each prescription; and

(viii) Information required in this section;

(B) Immediate, real-time updating of the prescription record each time a partial dispensing of the prescription is concluded; and

(C) Retrieval of partially dispensed Schedule II prescription information is the same as required for Schedules III, IV, and V prescription refill information.

(5) The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients such as a patient with severe intractable pain who is not diagnosed as terminal.

(e) Telephone or oral prescriptions.

(1)(A) In the case of an emergency situation, as defined by this part, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner provided that the quantity prescribed and dispensed is limited to the amount adequate to treat that patient during the emergency period, but never more than seventy-two (72) hours.

(B) Dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner.

(C) For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the List of Controlled Substances, 5 CAR pt. 22, "emergency situation" means those situations in which the prescribing practitioner determines that:

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

(ii) No appropriate alternative treatment is available, which includes the administration of a medication that is not a Schedule II medication; and

(iii) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the dispensing pharmacist prior to the dispensing.

(2)(A) The prescription shall be immediately reduced to writing by the pharmacist.

(B) Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

(C) Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription that had earlier been reduced to writing.

(D) The pharmacist must notify the nearest Drug Enforcement Administration if the prescribing individual practitioner fails to deliver a written prescription to him or her.

(3)(A) A pharmacist may dispense a controlled substance listed in Schedules III, IV, or V pursuant to an oral prescription:

(i) Made by an individual practitioner; or

(ii) Communicated by an employee or agent of the individual practitioner to a pharmacist.

(B) The pharmacist shall promptly either enter the prescription into the pharmacy's electronic prescription system or reduce it to writing.

(C) The prescription shall include all the information required in the case of a written prescription except for the written signature of the individual practitioner.

(f) Prescription transfers.

(1)(A) The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only.

(B) However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(C) Transfers are subject to the following requirements.

(D) The transfer is communicable directly between two (2) licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word "VOID" on the face of the invalidated prescriptions;

(ii) Record on the reverse side of the invalidated prescription the:

(a) Name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred; and

(b) Name of the pharmacist receiving the prescribing information; and

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(2) The pharmacist receiving the transferred prescription information shall electronically record or reduce to writing the following:

(A) Write the word "TRANSFER" on the face of the transferred prescription;

(B) Provide all information required to be on a prescription pursuant to federal law (21 C.F.R. § 1306.05) and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date and location of previous refills;

(v) Pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred; and

(vi) Name of pharmacist who transferred the prescription; and

(C) The original and transferred prescription shall be maintained for a period of two (2) years from the date of last refill.

(g) Facsimile.

(1)(A) A prescription for a Schedule II controlled substance may be transmitted by the prescribing practitioner to a pharmacy via facsimile equipment

provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subdivision (g)(2), subdivision (g)(3), or subdivision (g)(4) of this section.

(B) The original prescription shall be maintained in accordance with this part.

(2)(A) A prescription prepared in accordance with this part written for a Schedule II narcotic substance to be compounded for direct administration to a patient by parenteral, intravenous, subcutaneous, or intraspinal infusion may be transmitted by the prescribing practitioner to the home infusion pharmacy by facsimile.

(B) The facsimile:

(i) Serves as the original written prescription for purposes of this paragraph; and

(ii) Shall be maintained in accordance with this part.

(3)(A) A prescription prepared in accordance with this part written for a Schedule II substance for a resident of an LTCF may be transmitted by the prescribing individual practitioner to the dispensing pharmacy by facsimile.

(B) The facsimile:

(i) Serves as the original written prescription for purposes of this paragraph; and

(ii) Shall be maintained in accordance with this part.

(4)(A) A prescription written for a Schedule II substance for a home hospice patient may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(B) It must be noted on the prescription that this is a hospice patient.

(C) The facsimile serves as the original written prescription.

(5) A pharmacist may dispense directly a controlled substance listed in Schedules III, IV, or V that is a prescription drug only pursuant to:

(A) A written prescription signed by a prescribing individual practitioner;

(B) A facsimile of a written signed prescription transmitted by the prescribing practitioner to the pharmacy; or

(C) An oral prescription made by a prescribing individual practitioner and promptly either entered into the pharmacy's electronic prescription system or reduced to writing by the pharmacist, including all information required by this part except for the signature of the prescribing practitioner.

(6) An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedules III, IV, or V only pursuant to:

(A) A written prescription signed by a prescribing individual practitioner;

(B) A facsimile of a written prescription or order for medication transmitted directly by the prescribing practitioner to the pharmacist;

(C) An oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist, including all information required by this part except for the signature of the individual practitioner; or

(D) An order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

Authority. Arkansas Code §§ 20-64-219, 20-64-220, 20-64-317, 5-64-702.

Codification Notes. "LTCF" means long-term care facility.

20 CAR § 203-110. Schedule II prescriptions.

Prescriptions written for Schedule II controlled substances may be dispensed up to six (6) months from the date written if the dispenser is certain of the validity of the prescription, except for patients classified as terminally ill or long-term care patients.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-111. Violations.

Any violation of this part by any practitioner as defined in 20 CAR § 203-102 may be reported by Pharmacy Services and Drug Control Section of the Department of Health to the appropriate licensing board of the violator for possible disciplinary action.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-112. Suspension or revocation.

(a) The registration issued by the Department of Health to conduct procedures with controlled substances may be suspended or revoked for the following reasons:

- (1) The registrant has violated any provisions of this part;
- (2) The registrant has furnished false or fraudulent material or information in the application or renewal for registration;
- (3) The registrant has been convicted of a felony under any state or federal law relating to controlled substances;
- (4) The registrant has had his or her federal registration to handle controlled substances suspended or revoked; and
- (5) The registrant failed to renew his or her registration within sixty (60) days after the registration expired.

(b) Proceedings pursuant to such suspension or revocation shall be governed by the rules of procedure of the department.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.

20 CAR § 203-113. Labeling.

(a) Controlled substances dispensed by a practitioner to a patient shall bear a label that includes the:

- (1) Date of dispensing;
- (2) Name, address, and telephone number of the dispenser;
- (3) Serial number of the prescription;
- (4) Name of the patient;
- (5) Name of the prescribing practitioner;
- (6) Name, strength, and quantity of the medication dispensed; and
- (7) Directions for use including any required cautionary statements.

(b) This section shall not apply to:

(1) The dispensing of medication to inpatients in hospitals; or

(2) Manufacturers' samples in original containers issued by the prescribing physician.

(c) In an appropriate manner, the prescribing practitioners may indicate that the name, strength, and quantity of the medication dispensed shall be deleted from the label.

Authority. Arkansas Code §§ 20-64-219, 20-64-317, 5-64-702.