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BUREAU OF
LEGISLATIVE RESEARCH

REGULATION NO. 12

DISPENSING

1. Pursuant to other provisions of Act 515 of 1983 any physician licensed to practice medicine in the state of Arkansas who is a “dispensing physician” as defined by Act 515 of 1983 shall comply with all provisions of the Act and shall register with the Arkansas State Medical Board on a form provided by it for that purpose.
2. Any physician desiring to dispense legend drugs, who is not exempt by the terms of Act 515 of 1983 from the requirement of prior approval of the Arkansas State Medical Board shall apply to the Arkansas State Medical Board on a form provided for it for that purpose and shall be required to demonstrate the need for such dispensing of legend drugs prior to receiving approval.
- 3. All records maintained by a dispensing physician pursuant to the requirements of Act 515 of 1983 shall be subject to inspection by a designated inspector of the Arkansas State Medical Board and at its direction during all regular business hours.
4. Violation of the provision of Act 515 of 1983 or violations of these regulations shall constitute “unprofessional conduct” and shall subject the violator to disciplinary action as provided by Ark. Code Ann. 17-95-409.

SECTION I: APPROVAL TO DISPENSE: LEGEND DRUGS

1. Any physician desiring to dispense legend drugs, ~~who is not exempt by the terms of Act 515 of 1983 from the requirement of prior approval of the Arkansas State Medical Board~~ shall apply to the Arkansas State Medical Board on a form provided ~~for it~~ for that purpose and shall be required to demonstrate the need for such dispensing of legend drugs prior to receiving approval.
2. This section does not apply to:
 - a. Licensed physicians who were dispensing in the ordinary course of his/her practice before April 12, 2013 shall be exempt from the licensing requirements of this section.
 - b. Physicians who only dispense drugs in injectable form unless they are controlled substances, in which case this section shall apply fully.
 - c. Physicians dispensing topical medication, Naloxone, nicotine replacement therapy, contraceptives, acute care medication that is a legend but not a controlled substance prescribed for no more than fourteen (14) days, and initial treatment for maintenance medication.
 - i. Acute care medication includes the following oral medications:
 1. To treat infections;
 2. Anti-inflammatory medications;
 3. Antinausea medications;

4. Antihistamines; and
 5. Cough medications.
 - ii. Initial treatment for maintenance medication means a legend drug that:
 1. Is not a controlled substance;
 2. Is prescribed for no more than thirty (30) days;
 3. And is used to treat hypertension, diabetes mellitus, or hypercholesterolemia.
3. A “dispensing physician” is a physician licensed under the Arkansas Medical Practices Act who purchases legend drugs to be dispensed to his/her patients for the patients’ personal use and administration outside the physician’s office. A dispensing physician shall:
 - a. Personally dispense legend drugs, and the dispensing of legend drugs may be delegated;
 - b. Keep records of all receipts and distributions of legend drugs;
 - c. Label drugs with the following information:
 - i. Patient’s name and address;
 - ii. Prescribing physician’s address, narcotic registry number issued by the U.S. DEA, or national provider identification number;
 - iii. Date of dispensing; and
 - iv. Directions and cautionary statements, if any, required by law; and
 - d. Make all records readily accessible for inspection by a designated inspector of the Arkansas State Medical Board and at its direction during all regular business hours.

SECTION II: DISPENSING REQUIREMENTS

1. All records maintained by a dispensing physician shall be subject to inspection by a designated inspector of the Arkansas State Medical Board and at its direction during all regular business hours.
2. Any dispensing physician or delegated individual participating in the preparation of orders or dispensing of prescriptions or any dispensing physician who is responsible for supervising personnel participating in the preparation of orders or dispensing of prescriptions is responsible for the validity and legality of the order or prescription.
 - (a) Any dispensing physician who is responsible for supervising personnel is also responsible for any shortage of drugs classified as controlled drugs under state or federal law which occurs under ~~their~~ his/her supervision.
 - (b) The dispensing physician is responsible for the security and accountability of all

drugs stored and is responsible for the validity and legality of all prescriptions or ~~and/or~~ orders upon which drugs are dispensed. The dispensing physician is responsible for ensuring that delegated staff has been appropriately trained to follow all policies and procedures.

3. An inventory is to be maintained, monitored, and recorded jointly by the dispensing physician and delegated employees.

History: Adopted June 16, 1983, Amended Act 503 of 2021

1 State of Arkansas *As Engrossed: H2/24/21 H3/4/21*

2 93rd General Assembly

A Bill

3 Regular Session, 2021

HOUSE BILL 1246

4

5 *By: Representatives L. Johnson, Bragg, Eubanks*

6 By: Senators D. Wallace, Hester

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For An Act To Be Entitled

9 AN ACT TO ALLOW PHARMACISTS TO TREAT CERTAIN HEALTH
10 CONDITIONS; TO MODIFY PHYSICIAN DISPENSING; TO ALLOW
11 DELEGATION OF PHYSICIAN DISPENSING; AND FOR OTHER
12 PURPOSES.

13

14

15

Subtitle

16

TO ALLOW PHARMACISTS TO TREAT CERTAIN
17 HEALTH CONDITIONS; TO MODIFY PHYSICIAN
18 DISPENSING; AND TO ALLOW DELEGATION OF
19 PHYSICIAN DISPENSING.

20

21

22 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

23

24 SECTION 1. DO NOT CODIFY. Purpose.

25 It is the purpose of this act to authorize pharmacists in Arkansas to
26 test and screen for health conditions that the Centers for Medicare and
27 Medicaid Services has determined qualify for a waiver under the federal
28 Clinical Laboratory Improvement Amendments of 1988, the federal regulations
29 adopted, or any established screening procedures that can safely be performed
30 by a pharmacist.

31

32 SECTION 2. Arkansas Code § 17-92-101(17)(A)(x), concerning the
33 definition of "practice of pharmacy", is amended to read as follows:

34

(x)(a) Providing pharmacy care; ~~and.~~

35

(b) A pharmacist may treat the following
36 conditions within the framework of a statewide written protocol:



- 1 (1) Influenza;
- 2 (2) Pharyngitis caused by streptococcus
- 3 A; or
- 4 (3) Other health conditions that can be
- 5 screened utilizing the waived test under the Clinical Laboratory Improvement
- 6 Amendments of 1988, that may be adopted by rule of the Arkansas State Board
- 7 of Pharmacy, in consultation with and upon approval of the Arkansas State
- 8 Medical Board.

9 (c) A pharmacist shall only treat conditions
10 for which the pharmacist has tested and that are approved under this
11 subdivision (17)(A)(x)(c).

12 (d)(1) The Arkansas State Board of Pharmacy,
13 with consultation and upon approval of the Arkansas State Medical Board,
14 shall adopt by rule:

15 (A) A formulary of medicinal drugs
16 that a pharmacist may prescribe for treatment of conditions listed in
17 subdivision (17)(A)(x)(b) of this section; and

18 (B) A written statewide protocol
19 for conditions listed in subdivision (17)(A)(x)(b) of this section, which
20 shall including without limitation age of people that can be treated and
21 medications to be used to treat people under this subdivision.

22 (2) The formulary shall include
23 medicinal drugs approved by the United States Food and Drug Administration
24 which are indicated for treatment of these conditions, including without
25 limitation any over-the-counter medication.

26 (3) The formulary shall not include any
27 controlled substance in Schedule I-IV or 21 U.S.C. § 812, as existing on
28 January 1, 2021.

29 (e) A pharmacist may write a prescription for
30 over-the-counter medications, supplies, and devices; and

31

32 SECTION 3. Arkansas Code § 17-92-101(18), concerning the definition of
33 "prescription", is amended to read as follows:

34 (18)(A)(i) "Prescription" means an order for medicine or
35 medicines usually written as a formula by a physician, optometrist, dentist,
36 veterinarian, or other licensed medicinal practitioner.

1 (ii) A prescription ~~It~~ contains the names and
2 quantities of the desired substance, with instructions to the pharmacist for
3 its preparation and to the patient for the use of the medicine at a
4 particular time and may authorize the pharmacist to substitute a
5 therapeutically equivalent drug that is at a an equal or lower cost to the
6 patient and communicate that authorization by any generally accepted means of
7 communication of a prescription from a prescriber to a pharmacist.

8 (B)(i) A ~~substitution of a therapeutically equivalent drug~~
9 ~~shall occur only after the prescriber grants such authorization for each~~
10 ~~prescription.~~ pharmacist whose practice is located within this state may
11 substitute one (1) medication for a therapeutically equivalent medication.

12 (ii) However, a pharmacist shall not substitute one
13 (1) medication for a therapeutically equivalent medication if:

14 (a) A prescription is in writing and the
15 prescriber indicates in his or her own handwriting by name or initial that no
16 substitution is to be made;

17 (b) A prescription is not in writing and the
18 prescriber expressly indicates that the prescription is to be dispensed as
19 communicated; or

20 (c) The Arkansas State Board of Pharmacy has
21 determined that a therapeutically equivalent medication should not be
22 substituted and has notified all pharmacists of that determination.

23 (C)(i) Before dispensing, the pharmacist shall discuss
24 verbally any suggested substitution with the patient and inform the patient
25 that the patient has a right to refuse the substitution.

26 (ii) The discussion under subdivision (18)(C)(i) of
27 this section shall include without limitation:

28 (a) Notification to the patient that the
29 therapeutically equivalent drug does not contain the identical active
30 ingredient present in the prescribed drug; and

31 (b) All differences in dosage and frequency
32 between the prescribed drug and the therapeutically equivalent drug.

33 (D) The pharmacist shall send notice of the substitution
34 to the prescriber in writing or by electronic communication within twenty-
35 four (24) hours after the drug is dispensed to the patient.

36 (E) Subdivision (18)(B) of this section does not apply to

1 *specific acts of drug therapy management or disease state management*
2 *delegated to a pharmacist based upon a written protocol or patient care plan*
3 *approved by a physician under subdivision (17)(A)(ix) of this section;*
4

5 SECTION 4. Arkansas Code Title 17, Chapter 92, Subchapter 1, is
6 amended to add an additional section to read as follows:

7 17-92-118. Point-of-care treatment.

8 A pharmacist who tests for conditions under § 17-92-101(17)(A)(x)
9 shall:

10 (1) Hold a license to practice pharmacy in this state;

11 (2) Report a diagnosis or suspected existence of influenza to
12 the Department of Health;

13 (3) Furnish patient records to a healthcare practitioner
14 designated by the patient upon the request of the patient; and

15 (4) Maintain records of all patients receiving services under
16 this section for two (2) years.

17
18 SECTION 5. Arkansas Code § 17-95-102 is amended to read as follows:
19 17-95-102. Legend drugs.

20 (a) ~~A dispensing physician is~~ As used in this section, a "dispensing
21 physician" means a physician licensed under the Arkansas Medical Practices
22 Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq., who
23 purchases legend drugs to be dispensed to his or her patients for the
24 patients' personal use and administration outside the physician's office.

25 (b) This section ~~shall~~ does not apply to physicians who only dispense
26 drugs in injectable form unless they are controlled substances, in which case
27 the section shall fully apply.

28 (c) The dispensing physician shall:

29 (1) Personally dispense legend drugs, and the dispensing of such
30 drugs may ~~not~~ be delegated;

31 (2)(A) Keep records of all receipts and distributions of legend
32 drugs.

33 (B) The records shall be subject to inspection by the
34 proper enforcement authority and shall be readily accessible for inspection
35 and maintained in a central registry; and

36 (3) Label legend drugs with the following information:

- 1 (A) Patient's name and address;
- 2 (B) Prescribing physician's address and narcotic registry
- 3 number issued by the United States Drug Enforcement Administration or
- 4 national provider identification number;
- 5 (C) Date of dispensing; and
- 6 (D) Directions and cautionary statements, if any, as
- 7 required by law.

8 (d)(1) A physician licensed under the Arkansas Medical Practices Act,

9 § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq., shall not

10 dispense legend drugs without prior approval by the Arkansas State Medical

11 Board after application to the ~~board~~ Arkansas State Medical Board and on the

12 showing of need.

13 (2) Licensed physicians who were dispensing in the ordinary

14 course of their practice before April 12, 2013, shall be exempt from the

15 requirements of this subsection.

16 (3) The ~~board~~ Arkansas State Medical Board shall determine

17 whether need exists for a physician to dispense a specific legend drug to the

18 physician's patient for a patient's personal use and administration outside

19 of the physician's office based on such information as is necessary for the

20 ~~board~~ Arkansas State Medical Board to determine:

21 (A) The legend drug or drugs that the physician requests

22 to dispense;

23 (B) The ability of a physician's patient to obtain the

24 legend drug from other medical professionals;

25 (C) The availability of the legend drug to be prescribed

26 by the physician;

27 (D) The hours at which the legend drug may be obtained

28 from other medical professionals;

29 (E) The distance the physician's patient must travel to

30 obtain the legend drug from other medical professionals;

31 (F) Whether the physician has been investigated by the

32 ~~board~~ Arkansas State Medical Board concerning the improper prescribing or use

33 of a legend drug;

34 (G) Whether the physician has a financial relationship

35 with the manufacturer of a legend drug that would create the appearance of a

36 conflict of interest;

1 (H) Whether the physician dispensing a legend drug will
2 foster cost containment through improved efficiency and productivity; and

3 (I) The procedures the physician has implemented to:

4 (i) Assure compliance with the requirements of
5 subsection (c) of this section;

6 (ii) Monitor and guard against potential drug
7 interactions;

8 (iii) Store and safeguard the legend drugs; and

9 (iv) Comply with the Prescription Drug Monitoring
10 Program Act, § 20-7-601 et seq., concerning the reporting requirements to the
11 Prescription Drug Monitoring Program.

12 (4) This section does not apply to a prescription for:

13 (i) A prescription for a topical medication;

14 (ii) Naloxone;

15 (iii) Nicotine ~~nicotine~~ replacement therapy
16 products;

17 (iv) Contraceptives; ~~contraceptives is exempt from~~
18 ~~subdivision (d)(3) of this section~~

19 (v) Acute care medication; or

20 (vi) Initial treatment for maintenance medication.

21 (e)(1) ~~The board~~ Arkansas State Medical Board shall enforce the
22 provisions of this section and is authorized and directed to adopt rules to
23 carry out ~~its purpose~~ the purpose of this section.

24 (2) The Arkansas State Medical Board shall adopt rules for
25 physician dispensing that, at minimum, meet the same requirements for
26 dispensing and oversight established by the Arkansas State Board of Pharmacy.

27 (f) As used in this section:

28 (1)(A) "Acute care medication" means a legend drug that is not a
29 controlled substance and is prescribed for no more than fourteen (14) days of
30 therapy.

31 (B) "Acute care medication" includes the following oral
32 medications:

33 (i) Medications to treat infections;

34 (ii) Anti-inflammatory medications;

35 (iii) Antinausea medications;

36 (iv) Antihistamines; and

- 1 (v) Cough medications;
- 2 (2) "Initial treatment" means the first prescription written for
- 3 a specific prescription medication intended to initiate therapy on the
- 4 medication; and
- 5 (3) "Maintenance medication" means a legend drug that:
- 6 (A) Is not a controlled substance;
- 7 (B) Is prescribed for no more than thirty (30) days; and
- 8 (C) Is used to treat one (1) of the following medical
- 9 conditions:
- 10 (i) Hypertension;
- 11 (ii) Diabetes mellitus; or
- 12 (iii) Hypercholesterolemia.

13

14 SECTION 6. DO NOT CODIFY. Effective date.

15 Sections 1 -4 take effect on and after January 1, 2022.

16

17 /s/Johnson

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20 APPROVED: 4/1/21

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