

Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

1 State of Arkansas
2 85th General Assembly
3 Regular Session, 2005
4

As Engrossed: H1/11/05 H1/21/05

A Bill

HOUSE BILL 1031

5 By: Representatives Mahony, Medley, Pate, Abernathy, Bond, Borhauer, Boyd, Creekmore, D. Evans,
6 Key, Mathis, S. Prater, Roebuck, Saunders, L. Smith, Thomason, Walters, Mack, Petrus, Rainey, Wood
7 By: Senators Horn, Womack, Baker, Broadway, Higginbothom, T. Smith, *Salmon, Bryles*
8
9

For An Act To Be Entitled

11 AN ACT TO ALLOW DONATED PRESCRIPTION MEDICATIONS
12 TO BE DISPENSED TO PATIENTS AT CHARITABLE
13 CLINICS; AND FOR OTHER PURPOSES.
14

Subtitle

15 AN ACT TO ALLOW DONATED PRESCRIPTION
16 MEDICATIONS TO BE DISPENSED TO PATIENTS
17 AT CHARITABLE CLINICS.
18
19
20

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

23 SECTION 1. Arkansas Code Title 17, Chapter 92 is amended to add an
24 additional subchapter to read as follows:

25 17-92-1101. Purpose.

26 It is the purpose of this subchapter to:

27 (1) Improve the health of needy Arkansans through a prescription
28 drug redispensing program that authorizes charitable clinic pharmacies to
29 redispense medicines that would otherwise be destroyed; and

30 (2) Reaffirm the existing broad latitude of the Arkansas State
31 Board of Pharmacy to protect the safety of the prescription drug supply in
32 this state.
33

34 17-92-1102. Definitions.

35 As used in this subchapter:

36 (1) "Charitable clinic" means a charitable nonprofit corporation



1 or a facility organized as a not-for-profit corporation under §§ 4-28-201 -
2 4-28-206 and 4-28-209 - 4-28-224 that:

3 (A) Holds a valid exemption from federal income taxation
4 issued pursuant to the Internal Revenue Code, 26 U.S.C., § 501(a);

5 (B) Is listed as an exempt organization under the Internal
6 Revenue Code, 26 U.S.C. § 501(c)(3);

7 (C) Provides advice, counseling, diagnosis, treatment,
8 surgery, care, or services relating to the preservation or maintenance of
9 health on an outpatient basis for a period of less than twenty-four (24)
10 consecutive hours to persons not residing or confined at the facility;

11 (D) May charge an administrative fee or request a donation
12 not to exceed ten dollars (\$10.00) per visit; and

13 (E) Has a licensed outpatient pharmacy;

14 (2) "Charitable clinic pharmacy" means the practice of a
15 pharmacy at a site where prescriptions are dispensed by a charitable clinic
16 free of charge to appropriately screened and qualified indigent patients;

17 (3) "Controlled substances" means substances defined by the
18 Uniform Controlled Substances Act, § 5-64-101 et seq.;

19 (4) "Indigent" means a person with an income that is below two
20 hundred percent (200%) of the federal poverty level;

21 (5) "Nursing facility" means the same as under § 20-10-1401;

22 (6)(A)(i) "Prescription drug" means a drug limited by §
23 503(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq.
24 to being dispensed by or upon a medical practitioner's prescription because
25 the drug is:

26 (a) Habit-forming;

27 (b) Toxic or having potential for harm; or

28 (c) Limited in its use to use under a
29 practitioner's supervision by the new drug application for the drug.

30 (ii) The product label of a legend drug is required
31 to contain the statement:

32 (a) "CAUTION: FEDERAL LAW PROHIBITS DISPENSING
33 WITHOUT A PRESCRIPTION"; or

34 (b) "Rx only".

35 (iii) The drug is subject to the requirement of §
36 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt

1 from § 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if certain
2 specified conditions are met.

3 (B) "Prescription drug", for purposes of this subchapter,
4 does not include controlled substances; and

5 (7) "Properly transferred" means the storage, handling, and
6 distribution of the drug under this subchapter in:

7 (A) Accordance with the label; and

8 (B) Its dispensed, sealed, tamper-evident single user
9 unit.

10
11 17-92-1103. Prescription drug redispensing program.

12 (a) The prescription drug redispensing program established by this
13 subchapter shall be a pilot program to determine the efficacy of redispensing
14 prescription drugs to indigent patients.

15 (b) The Arkansas State Board of Pharmacy, in cooperation with the
16 Department of Human Services and the Department of Health, shall develop and
17 implement this pilot program consistent with public health and safety through
18 which unused prescription medications other than controlled substances may be
19 transferred from a nursing facility to a charitable clinic pharmacy for the
20 purpose of distributing the medication to Arkansas residents who are
21 indigent.

22 (c) The Arkansas State Board of Pharmacy, in cooperation with the
23 Department of Human Services and the Department of Health, shall monitor the
24 pilot program and submit two (2) reports along with any recommendations or
25 findings to the General Assembly:

26 (1) The first report on or before January 1, 2006; and

27 (2) The second report on or before October 1, 2006.

28 (d) Participation in this pilot program by any entity, including
29 individuals, pharmacies, charitable clinics, charitable clinic pharmacies,
30 nursing facilities, and drug manufacturers shall be voluntary.

31
32 17-92-1104. Donations of unused prescription drugs.

33 (a)(1) A charitable clinic may accept for redispensing prescription
34 drugs obtained from a nursing facility by the clinic pharmacy for relabeling
35 and dispensing free of charge and pursuant to a valid prescription order to
36 an indigent patient.

1 (2) The donor patient shall be considered to be the owner of the
2 prescription drug and entitled to donate the drug for use by a charitable
3 clinic.

4 (b)(1)(A)(i) Any nursing home may enter into a contract with any
5 charitable clinic for the transfer of drugs under this section.

6 (ii) No drugs may be transferred without a contract.

7 (B) A contract entered into under subdivision (b)(1)(A) of
8 this section shall be approved by the Arkansas State Board of Pharmacy, in
9 cooperation with the Department of Human Services and the Department of
10 Health.

11 (2)(A) A contract entered into under subdivision (b)(1)(A) of
12 this section shall set out procedures for ensuring a safe chain of custody to
13 protect the safety of all transferred drugs.

14 (B) The contract may specify that the charitable clinic
15 will either:

16 (i) Define a specified set of drugs that will be
17 transferred from the nursing home to the charitable clinic;

18 (ii) Request from time to time the transfer of
19 particular drugs;

20 (iii) Receive all the drugs that the nursing home is
21 authorized to transfer under this section; or

22 (iv) Make such other provisions as may be approved
23 by the Arkansas State Board of Pharmacy.

24 (3) The pharmacist in charge at the charitable clinic shall be
25 responsible for determining the description of the drugs that will be
26 included in the contract.

27 (c) Donations of prescription drugs to a charitable clinic pharmacy
28 shall meet the following requirements:

29 (1)(A) The charitable clinic pharmacy accepts the drugs only in
30 their original sealed and tamper-evident packaging.

31 (B) However, the charitable clinic pharmacy may accept
32 drugs packaged in single-unit doses or blister packs with the outside
33 packaging opened if the single-unit dose packaging remains intact;

34 (2) A pharmacist of the charitable clinic pharmacy determines
35 that the drug is not adulterated or misbranded and is safe to dispense;

36 (3) No product of which the integrity cannot be assured is

1 accepted for redispensing by the pharmacist of the charitable clinic
2 pharmacy;

3 (4) The drugs are physically transferred from the nursing
4 facility to a charitable clinic pharmacy by a person authorized by the
5 Arkansas State Board of Pharmacy to pick up the drugs for the charitable
6 clinic;

7 (5)(A) The donor executes a form stating that the donor is
8 authorized to donate the drugs and intends to voluntarily donate them to a
9 charitable clinic pharmacy.

10 (B) The nursing facility retains the donor form along with
11 other acquisition records;

12 (6) The donor patient's name, prescription number, and any other
13 identifying marks are obliterated from the packaging before the nursing
14 facility sends the drug to the charitable clinic;

15 (7) The drug name, strength, and expiration date remain on the
16 drug package label;

17 (8) The redispensed drug is assigned the same expiration date as
18 on the original package;

19 (9) Expired drugs accepted by a charitable clinic pharmacy are
20 not redispensed and are destroyed according to the charitable clinic
21 pharmacy's destruction procedures; and

22 (10) The charitable clinic pharmacy accepts no controlled
23 substances.

24 (d)(1) If a nursing facility that releases drugs to a charitable
25 clinic receives notice from a pharmacy that a drug has been recalled, the
26 nursing facility shall inform the clinic of the recall.

27 (2) If a charitable clinic receives a recall notification from a
28 nursing facility, the clinic shall perform a uniform destruction of all of
29 the recalled drug in the facility.

30 (e) No drug dispensed through a charitable clinic pharmacy shall be
31 eligible for reimbursement from the state Medicaid program.

32 (f) Indigent patients receiving prescription drugs through this
33 program shall sign a waiver form releasing the nursing facility, the donor,
34 and the donor's estate from liability.

35 (g) The board shall promulgate rules to develop:

36 (1) Forms and procedures for authorizations and certifications

1 required under subdivision (c)(4) of this section;

2 (2) The donor consent form required under subdivision (c)(5) of
3 this section;

4 (3) The waiver forms required under subsection (f) of this
5 section; and

6 (4)(A) Specific requirements for a charitable clinic pharmacy or
7 other specialty pharmacy for the medically indigent as defined by rules of
8 the Arkansas State Board of Pharmacy to qualify for participation in and to
9 participate in the pilot program.

10 (B) On request, the board shall provide the information
11 required under subdivision (4)(A) of this section to charitable clinics.

12 (h)(1) The following persons and entities that participate in the
13 pilot program shall not be subject to any professional disciplinary action or
14 criminal prosecution for actions taken under the program:

15 (A) The donor and the donor's estate;

16 (B) A nursing facility;

17 (C) The prescribing physician, physician's assistant,
18 registered nurse, advanced practice nurse, or nurse practitioner;

19 (D) Pharmacists and pharmacy technicians except where the
20 board has promulgated regulations dealing specifically with this program;

21 (E) The charitable clinic;

22 (F) The Department of Health;

23 (G) The Department of Human Services; or

24 (H) The Arkansas State Board of Pharmacy.

25 (2) Participation in the pilot program shall not be used as an
26 independent basis for a claim of liability in tort or other civil action
27 against any person or entity, including, but not limited to:

28 (A) The donor and the donor's estate;

29 (B) A nursing facility;

30 (C) The prescribing physician, physician's assistant,
31 nurse practitioner, or nurse;

32 (D) The charitable clinic;

33 (E) The charitable clinic pharmacy acting in conformity
34 with Arkansas State Board of Pharmacy regulations;

35 (F) The pharmacist who originally dispensed the donated
36 prescription drugs acting in conformity with Arkansas State Board of Pharmacy

1 regulations;

2 (G) A pharmacist dispensing donated prescription drugs
3 acting in conformity with Arkansas State Board of Pharmacy regulations;

4 (H) The Department of Health;

5 (I) The Department of Human Services; or

6 (J) The Arkansas State Board of Pharmacy.

7 (3) In the absence of bad faith, a drug manufacturer shall not
8 be subject to criminal prosecution or liability in tort or other civil action
9 for injury, death, or loss to person or property for matters related to the
10 donation, acceptance, or dispensing of a drug manufactured by the drug
11 manufacturer that is donated by any person under the pilot program,
12 including, but not limited to liability for failure to provide:

13 (i) Product or consumer package insert information;

14 or

15 (ii) The expiration date of the donated drug.

16 (B) Subdivision (3)(A) of this section does not apply to a
17 previously undisclosed product defect.

18
19 17-92-1105. Sample drug use not restricted.

20 Nothing in this subchapter shall restrict the use of samples by a
21 physician or advanced practice nurse during the course of working at a
22 charitable clinic whether or not the clinic has a licensed outpatient
23 pharmacy.

24
25 17-92-1106. Resale prohibited.

26 Nothing in this subchapter shall be construed to provide for the resale
27 of drugs by any person or entity.

28
29 17-92-1107. Applicability.

30 Nothing in this subchapter applies to any questions of liability
31 arising outside the scope of the pilot program.

32
33 /s/ Mahony, et al
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