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.

State of Arkansas
As Engrossed: H1/11/05  H1/21/05
85th General Assembly
Regular Session, 2005

HOUSE BILL 1031

A Bill

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

For An Act To Be Entitled
AN ACT TO ALLOW DONATED PRESCRIPTION MEDICATIONS TO BE DISPENSED TO PATIENTS AT CHARITABLE CLINICS; AND FOR OTHER PURPOSES.

Subtitle
AN ACT TO ALLOW DONATED PRESCRIPTION MEDICATIONS TO BE DISPENSED TO PATIENTS AT CHARITABLE CLINICS.

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

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

17-92-1101. Purpose.
It is the purpose of this subchapter to:

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

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

As used in this subchapter:

(1) "Charitable clinic" means a charitable nonprofit corporation
or a facility organized as a not-for-profit corporation under §§ 4-28-201 – 4-28-206 and 4-28-209 – 4-28-224 that:

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

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

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

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

(E) Has a licensed outpatient pharmacy;

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

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

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

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

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

(a) Habit-forming;
(b) Toxic or having potential for harm; or
(c) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

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

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

(b) "Rx only".

(iii) The drug is subject to the requirement of § 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt
from § 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if certain
specified conditions are met.

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

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

(A) Accordance with the label; and

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

17-92-1103. Prescription drug redispensing program.

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

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

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

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

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

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


(a)(1) A charitable clinic may accept for redispensing prescription
drugs obtained from a nursing facility by the clinic pharmacy for relabeling
and dispensing free of charge and pursuant to a valid prescription order to
an indigent patient.
(2) The donor patient shall be considered to be the owner of the prescription drug and entitled to donate the drug for use by a charitable clinic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) No product of which the integrity cannot be assured is
accepted for redispensing by the pharmacist of the charitable clinic pharmacy;

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

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

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

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

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

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

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

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

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

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

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

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

(g) The board shall promulgate rules to develop:

(1) Forms and procedures for authorizations and certifications
required under subdivision (c)(4) of this section;

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

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

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

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

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

(A) The donor and the donor’s estate;

(B) A nursing facility;

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

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

(E) The charitable clinic;

(F) The Department of Health;

(G) The Department of Human Services; or

(H) The Arkansas State Board of Pharmacy.

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

(A) The donor and the donor’s estate;

(B) A nursing facility;

(C) The prescribing physician, physician’s assistant,
nurse practitioner, or nurse;

(D) The charitable clinic;

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

(F) The pharmacist who originally dispensed the donated
prescription drugs acting in conformity with Arkansas State Board of Pharmacy
(G) A pharmacist dispensing donated prescription drugs acting in conformity with Arkansas State Board of Pharmacy regulations;

(H) The Department of Health;

(I) The Department of Human Services; or

(J) The Arkansas State Board of Pharmacy.

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

(i) Product or consumer package insert information;

or

(ii) The expiration date of the donated drug.

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

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

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

17-92-1106. Resale prohibited.

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


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

/s/ Mahony, et al