

1 HB423
2 116975-1
3 By Representative Page
4 RFD: Health
5 First Read: 26-JAN-10

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8 SYNOPSIS: Under existing law, legend drugs dispensed
9 to a patient at a hospital, nursing facility,
10 assisted living facility, or hospice may be donated
11 and transferred to charitable clinics to be used by
12 charitable patients without charge if certain
13 conditions are met.

14 This bill would allow legend drugs to be
15 dispensed by prescription but not administered to
16 patients at certain health care facilities to be
17 donated and transferred to charitable clinics under
18 certain conditions; to authorize the drugs to be
19 transferred in the same manner to charitable
20 pharmacies, as defined, to be dispensed to
21 charitable patients; and to further authorize
22 samples given to physicians to be donated and
23 transferred to charitable clinics and charitable
24 pharmacies.

25
26 A BILL
27 TO BE ENTITLED

1 AN ACT

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3 To amend Sections 20-3-2 and 20-3-3 of the Code of
4 Alabama 1975, authorizing legend drugs dispensed by
5 prescription to patients at certain health care facilities to
6 be donated and transferred to charitable clinics under certain
7 conditions; to authorize the drugs to be transferred in the
8 same manner to charitable pharmacies, as defined, to be
9 dispensed to charitable patients; and to further authorize
10 samples given to physicians to be donated and transferred to
11 charitable clinics and charitable pharmacies.

12 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

13 Section 1. Sections 20-3-2 and 20-3-3 of the Code of
14 Alabama 1975, are amended to read as follows:

15 "§20-3-2.

16 "As used in this chapter, the following terms shall
17 have the following meanings:

18 "(1) ASSISTED LIVING FACILITY. An institution or
19 facility licensed as an assisted living facility under
20 regulations of the State Board of Health.

21 "(2) CHARITABLE CLINIC. The term includes an
22 established free medical clinic as defined in subdivision (1)
23 of Section 6-5-662 and any community health center provided
24 for under the federal Public Health Service Law.

25 "(3) CHARITABLE PATIENT. For purposes of this
26 chapter, the term shall not include patients who are eligible
27 to receive drugs under the Alabama Medicaid Program or under

1 any other prescription drug program funded in whole or in part
2 by the state or by the federal government.

3 "(4) CHARITABLE PHARMACY. A pharmacy, registered
4 with the Board of Pharmacy as a retail pharmacy, that
5 dispenses to charitable income patients who meet the criteria
6 established by the Board of Pharmacy to receive free
7 prescription medications that does not charge for pharmacy
8 services or prescription medications and that does not
9 dispense controlled substances. A charitable pharmacy may
10 receive donated physician's samples.

11 "(4) (5) DRUGS. All medicinal substances and
12 preparations recognized by the United States Pharmacopoeia and
13 National Formulary, or any revision thereof, and all
14 substances and preparations intended for external and internal
15 use in the cure, diagnosis, mitigation, treatment, or
16 prevention of disease and all substances and preparations
17 other than food intended to affect the structure or any
18 function of the body.

19 "(5) (6) HOSPICE CARE PROGRAM. A hospice care
20 program licensed as a hospice care program under regulations
21 of the State Board of Health.

22 "(6) (7) HOSPITAL. An institution licensed as a
23 hospital under regulations of the State Board of Health.

24 "(7) (8) LEGEND DRUG. Any drug, medicine, chemical,
25 or poison bearing on the label the words, "caution, federal
26 law prohibits dispensing without prescription," or similar
27 wording indicating that such drug, medicine, chemical, or

1 poison may be sold or dispensed only upon the prescription of
2 a licensed medical practitioner.

3 "~~(8)~~ (9) NURSING FACILITY. An institution licensed
4 as a nursing facility or intermediate care facility under
5 regulations of the State Board of Health.

6 "~~(9)~~ (10) SPECIALTY CARE ASSISTED LIVING FACILITY.
7 An institution or facility licensed as a specialty care
8 assisted living facility under regulations of the State Board
9 of Health.

10 "\$20-3-3.

11 "(a) (1) Legend drugs, except controlled substances,
12 dispensed but not administered to a patient in a hospital,
13 nursing facility, assisted living facility, or specialty care
14 assisted living facility may be donated and transferred
15 pursuant to this section to a charitable clinic or charitable
16 pharmacy to be used by charitable patients free of charge when
17 all of the following conditions are met:

18 "a. The drugs are no longer needed by the original
19 patient.

20 "b. The drugs have been maintained in accordance
21 with United States Pharmacopoeia and National Formulary
22 storage requirements.

23 "c. The drugs were dispensed by unit dose or an
24 individually sealed dose.

25 "d. The drugs have not expired.

26 "(2) Legend drugs, except controlled substances,
27 dispensed but not administered to a patient cared for by a

1 hospice care program may be donated and transferred pursuant
2 to this section to a charitable clinic or charitable pharmacy
3 to be used by charitable patients free of charge when all of
4 the following conditions are met:

5 "a. The drugs are no longer needed by the original
6 patient.

7 "b. The drugs were dispensed by unit dose or bulk
8 packaging.

9 "c. The drugs have not expired.

10 "(b) The physician or licensed health care
11 professional of the charitable clinic or charitable pharmacy
12 shall be responsible for determining the suitability of the
13 product for reuse. No product where integrity may not be
14 assured shall be used by the physician at the charitable
15 clinic or dispensed by a charitable pharmacy. A legend drug
16 shall be assigned the expiration date stated on the package.

17 "(c) Pursuant to a voluntary agreement between a
18 nursing home, hospital, specialty care assisted living
19 facility, or hospice care program and a charitable clinic or
20 charitable pharmacy, legend drugs may be transferred pursuant
21 to this chapter from the nursing home, hospital, assisted
22 living facility, or specialty care assisted living facility or
23 from the residence of a hospice patient to the charitable
24 clinic or charitable pharmacy if the following procedures are
25 satisfied:

1 "(1) The legend drugs shall be physically
2 transferred to a person authorized in writing to pick up the
3 drugs for the charitable clinic or charitable pharmacy.

4 "(2) The file of a patient at the nursing home,
5 hospital, assisted living facility, or specialty care assisted
6 living facility or the file of a patient cared for by a
7 hospice care program shall document his or her consent, or in
8 the case of the death of a patient the patient's family's
9 consent, for the donation.

10 "(3) The patient's name, prescription number, and
11 any other identifying marks shall be obliterated from the drug
12 container prior to removal from the nursing home, hospital,
13 assisted living facility, or specialty care assisted living
14 facility or the residence of a hospice patient.

15 "(4) The name, strength, and expiration date of the
16 legend drug shall remain on the medication package label.

17 "(5) An inventory list of the legend drugs shall
18 accompany the drugs being transferred, which list, at a
19 minimum, shall contain for each drug the medication name,
20 strength, expiration date, and quantity.

21 "(6) Within one week after an inventoried list of
22 legend drugs is made available, the drugs shall be picked up
23 by a charitable clinic or charitable pharmacy, or the drugs
24 shall be destroyed.

25 "(d) A licensed nursing home, hospital, specialty
26 care assisted living facility, assisted living facility, or
27 hospice care program, or an owner, operator, employee, or

1 agent of a licensee, shall not be liable for civil damages or
2 for any criminal liability as a result of any acts or
3 omissions in transferring any drugs pursuant to this section
4 unless the act or omission was the result of willful
5 misconduct.

6 "(e) No pharmaceutical manufacturer shall be liable
7 for any claim or injury arising due to a transfer of any
8 legend drug pursuant to this chapter, including, but not
9 limited to, liability for failure to transfer or communicate
10 product or consumer information or the expiration date
11 regarding the transferred drug.

12 "(f) The State Board of Health may make rules and
13 regulations to carry out the provisions and purposes of this
14 section.

15 "(g) All legend drugs distributed under the
16 authority of this chapter shall be dispensed to a patient,
17 resident, or other user only on the order of a licensed
18 physician or other legally authorized licensed medical
19 practitioner.

20 "(h) Samples of legend drugs, except for controlled
21 substances, given to physicians may be donated and transferred
22 to charitable clinics and charitable pharmacies to be
23 dispensed to charitable patients without charge."

24 Section 2. This act shall become effective on the
25 first day of the third month following its passage and
26 approval by the Governor, or its otherwise becoming law.