

1 SB345  
2 116975-1  
3 By Senator Means  
4 RFD: Health  
5 First Read: 02-FEB-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

2  
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.