HB61

44002-5

By Representatives Page, Martin, Thigpen, Newton (C), Spicer, Boothe, Melton, Black (L), Graham, McDaniel, Willis, Mitchell, Hayden, Bandy, McClammy, Jackson and Knight

RFD: Health

First Read: 08-JAN-2002

PFD 01/07/2002
Enrolled, An Act,

To allow certain health care facilities and hospice care programs to transfer unused prescription medications to charitable clinics for use at the clinics under certain conditions; and to provide for immunity under certain conditions.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. This act shall be known and cited as the "John G. Page, Jr. Act."

Section 2. As used in this act, the following terms shall have the following meanings:

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

(2) CHARITABLE CLINIC. The term includes an established free medical clinic as defined in subdivision (1) of Section 4 of Act 2000-680 and any community health center provided for under the Federal Public Health Service Law.

(3) CHARITABLE PATIENT. For purposes of this act, the term shall not include patients who are eligible to receive drugs under the Alabama Medicaid Program or under any other prescription drug program funded in whole or in part by the state.
(4) DRUGS. All medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the cure, diagnosis, mitigation, treatment, or prevention of disease and all substances and preparations other than food intended to affect the structure or any function of the body.

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

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

(7) LEGEND DRUG. Any drug, medicine, chemical or poison bearing on the label the words, "caution, federal law prohibits dispensing without prescription," or similar wording indicating that such drug, medicine, chemical or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner.

(8) NURSING FACILITY. An institution licensed as a nursing facility or intermediate care facility under regulations of the State Board of Health.

(9) SPECIALTY CARE ASSISTED LIVING FACILITY. An institution or facility licensed as a specialty care assisted living facility under regulations of the State Board of Health.
Section 3. (a)(1) Legend drugs, except controlled substances, dispensed to a patient in a hospital, nursing facility, assisted living facility, or specialty care assisted living facility may be donated and transferred pursuant to this section to a charitable clinic to be used by charitable patients free of charge when all of the following conditions are met:

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

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

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

d. The drugs have not expired.

(2) Legend drugs, except controlled substances, dispensed to a patient cared for by a hospice care program may be donated and transferred pursuant to this section to a charitable clinic to be used by charitable patients free of charge when all of the following conditions are met:

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

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

c. The drugs have not expired.
(b) The physician or licensed health care professional of the charitable clinic shall be responsible for determining the suitability of the product for reuse. No product where integrity may not be assured shall be used by the physician at the charitable clinic. A legend drug shall be assigned the expiration date stated on the package.

(c) Pursuant to a voluntary agreement between a nursing home, hospital, specialty care assisted living facility, or hospice care program and a charitable clinic, legend drugs may be transferred pursuant to this act from the nursing home, hospital, assisted living facility, or specialty care assisted living facility or from the residence of a hospice patient to the charitable clinic if the following procedures are satisfied:

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

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

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

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

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

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

(d) A licensed nursing home, hospital, specialty care assisted living facility, assisted living facility, or hospice care program, or an owner, operator, employee, or agent of a licensee, shall not be liable for civil damages or for any criminal liability as a result of any acts or omissions in transferring any drugs pursuant to this section unless the act or omission was the result of willful misconduct.

(e) No pharmaceutical manufacturer shall be liable for any claim or injury arising from the due to a transfer of any prescription legend drug pursuant to this act, including, but not limited to, liability for failure to transfer or
communicate product or consumer information or the expiration
date regarding the transferred drug.

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

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

Section 4. This act shall become effective on the
first day of the third month following its passage and
approval by the Governor, or its otherwise becoming law.
HB61

Speaker of the House of Representatives

President and Presiding Officer of the Senate

House of Representatives

I hereby certify that the within Act originated in
and was passed by the House 31-JAN-2002, as amended.

Greg Pappas
Clerk

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APPROVED 4-26-02

GOVERNOR

Alabama Secretary of State

Act Num....: 2002-498
Bill Num....: H-61
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