By: Representative Barnett

To: Public Health and Human Services

HOUSE BILL NO. 121

AN ACT TO BRING FORWARD SECTIONS 43-13-501 THROUGH 43-13-509, 1 MISSISSIPPI CODE OF 1972, WHICH PROVIDE FOR A DRUG REPOSITORY 2 PROGRAM FOR DONATED DRUGS, FOR THE PURPOSE OF AMENDMENT; AND FOR 3 4 RELATED PURPOSES. 5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI: SECTION 1. Section 43-13-501, Mississippi Code of 1972, is 6 brought forward as follows: 7 43-13-501. As used in Sections 43-13-501 through 43-13-509, 8 9 the following terms have the following meanings, unless the context requires otherwise: 10 11 (a) "Board" means the State Board of Pharmacy. "Health care facility" means any of the following: 12 (b) (i) A hospital as defined under Section 41-9-3; 13 (ii) An institution for the aged or infirm as 14 defined in Section 43-11-1; 15 16 (iii) A hospice as defined in Section 41-85-3; 17 (C) "Hospital" has the meaning as defined in Section 41-9-3. 18 "Nonprofit clinic" means a charitable nonprofit 19 (d) 20 corporation organized and operated under Section 79-11-101 et 21 seq., or any charitable organization not organized and not 22 operated for profit, that provides health care services to indigent and uninsured persons. "Nonprofit clinic" does not 23 24 include a health care facility as defined in this section or a facility that is operated for profit. 25 26 (e) "Pharmacy" has the meaning as defined under Section 73-21-73. 27

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28 (f) "Prescription drug" means any drug to which the 29 following applies:

(i) Under the federal Food, Drug, and Cosmetic
Act, as amended (21 USCS Section 301), the drug is required to
bear a label containing the legend, "Caution: Federal law
prohibits dispensing without prescription" or "Caution: Federal
law restricts this drug to be used by or on the order of a
licensed veterinarian" or any similar restrictive statement, or
the drug may be dispensed only upon a prescription.

37 (ii) Under the Uniform Controlled Substances Law,
38 (Section 41-29-101 et seq.), the drug may be dispensed only upon a
39 prescription.

40 SECTION 2. Section 43-13-503, Mississippi Code of 1972, is
41 brought forward as follows:

42 43-13-503. (1) Not later than January 1, 2005, the State 43 Board of Pharmacy and the State Department of Health jointly shall 44 establish a plan for a drug repository program to accept and 45 dispense prescription drugs donated for the purpose of being 46 dispensed to individuals who meet the eligibility standards 47 established in the rules adopted by the board under Section 48 43-13-509. The plan shall be submitted to the Chairmen of the 49 Public Health and Welfare Committees of the Mississippi House of 50 Representatives and Senate for their review. Under the drug 51 repository program:

52 (a) Only drugs in their original sealed and53 tamper-evident packaging may be accepted and dispensed.

(b) The packaging must be unopened, except that drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed.

58 (c) The drugs must have been properly stored such that59 the integrity of the medicine remains intact.

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61 is reason to believe that it is adulterated as described in
62 Section 75-29-3.

(e) Subject to the limitation specified in this
subsection, unused drugs dispensed for the purposes of the
Medicaid program may be accepted and dispensed.

66 (2) Nothing in subsection (1) of this section shall be
67 construed as prohibiting a pharmacy from accepting drugs that are
68 not eligible to be dispensed under the drug repository program,
69 for the proper disposal of those drugs.

70 (3) The drug repository program shall be fully implemented71 not later than July 1, 2005.

72 SECTION 3. Section 43-13-505, Mississippi Code of 1972, is
73 brought forward as follows:

74 43-13-505. (1) Any person, including a drug manufacturer, 75 health care facility or government entity may donate prescription 76 drugs to the drug repository program. The drugs must be donated 77 at a pharmacy, hospital, or nonprofit clinic that participates in 78 the drug repository program under the criteria for participation 79 established in the rules adopted by the board under Section 80 43-13-509.

81 (2) A pharmacy, hospital, or nonprofit clinic that 82 participates in the drug repository program shall dispense drugs donated under this section to individuals who meet the eligibility 83 84 standards established in the rules adopted by the board under Section 43-13-509, or to other government entities and nonprofit 85 86 private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant to a 87 prescription issued by a licensed practitioner as defined in 88 89 Section 73-21-73. A pharmacy, hospital, or nonprofit clinic that accepts donated drugs shall comply with all applicable federal 90 91 laws and laws of this state dealing with storage and distribution of dangerous drugs, and shall inspect all drugs before dispensing 92

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them to determine that they are not adulterated. The pharmacy, 93 94 hospital, or nonprofit clinic may charge individuals receiving 95 donated drugs a handling fee established in accordance with the 96 rules adopted by the board under Sections 43-13-501 through 97 43-13-509. Drugs donated to the repository may not be resold. 98 SECTION 4. Section 43-13-507, Mississippi Code of 1972, is brought forward as follows: 99 43-13-507. (1) As used in this section, the term "health 100 care professional" means any of the following: 101 102 (a) Physicians and osteopaths licensed under Section 103 73-25-1 et seq.; Podiatrists licensed under Section 73-27-1 et seq.; 104 (b) 105 (c) Dentists and dental hygienists licensed under Section 73-9-1 et seq.; 106 107 (d) Optometrists licensed under Section 73-19-1 et 108 seq.; 109 (e) Pharmacists licensed under Section 73-21-71 et 110 seq.; 111 (f) Registered nurses and licensed practical nurses 112 licensed under Section 73-15-1 et seq.; and 113 Physician assistants licensed under Section 73-26-1 (g) 114 et seq. 115 (2) The State Board of Pharmacy; the State Department of 116 Health; the Division of Medicaid; any person, including a drug 117 manufacturer, or health care facility or government entity that donates drugs to the repository program; any pharmacy, hospital, 118 119 nonprofit clinic or health care professional that accepts or 120 dispenses drugs under the program; and any pharmacy, hospital, or nonprofit clinic that employs a health care professional who 121 122 accepts or dispenses drugs under the program, shall not be subject to any of the following for matters related to donating, 123 124 accepting, or dispensing drugs under the program: criminal

125 prosecution; liability in tort or other civil action or 126 professional disciplinary action.

A drug manufacturer shall not, be subject to criminal 127 128 prosecution or liability in tort or other civil action for matters 129 related to the donation, acceptance, or dispensing of a drug 130 manufactured by the drug manufacturer that is donated by any 131 person, health care facility or government entity under the program, including, but not limited to, liability for failure to 132 transfer or communicate product or consumer information, or for 133 134 improper storage or for the expiration date of the donated drug. 135 SECTION 5. Section 43-13-509, Mississippi Code of 1972, is

136 brought forward as follows:

137 43-13-509. (1) Not later than January 1, 2005, the State 138 Board of Pharmacy, in consultation with the State Department of 139 Health, shall adopt rules, in accordance with the Administrative 140 Procedures Law (Section 25-43-1 et seq.), governing the drug 141 repository program that establish all of the following:

142 (a) Eligibility criteria for pharmacies, hospitals and
143 nonprofit clinics to receive and dispense donated drugs under the
144 program;

145 (b) Standards and procedures for accepting, safely146 storing and dispensing donated drugs;

(c) Standards and procedures for inspecting donated drugs to determine that the original unit dose packaging is sealed and tamper-evident and that the drugs are unadulterated, safe and suitable for dispensing;

(d) Eligibility standards based on economic need forindividuals to receive drugs;

(e) A means, such as an identification card, by which an individual who is eligible to receive donated drugs may demonstrate eligibility to the pharmacy, hospital, or nonprofit clinic dispensing the drugs;

H. B. No. 121 07/HR40/R129 PAGE 5 (RF\BD) (f) A form that an individual receiving a drug from the repository must sign before receiving the drug to confirm that the individual understands the immunity provisions of the program, and waiving all right to sue any individual or entity involved in the program;

162 (g) A formula to determine the amount of a handling fee 163 that pharmacies, hospitals and nonprofit clinics may charge to 164 drug recipients to cover restocking and dispensing costs;

165 (h) In addition, for drugs donated to the repository by 166 individuals:

167 (i) A list of drugs, arranged either by category
168 or by individual drug, that the repository will accept from
169 individuals;

(ii) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from individuals. The list must include a statement as to why the drug is ineligible for donation; and

(iii) A form each donor must sign stating that the donor is the owner of the drugs and intends to voluntarily donate them to the repository;

177 (i) In addition, for drugs donated to the repository by178 health care facilities or government entities:

(i) A list of drugs, arranged either by category
or by individual drug, that the repository will accept from health
care facilities or government entities; and

(ii) A list of drugs, arranged either by category or by individual drug, that the repository will not accept from health care facilities or government entities. The list must include a statement as to why the drug is ineligible for donation; and

187 (j) Any other standards and procedures the board188 considers appropriate.

H. B. No. 121 07/HR40/R129 PAGE 6 (RF\BD) (2) The provisions of paragraphs (h)(ii) and (i)(ii) of subsection (1) of this section shall not be construed as prohibiting a pharmacy from accepting drugs that are not eligible to be dispensed under the drug repository program, for the proper disposal of those drugs.

194 **SECTION 6.** This act shall take effect and be in force from 195 and after July 1, 2007.