

The House Committee on Health and Human Services offers the following substitute to HB 897:

A BILL TO BE ENTITLED  
AN ACT

1 To amend Chapter 8 of Title 31 of the Official Code of Georgia Annotated, relating to the  
2 care and protection of indigent and elderly patients, so as to provide for the establishment and  
3 operation of a drug repository program to accept and dispense unused over-the-counter and  
4 prescription drugs; to provide for definitions; to provide for criteria and requirements for  
5 unused over-the-counter and prescription drugs; to provide procedures for donation and  
6 dispensing of unused over-the-counter and prescription drugs; to provide for limited liability;  
7 to provide for rules and regulations; to amend Chapter 4 of Title 26 of the Official Code of  
8 Georgia Annotated, relating to pharmacists and pharmacies, so as to repeal the "Utilization  
9 of Unused Prescription Drugs Act"; to amend Article 7 of Chapter 4 of Title 49 of the  
10 Official Code of Georgia Annotated, relating to medical assistance generally, so as to revise  
11 a provision for purposes of conformity; to provide for related matters; to repeal conflicting  
12 laws; and for other purposes.

13 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

14 **SECTION 1.**

15 Chapter 8 of Title 31 of the Official Code of Georgia Annotated, relating to the care and  
16 protection of indigent and elderly patients, is amended by adding a new article to read as  
17 follows:

18 "ARTICLE 10

19 31-8-300.

20 As used in this article, the term:

21 (1) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules  
22 I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of  
23 21 C.F.R. Part 1308.

24 (2) 'Eligible patient' means an individual who is indigent, uninsured, underinsured, or  
 25 enrolled in a public assistance health benefits program, in accordance with criteria  
 26 established by the Department of Public Health pursuant to Code Section 31-8-304.  
 27 Other individuals may be considered eligible patients if the need for donated drugs for  
 28 indigent, uninsured, underinsured, and public assistance health benefits program patients  
 29 is less than the supply of donated drugs.

30 (3) 'Eligible recipient' means a pharmacy, hospital, federally qualified health center,  
 31 nonprofit clinic, or other entity meeting the criteria established by the Department of  
 32 Public Health pursuant to Code Section 31-8-304.

33 (4) 'Health care facility' means a:

- 34 (A) Nursing home licensed pursuant to Article 1 of Chapter 7 of this title;
- 35 (B) Personal care home licensed pursuant to Code Section 31-7-12;
- 36 (C) Assisted living community licensed pursuant to Code Section 31-7-12.2;
- 37 (D) Hospice licensed pursuant to Article 9 of Chapter 7 of this title; and
- 38 (E) Home health agency licensed pursuant to Article 7 of Chapter 7 of this title.

39 (5) 'Health care professional' means any of the following who provide medical, dental,  
 40 or other health related diagnosis, care, or treatment:

- 41 (A) Physicians licensed to practice medicine under Chapter 34 of Title 43;
- 42 (B) Registered nurses and licensed practical nurses licensed under Chapter 26 of Title  
 43 43;
- 44 (C) Physician assistants licensed under Chapter 34 of Title 43;
- 45 (D) Dentists and dental hygienists licensed under Chapter 11 of Title 43;
- 46 (E) Optometrists licensed under Chapter 30 of Title 43; and
- 47 (F) Pharmacists licensed under Chapter 4 of Title 26.

48 (6) 'Hospital' means a facility licensed pursuant to Chapter 7 of this title.

49 (7) 'Program' means the drug repository program established pursuant to Code Section  
 50 31-8-301.

51 31-8-301.

52 (a) The Department of Public Health shall establish a drug repository program to accept  
 53 and dispense over-the-counter and prescription drugs donated for the purpose of being  
 54 dispensed to eligible patients.

55 (b) Drugs shall only be dispensed pursuant to the program if:

- 56 (1) For prescription drugs, they do not expire before the completion of the medication  
 57 by the eligible patient based on the prescribing health care professional's directions for  
 58 use and, for over-the-counter drugs, they do not expire before use by the eligible patient  
 59 based on the directions for use on the manufacturer's label; and

60 (2) The drugs were donated in unopened tamper-evident packaging as defined by United  
61 States Pharmacopeia General Chapter 659, Packaging and Storage Requirements,  
62 including but not limited to unopened unit-dose and multiple-dose packaging.

63 (c) The following drugs shall not be donated to the program:

64 (1) Controlled substances;

65 (2) Drugs subject to a federal Food and Drug Administration managed risk evaluation  
66 and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code  
67 if inventory transfer is prohibited by such strategy; or

68 (3) Drugs that there is reason to believe are adulterated pursuant to Code Section 26-3-7.

69 31-8-302.

70 (a) Any person, including a drug manufacturer, wholesaler, reverse distributor pharmacy,  
71 third-party logistics provider, government entity, hospital, or health care facility, may  
72 donate over-the-counter and prescription drugs to the program. The drugs shall be donated  
73 to an eligible recipient that voluntarily elects to participate in the program. Nothing in this  
74 or any other Code section shall require an eligible recipient to participate in the program.

75 (b) An eligible recipient may do any of the following:

76 (1) Accept and dispense donated drugs to eligible patients. Prescription drugs shall only  
77 be dispensed pursuant to a valid prescription drug order. Eligible patients who are  
78 indigent, uninsured, underinsured, or enrolled in a public assistance health benefits  
79 program in accordance with criteria established by the Department of Public Health  
80 pursuant to Code Section 31-8-304 shall be prioritized over other individuals;

81 (2) Transfer donated drugs to another eligible recipient participating in the program or  
82 to a drug repository program operated by another state;

83 (3) Repackage donated drugs as necessary for dispensing, administration, or transfers;  
84 and

85 (4) Replenish drugs previously dispensed or administered to eligible patients.

86 (c) An eligible recipient that accepts donated drugs shall comply with all applicable federal  
87 laws and laws of this state dealing with storage and distribution of dangerous drugs and  
88 shall inspect all drugs prior to dispensing them to determine that they are not adulterated.

89 (d) An eligible recipient may charge a handling fee established in accordance with rules  
90 and regulations adopted by the Department of Public Health pursuant to Code Section  
91 31-8-304; provided, however, that any such fee shall not exceed the reasonable costs of  
92 participating in the program.

93 (e) Drugs donated to the program shall not be resold; provided, however, that  
94 reimbursement for any fee charged as authorized pursuant to this article by a health plan  
95 or pharmacy benefits manager for donated drugs shall not constitute reselling. Nothing in

96 this article shall require a health plan or pharmacy benefits manager to be reimbursed for  
 97 donated drugs.

98 31-8-303.

99 When complying with the provisions of this article and the rules and regulations adopted  
 100 pursuant to this chapter, unless an action or omission constitutes willful or wanton  
 101 misconduct, the following persons or entities shall not be subject to criminal or civil  
 102 prosecution, criminal or civil liability for injury, death, or loss to person or property, other  
 103 criminal or civil action, or disciplinary actions by licensing, professional, or regulatory  
 104 agencies:

105 (1) A person that donates or gives drugs to an eligible recipient, including a drug  
 106 manufacturer, wholesaler, reverse distributor pharmacy, third-party logistics provider,  
 107 government entity, hospital, or health care facility;

108 (2) An eligible recipient;

109 (3) A health care professional who prescribes or dispenses a donated drug;

110 (4) The Department of Public Health and State Board of Pharmacy;

111 (5) An intermediary that helps administer the program by facilitating the donation or  
 112 transfer of drugs to eligible recipients;

113 (6) A manufacturer or repackager of a donated drug; and

114 (7) Any employee, volunteer, trainee, or other staff of individuals and entities listed in  
 115 paragraphs (1) through (6) of this Code section.

116 31-8-304.

117 (a) No later than January 1, 2017, the Department of Public Health shall establish rules and  
 118 regulations to implement the program according to the provisions of this article for criteria  
 119 for eligible recipients; standards and procedures for safely storing and dispensing donated  
 120 drugs; criteria for eligible patients to receive donated drugs, including priority for patients  
 121 who are indigent, uninsured, underinsured, or enrolled in a public assistance health benefits  
 122 program; and handling fees that may be charged by eligible recipients to eligible patients  
 123 to cover restocking, marketing, administrative, and dispensing costs.

124 (b) The Department of Public Health may waive any provision of this article if it  
 125 determines that the waiver is in the interest of public health and safety."

## 126 **SECTION 2.**

127 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and  
 128 pharmacies, is amended by repealing and reserving Article 11, the "Utilization of Unused  
 129 Prescription Drugs Act," in its entirety.

130 **SECTION 3.**

131 Article 7 of Chapter 4 of Title 49 of the Official Code of Georgia Annotated, relating to  
132 medical assistance generally, is amended by revising Code Section 49-4-152.5, relating to  
133 restocking fees, as follows:

134 "49-4-152.5.

135 In the provision of medical assistance pursuant to this article, the department shall allow  
136 for the payment and coverage of appropriate restocking fees incurred by a pharmacy which  
137 receives and dispenses unused over-the-counter and prescription drugs pursuant to ~~Article~~  
138 ~~11 of Chapter 4 of Title 26, the 'Utilization of Unused Prescription Drugs Act.'~~ Article 10  
139 of Chapter 8 of Title 31."

140 **SECTION 4.**

141 All laws and parts of laws in conflict with this Act are repealed.