The Senate Committee on Health and Human Services offered the following substitute to HB 1072:

A BILL TO BE ENTITLED AN ACT

1 To amend Titles 26, 31, and 48 of the Official Code of Georgia Annotated, relating to food, 2 drugs, and cosmetics, health, and revenue and taxation, respectively, so as to increase the 3 public's access to prescription drugs by increasing the number of pharmacy technicians 4 authorized to be supervised by a pharmacist in certain circumstances and by revising 5 provisions relative to the drug repository program; to authorize the Georgia State Board of 6 Pharmacy to increase the maximum ratio of pharmacists to pharmacy technicians in 7 closed-door pharmacies; to provide definitions; to provide for additional pharmacy 8 technicians for certain non-dispensing related duties in the drug repository program; to 9 require reverse drug distributors to make and document diligent efforts to donate drugs rather 10 than destroy them; to provide for an eligible recipient to substitute a drug under certain 11 circumstances; to provide for legislative intent regarding certain settlement funds received 12 by the state; to provide for referrals to the drug repository program; to exempt sales to or by 13 certain eligible recipients in the drug repository program; to provide for related matters; to 14 provide for legislative findings; to provide for an effective date and applicability; to repeal 15 conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

17	PART I
18	Closed-door pharmacies
19	SECTION 1-1.
20	Title 26 of the Official Code of Georgia Annotated, relating to food, drugs, and cosmetics
21	is amended in Code Section 26-4-82, relating to duties requiring professional judgment and
22	responsibilities of a licensed pharmacist, by revising subsection (d) as follows:
23	"(d) The board of pharmacy shall promulgate rules and regulations regarding the activities
24	and utilization of pharmacy technicians in pharmacies, including the establishment of a
25	registry as required in paragraph (7) of subsection (a) of Code Section 26-4-28; provided
26	however, that the pharmacist to pharmacy technician ratio shall not exceed one pharmacis
27	providing direct supervision of four pharmacy technicians. The board may consider and
28	approve an application to increase the ratio in a pharmacy located in a licensed hospital or
29	in a closed-door pharmacy. Such application must be made in writing and must be
30	submitted to the board by the pharmacist in charge of a specific hospital pharmacy in this
31	state or a specific closed-door pharmacy. At any time during which the pharmacist directly
32	supervises four or more pharmacy technicians, two of such technicians must be certified
33	At any time during which the pharmacist directly supervises three pharmacy technicians
34	one of such technicians must be certified. No certification is required for pharmacy
35	technicians in pharmacies at any time during which the pharmacist directly supervises one
36	or two pharmacy technicians. In order to be certified, pharmacy technicians must:
37	(1) Have successfully passed a certification program approved by the board of pharmacy
38	(2) Have successfully passed an employer's training and assessment program which has
39	been approved by the board of pharmacy; or
40	(3) Have been certified by either the Pharmacy Technician Certification Board or any
41	other nationally recognized certifying body approved by the board of pharmacy.

As used in this subsection, the term 'closed-door pharmacy' means a pharmacy that

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43 provides specialized services and is not open to the general public." 44 **PART II** 45 Drug repository program 46 **SECTION 2-1.** 47 The General Assembly finds: 48 (1) Access to affordable medications is a public health issue that disproportionately 49 impacts vulnerable patients, and a state's drug repository program can serve as a solution 50 to thousands of families for life-saving and life-preserving medications; and 51 (2) Participating recipient organizations can provide a valuable community benefit to 52 families in need by making donated medications available and will be authorized to utilize 53 additional pharmacy technicians to distribute donated medications under the drug 54 repository program. 55 **SECTION 2-2.** 56 Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by revising Code Section 31-8-300, relating to definitions relative to the drug repository program, as 58 follows: 59 "31-8-300. 60 As used in this article, the term: 61 (1) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules 62 I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 63 21 C.F.R. Part 1308 as of January 1, 2023. 64 (2) 'Disposition' means destroy, dispose of, return, quarantine, or otherwise prevent from 65 further distribution.

66 (3) 'Eligible drug' means an over-the-counter or prescription drug, including drugs

- 67 <u>labeled specifically for investigational use and approved by the United States Food and</u>
- Drug Administration as such, which may be donated to the program pursuant to Code
- 69 Section 31-8-301.
- 70 (2)(4) 'Eligible patient' means an individual who is indigent, uninsured, underinsured, or
- enrolled in a public assistance health benefits program, in accordance with criteria
- established by the Department of Public Health pursuant to Code Section 31-8-304.
- 73 Other individuals may be considered eligible patients if the need for donated drugs for
- indigent, uninsured, underinsured, and public assistance health benefits program patients
- is less than the supply of donated drugs.
- 76 (3)(5) 'Eligible recipient' means a pharmacy, hospital, federally qualified health center,
- 77 nonprofit clinic, or other entity meeting the criteria established by the Department of
- 78 Public Health pursuant to Code Section 31-8-304.
- 79 (6) 'Expiration date' means the original expiration date provided by the manufacturer or
- 80 repackager or the expiration date provided on the medication's packaging or prescription
- 81 <u>drug label.</u>
- 82 (4)(7) 'Health care facility' means a:
- 83 (A) Nursing home licensed pursuant to Article 1 of Chapter 7 of this title;
- (B) Personal care home licensed pursuant to Code Section 31-7-12;
- 85 (C) Assisted living community licensed pursuant to Code Section 31-7-12.2;
- 86 (D) Hospice licensed pursuant to Article 9 of Chapter 7 of this title; and
- 87 (E) Home health agency licensed pursuant to Article 7 of Chapter 7 of this title.
- 88 (5)(8) 'Health care professional' means any of the following who provide medical, dental,
- 89 or other health related diagnosis diagnoses, care, or treatment:
- 90 (A) Physicians licensed to practice medicine under Chapter 34 of Title 43;
- 91 (B) Registered nurses and licensed practical nurses licensed under Chapter 26 of
- 92 Title 43;

- 93 (C) Physician assistants licensed under Chapter 34 of Title 43;
- 94 (D) Dentists and dental hygienists licensed under Chapter 11 of Title 43;
- 95 (E) Optometrists licensed under Chapter 30 of Title 43; and
- 96 (F) Pharmacists licensed under Chapter 4 of Title 26.
- 97 (6)(9) 'Hospital' means a facility licensed pursuant to Chapter 7 of this title.
- 98 (7)(10) 'Program' means the drug repository program established pursuant to Code
- 99 Section 31-8-301.
- 100 (11) 'Short-dated' means within five months of a drug's expiration date."
- 101 **SECTION 2-3.**
- 102 Said title is further amended by revising Code Section 31-8-301, relating to the establishment
- 103 of a drug repository program and criteria and requirements for unused over-the-counter and
- 104 prescription drugs, as follows:
- 105 "31-8-301.
- 106 (a) The Department of Public Health shall establish a drug repository program to accept
- and dispense over-the-counter and prescription drugs donated for the purpose of being
- dispensed to eligible patients.
- 109 (b) Drugs shall only be dispensed pursuant to the program if:
- (1) For prescription drugs, they do with an expiration date that does not expire before the
- 111 completion of the medication by the eligible patient based on the prescribing health care
- professional's directions for use and, for over-the-counter drugs, they do with an
- expiration date that does not expire before use by the eligible patient based on the
- directions for use on the manufacturer's label; and
- 115 (2) The drugs were donated in unopened tamper-evident packaging as defined by United
- States Pharmacopeia General Chapter 659, Packaging and Storage Requirements,
- including but not limited to unopened unit-dose and multiple-dose packaging.
- 118 (c) The following drugs shall not be donated to the program:

- 119 (1) Controlled substances;
- 120 (2) Drugs subject to a federal Food and Drug Administration managed risk evaluation
- and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code
- if inventory transfer is prohibited by such strategy; or
- 123 (3) Drugs that there is reason to believe are adulterated pursuant to Code Section 26-3-7."

124 **SECTION 2-4.**

- 125 Said title is further amended in Code Section 31-8-302, relating to procedures for donation
- 126 and dispensing of unused over-the-counter and prescription drugs, by adding new subsections
- 127 to read as follows:
- 128 "(f) In addition to the maximum number of pharmacy technicians that are authorized to be
- 129 under the direct supervision of a pharmacist pursuant to subsection (d) of Code
- 130 Section 26-4-82, a participating pharmacy may utilize up to two additional pharmacy
- technicians under the direct supervision of such pharmacist for duties related to the
- program; provided, however, that the two such additional pharmacy technicians shall not
- be authorized to assist the supervising pharmacist in connection with any activities related
- to completing a prescription drug order or preparation of a prescription drug for a patient,
- but shall only be authorized to perform non-dispensing related duties, such as, but not
- limited to, receiving and stocking inventory.
- 137 (g) A reverse drug distributor permitted or licensed by the State Board of Pharmacy shall:
- 138 (1) Make and document diligent efforts to donate eligible drugs within 30 days of taking
- possession to the program in accordance with Code Section 31-8-301 rather than destroy
- such drugs;
- 141 (2) Not directly or indirectly by transferring to another entity or by other means, cause
- eligible drugs to be dispositioned, become short-dated, expire, or otherwise become
- ineligible for donation; and

144 (3) Make and document diligent efforts to ensure that any policy, contract, or other 145 business arrangement between the reverse drug distributor and its clients or other parties does not prohibit the donation of eligible drugs received from any such client or other 146 147 party to the program in accordance with Code Section 31-8-301; provides for the same rate of compensation for the client or other party for donation of eligible drugs and other 148 disposition of such drugs; and does not require an eligible drug to be dispositioned, 149 become short-dated, expire, or otherwise become ineligible for donation. 150 151 (h) Any person or entity eligible to donate drugs under the program shall be allowed to donate eligible drugs in the same manner, at the same rate of compensation, and paid for 152 by the same parties as applies to the disposition of drugs regardless of any policy, contract, 153 or other business arrangement that would have otherwise directly or indirectly by 154 transferring to another entity or by other means required an eligible drug to be 155 dispositioned, become short-dated, expire, or otherwise become ineligible for donation. 156 157 (i) The donation, brokering, or other facilitation of a donation of a drug pursuant to this 158 program shall not be considered wholesale distribution as defined in Code Section 26-4-201 and shall not be subject to or require licensure as a wholesale distributor pursuant 159 160 to Chapter 4 of Title 26. 161 (i) Eligible recipients that provide pharmacy related services only for the purpose of 162 dispensing donated or purchased drugs pursuant to the program shall not be subject to comprehensive formulary or minimum supply of drugs requirements contained in 163 164 Chapter 4 of Title 26."

165 **SECTION 2-5.**

166 Said article is further amended by adding new Code sections to read as follows:

- 167 "<u>31-8-305.</u>
- 168 (a) Notwithstanding Article 5 of Chapter 4 of Title 26, an eligible recipient may substitute:
- (1) A prescribed drug with a therapeutically equivalent drug; or

- 170 (2) A biological product with an interchangeable biological product.
- 171 (b) Substitutions made pursuant to subsection (a) of this Code section may include, but are
- 172 <u>not limited to:</u>
- (1) Splitting a combination drug into two or more drugs;
- (2) Combining two or more drugs into a combination drug; and
- 175 (3) Substituting a different form of a prescribed drug, including, but not limited to, an
- oral tablet or capsule.
- 177 (c) If an eligible recipient dispenses or administers a substitute drug pursuant to this Code
- 178 section, such substitution shall be communicated to the patient and the prescribing health
- care professional, unless the program's substitution policy is readily available on the
- 180 eligible recipient's website.
- 181 (d) Whenever a substitution is made, the eligible recipient shall record on the original
- prescription or the patient's prescription drug label that there has been a substitution and
- the identity of the dispensed drug product or interchangeable biological product.
- 184 31-8-306.
- 185 (a) It is the intent of the General Assembly that a portion of the proceeds of settlements
- 186 received by the state relating to prescription drugs that are not controlled substances be
- appropriated for purposes of the program and distributed to eligible recipients in proportion
- to each such recipient's participation rate in the program.
- 189 (b) It is further the intent of the General Assembly that if funds are appropriated for
- purposes of this article, the department shall be required to distribute such appropriations
- 191 to eligible recipients in proportion to each such recipient's level of participation in the
- 192 program.

- 193 31-8-307.
- 194 (a) Hospitals and pharmacies licensed in this state and state programs that provide health
- care coverage or health care services to patients, recipients, or other individuals in this
- state, including, but not limited to, Medicaid, PeachCare for Kids Program, alcohol and
- drug awareness programs, and the Department of Corrections shall provide such patients,
- 198 recipients, or other individuals with referral information to the program for eligible drugs
- 199 available through the program for:
- 200 (1) Drugs not currently covered under a state program;
- 201 (2) Patients who do not meet the eligibility coverage for a state program or become
- 202 <u>unenrolled or leave a state program;</u>
- 203 (3) Drugs that are covered under a state program but are otherwise inaccessible to a
- 204 patient due to, but not limited to a gap in coverage or out-of-pocket costs that are too high
- 205 <u>for a specific patient, recipient, or other individual; a prior authorization requirement; step</u>
- 206 <u>therapy requirements; or high co-payments; or</u>
- 207 (4) A patient, recipient, or other individual for a drug that is covered under a state
- program but that the claim for coverage is denied with respect to the specific patient,
- 209 <u>recipient, or other individual.</u>
- 210 (b) Recipients of the federal Title X Family Planning Program shall make and document
- 211 <u>diligent efforts to subcontract with interested eligible recipients participating in the</u>
- 212 program to offer family planning services to rural and low-income populations.
- 213 (c) If an eligible recipient offers value-added services and referrals, in addition to just
- 214 providing medicine, such eligible recipient may also be eligible for discounted medication
- 215 pricing to help widen such eligible recipient's formularies of medication and increase
- 216 <u>financial sustainability of its participation in the program.</u>"

217	SECTION 2-6.
218	Title 48 of the Official Code of Georgia Annotated, relating to revenue and taxation, is
219	amended in Code Section 48-8-3, relating to exemptions from sales and use taxes, by
220	deleting "or" at the end of paragraph (103), by replacing the period with "; or" at the end of
221	paragraph (104), and by adding a new paragraph to read as follows:
222	"(105) Sales to or by an eligible recipient, as defined in Code Section 31-8-300, which
223	provides pharmacy related services only for the purpose of dispensing donated or
224	purchased drugs pursuant to the drug repository program established under Article 10 of
225	Chapter 8 of Title 31, if such organization qualifies as a tax-exempt organization under
226	Section 501(c)(3) of the Internal Revenue Code or is an organization that is treated for
227	federal income tax purposes as a disregarded entity of a tax-exempt organization under
228	Section 501(c)(3) of the Internal Revenue Code."
229	PART III
230	Effective date and repealer
231	SECTION 3-1.
232	This Act shall become effective upon its approval by the Governor or upon its becoming law
233	without such approval; provided, however, that Section 2-6 of this Act shall be applicable
234	to taxable years beginning on or after January 1, 2025.
235	SECTION 3-2.
236	All laws and parts of laws in conflict with this Act are repealed.