House Bill 1072

By: Representatives Cooper of the 45th, Newton of the 127th, Parrish of the 158th, Jackson of the 128th, Stephens of the 164th, and others

A BILL TO BE ENTITLED AN ACT

To amend Article 10 of Chapter 8 of Title 31 of the Official Code of Georgia Annotated, 1 relating to the drug repository program, so as to revise definitions; to provide for pharmacist 2 3 to pharmacy technician ratios in the program; to require reverse drug distributors to make and 4 document diligent efforts to donate drugs rather than destroy them; to provide for substitution 5 of drugs in some instances; to provide for the intent of the General Assembly with respect 6 to settlement funds received by the state relating to prescription drugs; to amend Code 7 Section 48-8-3 of the Official Code of Georgia Annotated, relating to exemptions from sales 8 and use taxes, so as to exempt sales to or by certain eligible recipients; to provide for related 9 matters; to provide for legislative findings; to repeal conflicting laws; and for other purposes.

10 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

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SECTION 1.

12 The General Assembly finds:

13 (1) Access to affordable medications is a public health issue that disproportionately

14 impacts vulnerable patients, and a state's drug repository program can serve as a solution

15 to thousands of families for life-saving and life-preserving medications; and

(2) Participating recipient organizations can provide a valuable community benefit to
 families in need by making donated medications available and will be authorized to utilize
 additional pharmacy technicians to distribute donated medications under the drug
 repository program.

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SECTION 2.

Article 10 of Chapter 8 of Title 31 of the Official Code of Georgia Annotated, relating to the
drug repository program, is amended by revising Code Section 31-8-300, relating to
definitions, as follows:

24 *"*31-8-300.

25 As used in this article, the term:

26 (1) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules

27 I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of

28 21 C.F.R. Part 1308 <u>as of January 1, 2023</u>.

(2) 'Disposition' means destroy, dispose of, return, quarantine, or otherwise prevent from
 further distribution.

31 (3) 'Eligible drug' means an over-the-counter or prescription drug, including drugs
 32 labeled specifically for investigational use and approved by the United States Food and
 33 Drug Administration as such, which may be donated to the program pursuant to Code
 34 Section 31-8-301.

(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.
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.

41	(3)(5) 'Eligible recipient' means a pharmacy, hospital, federally qualified health center,
42	nonprofit clinic, or other entity meeting the criteria established by the Department of
43	Public Health pursuant to Code Section 31-8-304.
44	(6) 'Expiration date' means the original expiration date provided by the manufacturer or
45	repackager or the expiration date provided on the medication's packaging or prescription
46	drug label.
47	(4)(7) 'Health care facility' means a:
48	(A) Nursing home licensed pursuant to Article 1 of Chapter 7 of this title;
49	(B) Personal care home licensed pursuant to Code Section 31-7-12;
50	(C) Assisted living community licensed pursuant to Code Section 31-7-12.2;
51	(D) Hospice licensed pursuant to Article 9 of Chapter 7 of this title; and
52	(E) Home health agency licensed pursuant to Article 7 of Chapter 7 of this title.
53	(5)(8) 'Health care professional' means any of the following who provide medical, dental,
54	or other health related diagnosis diagnoses, care, or treatment:
55	(A) Physicians licensed to practice medicine under Chapter 34 of Title 43;
56	(B) Registered nurses and licensed practical nurses licensed under Chapter 26 of Title
57	43;
58	(C) Physician assistants licensed under Chapter 34 of Title 43;
59	(D) Dentists and dental hygienists licensed under Chapter 11 of Title 43;
60	(E) Optometrists licensed under Chapter 30 of Title 43; and
61	(F) Pharmacists licensed under Chapter 4 of Title 26.
62	(6)(9) 'Hospital' means a facility licensed pursuant to Chapter 7 of this title.
63	(7)(10) 'Program' means the drug repository program established pursuant to Code
64	Section 31-8-301.
65	(11) 'Short-dated' means within five months of a drug's expiration date."

66	SECTION 3.
67	Said article is further amended by revising Code Section 31-8-301, relating to the
68	establishment of a drug repository program and criteria and requirements for unused
69	over-the-counter and prescription drugs, as follows:
70	"31-8-301.
71	(a) The Department of Public Health shall establish a drug repository program to accept
72	and dispense over-the-counter and prescription drugs donated for the purpose of being
73	dispensed to eligible patients.
74	(b) Drugs shall only be dispensed pursuant to the program if:
75	(1) For prescription drugs, they do with an expiration date that does not expire before the
76	completion of the medication by the eligible patient based on the prescribing health care
77	professional's directions for use and, for over-the-counter drugs, they do with an
78	expiration date that does not expire before use by the eligible patient based on the
79	directions for use on the manufacturer's label; and
80	(2) The drugs were donated in unopened tamper-evident packaging as defined by United
81	States Pharmacopeia General Chapter 659, Packaging and Storage Requirements,
82	including but not limited to unopened unit-dose and multiple-dose packaging.
83	(c) The following drugs shall not be donated to the program:
84	(1) Controlled substances;
85	(2) Drugs subject to a federal Food and Drug Administration managed risk evaluation
86	and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code
87	if inventory transfer is prohibited by such strategy; or
88	(3) Drugs that there is reason to believe are adulterated pursuant to Code Section 26-3-7."

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89	SECTION 4.
90	Said article is further amended in Code Section 31-8-302, relating to procedures for donation
91	and dispensing of unused over-the-counter and prescription drugs, by adding new subsections
92	to read as follows:
93	"(f) In addition to the maximum number of pharmacy technicians that are authorized to be
94	under the direct supervision of a pharmacist pursuant to subsection (d) of Code Section
95	26-4-82, a participating pharmacy may utilize up to two additional pharmacy technicians
96	under the direct supervision of such pharmacist for duties related to the program; provided,
97	however, that the two such additional pharmacy technicians shall not be authorized to assist
98	the supervising pharmacist in connection with any activities related to completing a
99	prescription drug order or preparation of a prescription drug for a patient, but shall only be
100	authorized to perform non-dispensing related duties, such as, but not limited to, receiving
101	and stocking inventory.
102	(g) A reverse drug distributor permitted or licensed by the State Board of Pharmacy shall:
103	(1) Make and document diligent efforts to donate eligible drugs within 30 days of taking
104	possession to the program in accordance with Code Section 31-8-301 rather than destroy
105	such drugs;
106	(2) Not directly or indirectly by transferring to another entity or by other means, cause
107	eligible drugs to be dispositioned, become short-dated, expire, or otherwise become
108	ineligible for donation; and
109	(3) Make and document diligent efforts to ensure that any policy, contract, or other
110	business arrangement between the reverse drug distributor and its clients or other parties
111	does not prohibit the donation of eligible drugs received from any such client or other
112	party to the program in accordance with Code Section 31-8-301; provides for the same
113	rate of compensation for the client or other party for donation of eligible drugs and other
114	disposition of such drugs; and does not require an eligible drug to be dispositioned,
115	become short-dated, expire, or otherwise become ineligible for donation.

116	(h) Any person or entity eligible to donate drugs under the program shall be allowed to
117	donate eligible drugs in the same manner, at the same rate of compensation, and paid for
118	by the same parties as applies to the disposition of drugs regardless of any policy, contract,
119	or other business arrangement that would have otherwise directly or indirectly by
120	transferring to another entity or by other means required an eligible drug to be
121	dispositioned, become short-dated, expire, or otherwise become ineligible for donation.
122	(i) The donation, brokering, or other facilitation of a donation of a drug pursuant to this
123	program shall not be considered wholesale distribution as defined in Code Section
124	26-4-201 and shall not be subject to or require licensure as a wholesale distributor pursuant
125	to Chapter 4 of Title 26.
126	(j) Eligible recipients that provide pharmacy related services only for the purpose of
127	dispensing donated or purchased drugs pursuant to the program shall not be subject to
128	comprehensive formulary or minimum supply of drugs requirements contained in
129	Chapter 4 of Title 26."
130	SECTION 5.
131	Said article is further amended by adding new Code sections to read as follows:
132	″ <u>31-8-305.</u>
133	(a) Notwithstanding Article 5 of Chapter 4 of Title 26, an eligible recipient may substitute:
134	(1) A prescribed drug with a therapeutically equivalent drug; or
135	(2) A biological product with an interchangeable biological product.
136	(b) Substitutions made pursuant to subsection (a) of this Code section may include, but are
137	not limited to:
138	(1) Splitting a combination drug into two or more drugs;
139	(2) Combining two or more drugs into a combination drug; and
140	(3) Substituting a different form of a prescribed drug, including, but not limited to, an
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141 <u>oral tablet or capsule.</u>

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142	(c) If an eligible recipient dispenses or administers a substitute drug pursuant to this Code
143	section, such substitution shall be communicated to the patient and the prescribing health
144	care professional, unless the program's substitution policy is readily available on the
145	eligible recipient's website.
146	(d) Whenever a substitution is made, the eligible recipient shall record on the original
147	prescription or the patient's prescription drug label that there has been a substitution and
148	the identity of the dispensed drug product or interchangeable biological product.
149	<u>31-8-306.</u>
150	(a) It is the intent of the General Assembly that a portion of the proceeds of settlements
151	received by the state relating to prescription drugs that are not controlled substances be
152	appropriated for purposes of the program and distributed to eligible recipients in proportion
153	to each such recipient's participation rate in the program.
154	(b) It is further the intent of the General Assembly that if funds are appropriated for
155	purposes of this article, the department shall be required to distribute such appropriations
156	to eligible recipients in proportion to each such recipient's level of participation in the
157	program.
158	<u>31-8-307.</u>
159	(a) Hospitals and pharmacies licensed in this state and state programs that provide health
160	care coverage or health care services to patients, recipients, or other individuals in this
161	state, including, but not limited to, Medicaid, PeachCare for Kids Program, alcohol and
162	drug awareness programs, and the Department of Corrections shall provide such patients,
163	recipients, or other individuals with referral information to the program for eligible drugs
164	available through the program for:
165	(1) Drugs not currently covered under a state program;

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166	(2) Patients who do not meet the eligibility coverage for a state program or become
167	unenrolled or leave a state program;
168	(3) Drugs that are covered under a state program but are otherwise inaccessible to a
169	patient due to, but not limited to a gap in coverage or out-of-pocket costs that are too high
170	for a specific patient, recipient, or other individual; a prior authorization requirement; step
171	therapy requirements; or high co-payments; or
172	(4) A patient, recipient, or other individual for a drug that is covered under a state
173	program but that the claim for coverage is denied with respect to the specific patient,
174	recipient, or other individual.
175	(b) Recipients of the federal Title X Family Planning Program shall make and document
176	diligent efforts to subcontract with interested eligible recipients participating in the
177	program to offer family planning services to rural and low-income populations.
178	(c) If an eligible recipient offers value-added services and referrals, in addition to just
179	providing medicine, such eligible recipient may also be eligible for discounted medication
180	pricing to help widen such eligible recipient's formularies of medication and increase
181	financial sustainability of its participation in the program."
182	SECTION 6.

Code Section 48-8-3 of the Official Code of Georgia Annotated, relating to exemptions from sales and use taxes, is amended by striking "or" at the end of paragraph (103), by striking the period and substituting in lieu thereof "; or" at the end of paragraph (104), and by adding a new paragraph to read as follows:

- 187 "(105) Sales to or by an eligible recipient, as defined in Code Section 31-8-300, which
- 188 provides pharmacy related services only for the purpose of dispensing donated or
- 189 purchased drugs pursuant to the drug repository program established under Article 10 of
- 190 <u>Chapter 8 of Title 31, if such organization qualifies as a tax-exempt organization under</u>
- 191 Section 501(c)(3) of the Internal Revenue Code or is an organization that is treated for

- 192 <u>federal income tax purposes as a disregarded entity of a tax-exempt organization under</u>
- 193 <u>Section 501(c)(3) of the Internal Revenue Code.</u>"

194 **SECTION 7.**

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