House Bill 261 (COMMITTEE SUBSTITUTE)

By: Representatives Parham of the 94th, Stephens of the 123rd, Parrish of the 102nd, Twiggs of the 8th, and Graves of the 106th

A BILL TO BE ENTITLED AN ACT

- 1 To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to
- 2 controlled substances, so as to change the listings of controlled substances and dangerous
- 3 drugs; to provide for exempt over-the-counter controlled substances; to require certain
- 4 information to be included on certain prescription drug orders; to permit prescription drug
- 5 orders to be transmitted by electronic means; to provide for related matters; to provide for
- 6 an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 SECTION 1.

- 9 Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled
- substances, is amended by adding to Code Section 16-13-21, relating to definitions, new
- 11 paragraphs (6.1), (6.2), and (12.5) to read as follows:
- 12 "(6.1) 'Dangerous drug' means any drug, other than a controlled substance, which cannot
- be dispensed except upon the issuance of a prescription drug order by a practitioner
- authorized under this chapter.

7

- 15 (6.2) 'DEA' means the United States Drug Enforcement Administration."
- 16 "(12.05) 'FDA' means the United States Food and Drug Administration."

17 SECTION 2.

- 18 Said chapter is further amended by striking paragraphs (5) and (6) of Code Section 16-13-25,
- 19 relating to Schedule I controlled substances, and inserting in lieu thereof the following:
- 20 "(5) Any material, compound, mixture, or preparation which contains any quantity of the
- following substances, their salts, isomers (whether optical, position, or geometrics), and
- salts of isomers, unless specifically excepted, whenever the existence of these substances,
- their salts, isomers, and salts of isomers is possible within the specific chemical
- 24 designation:

1	(A) Gamma hydroxybutyric acid (gamma hydroxy butyrate); provided, however, that
2	this does not include any amount naturally and normally occurring in the human body;
3	and
4	(B) Sodium oxybate, when the FDA approved form of this drug is not:
5	(i) In a container labeled in compliance with subsection (a) or (b) of Code Section
6	<u>26-3-8; and</u>
7	(ii) In the possession of:
8	(I) A registrant permitted to dispense the drug;
9	(II) Any person other than to whom the drug was prescribed; or
0	(III) Any person who attempts to or does unlawfully possess, sell, distribute, or
1	give this drug to any other person;
12	(6) Notwithstanding the fact that Schedule I substances have no currently accepted
13	medical use, the General Assembly recognizes certain of these substances which are
4	currently accepted for certain limited medical uses in treatment in the United States but
15	have a high potential for abuse. Accordingly, unless specifically excepted or unless listed
6	in another schedule, any material, compound, mixture, or preparation which contains any
17	quantity of methaqualone, including its salts, isomers, optical isomers, salts of their
8	isomers, and salts of these optical isomers, is included in Schedule I:
9	(7) 2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7);
20	(8) 1-(3-Trifluromethylphenyl) Piperazine (TFMPP);
21	(9) N-Benzylpiperazine (BZP)."
22	SECTION 3.
23	Said chapter is further amended by striking paragraph (8) of Code Section 16-13-27, relating
24	to Schedule III controlled substances, and inserting in its place the following:
25	"(8) Dronabinol (synthetic) in sesame oil and encapsulated in a U.S. Food and Drug
26	Administration approved drug product also known as Marinol-:
27	(9) Sodium oxybate, when the FDA approved form of this drug is in a container labeled
28	in compliance with subsection (a) or (b) of Code Section 26-3-8, in the possession of a
29	registrant permitted to dispense the drug, or in the possession of a person to whom it has
30	been lawfully prescribed;
31	(10) Buprenorphine."
32	SECTION 4.
33	Said chapter is further amended by striking paragraph (9), designating said paragraph as
34	reserved, and by adding a new paragraph (30.05) to subsection (a) of Code Section 16-13-28,
35	relating to Schedule IV controlled substances, to read as follows:

- 1 "(9) Dextropropoxyphene Reserved;"
- 2 "(30.05) Propoxyphene (including all salts and optical isomers);".

3 SECTION 5.

- 4 Said chapter is further amended by striking paragraph (2) from Code Section 16-13-29,
- 5 relating to Schedule V controlled substances, and inserting in its place the following:
- 6 "(2) Buprenorphine Reserved."

7 SECTION 6.

- 8 Said chapter is further amended by adding a new Code Section 16-13-29.2 to read as follows:
- 9 "16-13-29.2.
- 10 The Georgia State Board of Pharmacy shall have the authority to exempt and control the
- sale of Schedule V controlled substances by rule which shall allow the sale of such
- substances without the need for issuance of a prescription from a medical practitioner and
- shall require such substances to be sold only in a pharmacy when such substances are sold
- without a prescription. Such substances shall be known as Exempt Over-the-Counter
- 15 (OTC) Schedule V Controlled Substances."

SECTION 7.

- 17 Said chapter is further amended by striking subsection (b) and paragraph (2) of subsection
- 18 (d) of Code Section 16-13-41, relating to prescriptions, and inserting in their respective
- 19 places the following:
- 20 "(b) When a registered practitioner writes a prescription drug order to cause the dispensing
- of a Schedule II substance, he or she shall include the name and address of the person for
- 22 whom it is prescribed, the kind and quantity of such Schedule II controlled substance, the
- directions for taking, the signature, and the name, address, <u>telephone number</u>, and federal
- 24 <u>DEA</u> registration number of the prescribing practitioner. Such prescriptions shall be signed
- and dated by the prescribing practitioner on the date when issued, and the nature of such
- 26 <u>signatures shall be defined in regulations promulgated by the State Board of Pharmacy</u>.
- 27 Prescription drug orders for Schedule II controlled substances may be transmitted via
- 28 facsimile machine or other electronic means only in accordance with regulations
- promulgated by the State Board of Pharmacy in accordance with Code Section 26-4-80 or
- 30 26-4-80.1, or in accordance with DEA regulations at 21 C.F.R. 1306."
- 31 "(2) When a registered practitioner writes a prescription drug order to cause the
- dispensing of a Schedule III, IV, or V controlled substance, he <u>or she</u> shall include the
- name and address of the person for whom it is prescribed, the kind and quantity of such
- 34 controlled substance, the directions for taking, the signature, and the name, address,

1 <u>telephone number</u>, and <u>federal DEA</u> registration number of the <u>prescribing</u> practitioner.

- 2 Such prescriptions shall be signed and dated <u>or may be issued orally</u> by the prescribing
- 3 practitioner on the date when issued, and the nature of the signature of the prescriber shall
- 4 <u>meet the guidelines set forth in Chapter 4 of Title 26, the regulations promulgated by the</u>
- 5 State Board of Pharmacy, or both such guidelines and regulations."
- 6 SECTION 8.
- 7 Said chapter is further amended by striking from subsection (b) of Code Section 16-13-71,
- 8 relating to the list of dangerous drugs, the following paragraphs:
- 9 "(119.05) Butenafine;"
- 10 "(349.7) Reserved;"
- 11 "(529.9) Loratadine;"
- 12 "(623.5) Mometazone;"
- 13 "(752.2) Poractant Alpha;"
- 14 "(1002) Triprolidine;".
- 15 SECTION 9.
- 16 Said chapter is further amended by adding in the appropriate positions in subsection (b) of
- 17 Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:
- 18 "(22.2) Almotriptan;"
- 19 "(50.4) Anakinra;"
- 20 "(68.15) Atomoxetine;"
- 21 "(98.2) Bimatoprost;"
- 22 "(102.5) Bivalirudin;"
- 23 "(105.5) Bosentan;"
- 24 "(105.7) Botulinum toxin (B);"
- 25 "(119.05) Butenafine See exceptions;"
- 26 "(146.6) Caspofungin;"
- 27 "(151.45) Cefditoren;"
- 28 "(240.5) Darbepoetin alfa;"
- 29 "(251.5) Desloratadine;"
- 30 "(293.5) Dimyristoyl;"
- 31 "(325.3) Drospirenone;"
- 32 "(325.4) Drotrecogin alfa;"
- 33 "(325.5) Dutasteride;"
- 34 "(346.5) Ertapenem;"
- 35 "(349.7) Esomeprazole;"

- 1 "(404.7) Fondaparinux;"
- 2 "(406.2) Formoterol;"
- 3 "(406.95) Frovatriptan;"
- 4 "(408.9) Galantamine;"
- 5 "(464.8) Imatinib;"
- 6 "(474.2) Insulin aspart;"
- 7 "(513.8) Letrozole;"
- 8 "(529.9) Loratadine See exceptions;"
- 9 "(623.5) Mometasone;"
- 10 "(625.3) Moxidectin;"
- 11 "(640.2) Nesiritide;"
- 12 "(644.8) Nitisinone;"
- 13 "(703.45) Perflexane;"
- 14 "(703.65) Perflutren;"
- 15 "(732.9) Pimecrolimus;"
- 16 "(752.2) Poractant alfa;"
- 17 "(930.9) Tadalafil;"
- 18 "(931.55) Tegaserod;"
- 19 "(931.85) Tenofovir;"
- 20 "(932.3) Teriparatide;"
- 21 "(974.4) Travoprost;"
- 22 "(974.7) Treprostinil;"
- 23 "(1002) Triprolidine See exceptions;"
- 24 "(1021.8) Valdecoxib;"
- 25 "(1022.2) Valganciclovir;"
- 26 "(1037.5) Voriconazole;"
- 27 "(1042.75) Ziprasidone;"
- 28 "(1042.8) Zoledronic Acid;".
- 29 **SECTION 10.**
- 30 Said chapter is further amended by striking from subsection (c) of Code Section 16-13-71,
- 31 relating to the list of dangerous drugs, the following paragraphs:
- 32 "(12) Insulin, All;"
- 33 "(14.1) Miconazole when used as antifungal powder, cream, or both, and containing
- not more than 4 percent of miconazole nitrate, and when used as a vaginal insert of up to
- 35 200 mg. in strength;".

SECTION 11.

- 2 Said chapter is further amended by adding in the appropriate positions in subsection (c) of
- 3 Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:
- 4 "(6.2) Butenafine when used with a strength of 1 percent or less as a topical
- 5 preparation;"
- 6 "(12) Insulin all injectable products which do not require a prescription drug order and
- bear a label which indicates 'Rx Use Only' or are otherwise listed under subsection (b) of
- 8 this Code section; and no injectable insulin product may be sold except by a pharmacy
- 9 issued a permit by the State Board of Pharmacy or by a medical practitioner authorized
- to dispense medications;"
- 11 "(13.7) Loratadine when used in a single dose of 10 mg. or less, including doses used
- in combination with other drugs provided for under this subsection;"
- 13 "(14.1) Miconazole when used as antifungal powder or cream, or both, and containing
- not more than 4 percent of miconazole, or when used as a vaginal insert and containing
- not more than 1,200 mg. of miconazole;"
- 16 "(28.5) Triprolidine when a single dose is 5 mg. or less when combined in the same
- preparation as one or more other drug products for use as an antihistamine or
- decongestant or an antihistimine and decongestant;".

19 **SECTION 12.**

- 20 Said chapter is further amended by striking subsection (a) of Code Section 16-13-74, relating
- 21 to written prescriptions for dangerous drugs, content, and signature, and inserting in its place
- 22 the following:

29

- 23 "(a) All written prescriptions prescription drug orders for dangerous drugs shall be dated
- as of, and be signed on, the date when issued and shall bear the full name and address of
- 25 the patient, together with the name and strength of the drug, the quantity to be dispensed,
- 26 complete directions for administration, <u>the printed name</u>, <u>address</u>, and <u>telephone number</u>
- 27 <u>of the practitioner,</u> and the number of permitted refills. A practitioner may sign a
- 28 prescription as he would sign a check or a legal document. The prescription shall be written
- 30 practitioner. The prescription may be prepared by a secretary or other agent, for the

with indelible pencil or indelible ink or typewritten and shall be manually signed by the

- 31 signature of the practitioner, but the prescribing practitioner shall be responsible if the
- 32 prescription does not conform in all essential respects to state and federal laws and
- regulations. A prescription drug order for a dangerous drug is not required to bear the DEA
- permit number of the prescribing practitioner. A prescription drug order for a dangerous
- drug may be prepared by the practitioner or the practitioner's agent. The practitioner's
- 36 <u>signature must appear on each prescription prepared by the practitioner or the practitioner's</u>

1 agent and the nature of the practitioner's signature must meet the guidelines set forth in

- 2 Chapter 4 of Title 26, the regulations promulgated by the State Board of Pharmacy, or both
- 3 <u>such guidelines and regulations</u>. Any practitioner who shall dispense dangerous drugs shall
- 4 comply with the provisions of Code Section 16-13-73."

5 SECTION 13.

- 6 This Act shall become effective upon its approval by the Governor or upon its becoming law
- 7 without such approval.

8 SECTION 14.

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