House Bill 261 (AS PASSED HOUSE AND SENATE)

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.

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- 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,
- 23 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
10	(III) Any person who attempts to or does unlawfully possess, sell, distribute, or
11	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
14	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
16	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
18	isomers, and salts of these optical isomers, is included in Schedule I- $\underline{:}$
19	(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:

- "(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.

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- 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 <u>or she</u> 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, telephone number, 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:

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- 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, the printed name, address, and telephone number
- 27 of the practitioner, 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
- 29 with indelible pencil or indelible ink or typewritten and shall be manually signed by the
- 30 practitioner. The prescription may be prepared by a secretary or other agent, for the
- 32 prescription does not conform in all essential respects to state and federal laws and

signature of the practitioner, but the prescribing practitioner shall be responsible if the

- 33 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 signature must appear on each prescription prepared by the practitioner or the practitioner's

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.