Senators Lamutt of the 21st, Balfour of the 9th and Thomas of the 54th offered the following substitute to HB 261:

A BILL TO BE ENTITLED
AN ACT

To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to change the listings of controlled substances and dangerous drugs; to provide for exempt over-the-counter controlled substances; to require certain information to be included on certain prescription drug orders; to permit prescription drug orders to be transmitted by electronic means; to enact the "Patient Safe Prescription Drug Act"; to amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to provide for electronic prescription drug orders; to define certain terms; to require electronic prescription drug orders to meet certain requirements; to prohibit access to electronic prescription drug orders from the time of transmission until receipt by the designated pharmacy; to prohibit certain restrictions of practitioners; to prohibit a patient´s choice of retail pharmacy; to provide for an exemption for institutions using electronic medical record systems; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

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 paragraphs (6.1), (6.2), and (12.5) to read as follows:

″(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.

(6.2) 'DEA' means the United States Drug Enforcement Administration.″

″(12.05) 'FDA' means the United States Food and Drug Administration.″

SECTION 2.

Said chapter is further amended by striking paragraphs (5) and (6) of Code Section 16-13-25, relating to Schedule I controlled substances, and inserting in lieu thereof the following:

"(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 designation:

(A) Gamma hydroxybutyric acid (gamma hydroxy butyrate); provided, however, that this does not include any amount naturally and normally occurring in the human body; and

(B) Sodium oxybate, when the FDA approved form of this drug is not:

(i) In a container labeled in compliance with subsection (a) or (b) of Code Section 26-3-8; and

(ii) In the possession of:

(I) A registrant permitted to dispense the drug;

(II) Any person other than to whom the drug was prescribed; or

(III) Any person who attempts to or does unlawfully possess, sell, distribute, or give this drug to any other person;

(6) Notwithstanding the fact that Schedule I substances have no currently accepted medical use, the General Assembly recognizes certain of these substances which are currently accepted for certain limited medical uses in treatment in the United States but have a high potential for abuse. Accordingly, unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of methaqualone, including its salts, isomers, optical isomers, salts of their isomers, and salts of these optical isomers, is included in Schedule I.;

(7) 2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7);

(8) 1-(3-Trifluromethylphenyl) Piperazine (TFMPP);

(9) N-Benzylpiperazine (BZP)."

SECTION 3.

Said chapter is further amended by striking paragraph (8) of Code Section 16-13-27, relating to Schedule III controlled substances, and inserting in its place the following:

"(8) Dronabinol (synthetic) in sesame oil and encapsulated in a U.S. Food and Drug Administration approved drug product also known as Marinol.;

(9) Sodium oxybate, when the FDA approved form of this drug is in a container labeled in compliance with subsection (a) or (b) of Code Section 26-3-8, in the possession of a

registrant permitted to dispense the drug, or in the possession of a person to whom it has been lawfully prescribed;

(10) Buprenorphine.″

SECTION 4.

Said chapter is further amended by striking paragraph (9), designating said paragraph as reserved, and by adding a new paragraph (30.05) to subsection (a) of Code Section 16-13-28, relating to Schedule IV controlled substances, to read as follows:

″(9) ~~Dextropropoxyphene~~ Reserved;″

″(30.05) Propoxyphene (including all salts and optical isomers);″.

SECTION 5.

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

″(2) ~~Buprenorphine~~ Reserved.″

SECTION 6.

Said chapter is further amended by adding a new Code Section 16-13-29.2 to read as follows:

″16-13-29.2.

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 (OTC) Schedule V Controlled Substances.″

SECTION 7.

Said chapter is further amended by striking subsection (b) and paragraph (2) of subsection (d) of Code Section 16-13-41, relating to prescriptions, and inserting in their respective places the following:

″(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 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~~ DEA 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 signatures shall be defined in regulations promulgated by the State Board of Pharmacy.

Prescription drug orders for Schedule II controlled substances may be transmitted via 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 26-4-80.1, or in accordance with DEA regulations at 21 C.F.R. 1306.″

″(2) When a ~~registered~~ practitioner writes a prescription drug order to cause the dispensing of a Schedule III, IV, or V controlled substance, he or she shall include the name and address of the person for whom it is prescribed, the kind and quantity of such controlled substance, the directions for taking, the signature, and the name, address, telephone number, and ~~federal~~ DEA registration number of the ~~prescribing~~ practitioner. Such prescriptions shall be signed and dated or may be issued orally by the ~~prescribing~~ practitioner on the date when issued, and the nature of the signature of the prescriber shall meet the guidelines set forth in Chapter 4 of Title 26, the regulations promulgated by the State Board of Pharmacy, or both such guidelines and regulations.″

SECTION 8.

Said chapter is further amended by striking from subsection (b) of Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:

″(119.05) Butenafine;″

″(349.7) Reserved;″

″(529.9) Loratadine;″

″(623.5) Mometazone;″

″(752.2) Poractant Alpha;″

″(1002) Triprolidine;″.

SECTION 9.

Said chapter is further amended by adding in the appropriate positions in subsection (b) of Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:

″(22.2) Almotriptan;″

″(50.4) Anakinra;″

″(68.15) Atomoxetine;″

″(98.2) Bimatoprost;″

″(102.5) Bivalirudin;″

″(105.5) Bosentan;″

″(105.7) Botulinum toxin (B);″

″(119.05) Butenafine — See exceptions;″

″(146.6) Caspofungin;″

″(151.45) Cefditoren;″

″(240.5) Darbepoetin alfa;″

″(251.5) Desloratadine;″

″(293.5) Dimyristoyl;″

″(325.3) Drospirenone;″

″(325.4) Drotrecogin alfa;″

″(325.5) Dutasteride;″

″(346.5) Ertapenem;″

″(349.7) Esomeprazole;″

″(404.7) Fondaparinux;″

″(406.2) Formoterol;″

″(406.95) Frovatriptan;″

″(408.9) Galantamine;″

″(464.8) Imatinib;″

″(474.2) Insulin aspart;″

″(513.8) Letrozole;″

″(529.9) Loratadine — See exceptions;″

″(623.5) Mometasone;″

″(625.3) Moxidectin;″

″(640.2) Nesiritide;″

″(644.8) Nitisinone;″

″(703.45) Perflexane;″

″(703.65) Perflutren;″

″(732.9) Pimecrolimus;″

″(752.2) Poractant alfa;″

″(930.9) Tadalafil;″

″(931.55) Tegaserod;″

″(931.85) Tenofovir;″

″(932.3) Teriparatide;″

″(974.4) Travoprost;″

″(974.7) Treprostinil;″

″(1002) Triprolidine — See exceptions;″

″(1021.8) Valdecoxib;″

″(1022.2) Valganciclovir;″

″(1037.5) Voriconazole;″

″(1042.75) Ziprasidone;″

″(1042.8) Zoledronic Acid;″.

SECTION 10.

Said chapter is further amended by striking from subsection (c) of Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:

"(12) Insulin, All;"

"(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 200 mg. in strength;".

SECTION 11.

Said chapter is further amended by adding in the appropriate positions in subsection (c) of Code Section 16-13-71, relating to the list of dangerous drugs, the following paragraphs:

"(6.2) Butenafine — when used with a strength of 1 percent or less as a topical preparation;"

"(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 this Code section; and no injectable insulin product may be sold except by a pharmacy issued a permit by the State Board of Pharmacy or by a medical practitioner authorized to dispense medications;"

"(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;"

"(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;"

"(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;".

SECTION 12.

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

"(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 the patient, together with the name and strength of the drug, the quantity to be dispensed, complete directions for administration, the printed name, address, and telephone number of the practitioner, and the number of permitted refills. ~~A practitioner may sign a prescription as he would sign a check or a legal document. The prescription shall be written~~

~~with indelible pencil or indelible ink or typewritten and shall be manually signed by the practitioner. The prescription may be prepared by a secretary or other agent, for the signature of the practitioner, but the prescribing practitioner shall be responsible if the 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 signature must appear on each prescription prepared by the practitioner or the practitioner´s agent and the nature of the practitioner´s signature must meet the guidelines set forth in Chapter 4 of Title 26, the regulations promulgated by the State Board of Pharmacy, or both such guidelines and regulations. Any practitioner who shall dispense dangerous drugs shall comply with the provisions of Code Section 16-13-73.″

SECTION 13.

This Act shall be known and may be cited as the "Patient Safe Prescription Drug Act."

SECTION 14.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by adding to Code Section 26-4-5, relating to definitions, new paragraphs (14.1) through (14.5), (18.05), and (38.5) to read as follows:

″(14.1) 'Electronic data prescription drug order' means any digitalized prescription drug order transmitted to a pharmacy, other than by facsimile, which contains the secure, personalized digital key, code, number, or other identifier used to identify and authenticate the prescribing practitioner in a manner required by state laws and board regulations and includes all other information required by state laws and board regulations.

(14.2) 'Electronic data signature' means a secure, personalized digital key, code, number, or other identifier used for secure electronic data transmissions which identifies and authenticates the prescribing practitioner as a part of an electronic data prescription drug order transmitted to a pharmacy.

(14.3) 'Electronic signature' means an electronic visual image signature or an electronic data signature of a practitioner which appears on an electronic prescription drug order.

(14.4) 'Electronic visual image prescription drug order' means any exact visual image of a prescription drug order issued by a practitioner electronically and which bears an electronic reproduction of the visual image of the practitioner´s signature, is either printed on security paper and presented as a hard copy to the patient or transmitted by the

practitioner via facsimile machine or equipment to a pharmacy, and contains all information required by state law and regulations of the board.

(14.5) 'Electronic visual image signature' means any exact visual image of a practitioner´s signature which is reproduced electronically on a hard copy prescription drug order presented to the patient by the practitioner or is a prescription drug order transmitted to a pharmacy by a practitioner via facsimile machine or equipment.″

″(18.05) 'Hard copy prescription drug order' means a written, typed, reproduced, or printed prescription drug order prepared on a piece of paper.″

″(38.5) 'Security paper' means paper utilizing security features on which the electronic visual image prescription drug order of a practitioner is printed and presented to a patient so as to ensure that the prescription drug order is not subject to any form of copying, reproduction, or alteration, or any combination of copying, reproduction, or alteration, and may include a watermark produced by the electronic digital process when a prescription is printed to clearly show if a prescription has been reproduced or copied in an unauthorized manner.″

SECTION 15.

Said chapter is further amended by striking paragraph (36) of Code Section 26-4-5, relating to definitions, and inserting in its place the following:

″(36) 'Prescription drug order' means a lawful order of a practitioner for a drug or device for a specific patient; such order includes an electronic visual image prescription drug order and an electronic data prescription drug order.″

SECTION 16.

Said chapter is further amended by striking subsections (c), (i), and (l) of Code Section 26-4-80, relating to dispensing, electronically transmitted drug orders, refills, and Schedule II controlled substance prescriptions, and inserting in their respective places the following:

″(c) A prescription drug order may be accepted by a pharmacist, ~~or~~ pharmacy intern, or extern in written form, orally, ~~via facsimile, or electronically~~ via an electronic visual image prescription drug order, or an electronic data prescription drug order as set forth in this chapter or as set forth in regulations promulgated by the board. Provisions for accepting a prescription drug order for a Schedule II controlled substance are set forth in subsection (l) of this Code section, the board´s regulations, or the regulations of the United States Drug Enforcement Administration in 21 C.F.R. 1306. Electronic prescription drug orders shall either be an electronic visual image of a prescription drug order or an electronic data prescription drug order and shall meet the requirements set forth in regulations promulgated by the board. A hard copy prescription prepared by a practitioner or a

practitioner´s agent, which bears an electronic visual image of the practitioner´s signature and is not sent by facsimile, must be printed on security paper. Prescriptions transmitted either electronically or via facsimile shall meet the following requirements:

(1) Electronically transmitted prescription drug orders shall be transmitted by the practitioner or, in the case of a prescription drug order to be transmitted via facsimile, by the practitioner or the practitioner´s agent under supervision of the practitioner, to the pharmacy of the patient´s choice with no intervening person or intermediary having access to the prescription drug order;

(2) Prescription drug orders transmitted by facsimile or computer shall include:

(A) In the case of a prescription drug order for a dangerous drug, the complete name and address of the practitioner;

(B) In the case of a prescription drug order for a controlled substance, the complete name, address, and DEA registration number of the practitioner;

(C) The telephone number of the practitioner for verbal confirmation;

(D) The name and address of the patient;

(E) The time and date of the transmission; ~~and~~

(F) The full name of the person transmitting the order; and

(G) The signature of the practitioner in a manner as defined in regulations promulgated by the board or, in the case of a controlled substances prescription, in accordance with 21 C.F.R. 1301.22;

(3) An electronically transmitted, issued, or produced prescription drug order which meets the requirements of this Code section shall be deemed the original order;

(4) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of ~~the~~ any electronically transmitted, issued, or produced prescription drug order consistent with federal and state laws and rules and regulations adopted pursuant to the same;

(5) An electronically ~~transmitted~~ encrypted, issued, or produced prescription drug order transmitted from a ~~prescriber~~ practitioner to a pharmacist shall be considered a highly confidential transaction and the said transmission, issuance, or production shall not be compromised by interventions, control, change, altering, ~~or~~ manipulation, or accessing patient record information by any other person or party in any manner whatsoever between the time after the practitioner has electronically transmitted, issued, or produced a prescription drug order and such order has been received by the pharmacy of the patient´s choice;

(6) Any pharmacist that transmits, receives, or maintains any prescription or prescription refill either orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription and any information contained therein; and

(7) The board shall promulgate rules and regulations which may provide specific exceptions under this Code section for institutional settings such as hospital pharmacies, nursing home pharmacies, clinic pharmacies, or pharmacies owned or operated directly by health maintenance organizations."

"(i) ~~A written~~ All prescription drug ~~order~~ orders must bear ~~an original~~ the signature of the prescribing practitioner or, in the case of physician assistants, must comply with all applicable laws regarding signatures. Further, the nature of such signature must meet the requirements set forth in regulations promulgated by the board. A physically applied signature stamp ~~or other signature facsimile~~ is not acceptable in lieu of an original signature. When an oral prescription drug order or the oral authorization for the refilling of a prescription drug order is received ~~which is~~ which has been transmitted by someone other than the practitioner, the name of the individual making the transmission and the date, time, and location of the origin of the transmission must be recorded on the original prescription drug order or other ~~uniform~~ record by the pharmacist receiving the transmission. No one other than the practitioner or an agent employed by the practitioner shall transmit such prescriptions in any manner."

"(l) A Schedule II controlled substance prescription drug order in written form signed in indelible ink by the practitioner may be accepted by a pharmacist and the Schedule II controlled substance may be dispensed by such pharmacist. Other forms of Schedule II controlled substance prescription ~~forms~~ drug orders may be accepted by a pharmacist and the Schedule II controlled substance may be dispensed by such pharmacist in accordance with regulations promulgated by the board and in accordance with DEA regulations found in 21 C.F.R. 1306."

SECTION 17.

Said chapter is further amended by adding at the end of Code Section 26-4-80, relating to dispensing, electronically transmitted drug orders, refills, and Schedule II controlled substance prescriptions, new subsections (m) and (n) to read as follows:

"(m) No licensee nor any other entity shall be permitted to provide facsimile machines or equipment, computer software, technology, hardware, or supplies related to the electronic transmission of prescription drug orders to any practitioner which restricts such practitioner from issuing prescription drug orders for certain prescription drugs or restricts a patient from choosing the retail pharmacy to which an electronic prescription drug order may be transmitted.

(n) Institutions including, but not limited to, hospitals, long-term care facilities, and inpatient hospice facilities which utilize electronic medical record systems that meet the

information requirements for prescription drug orders for patients pursuant to this Code section shall be considered to be in compliance with this Code section."

SECTION 18.

Said chapter is further amended by striking subsection (g) of Code Section 26-4-81, relating to substitution of generic drugs for name brand drugs, and inserting in its place the following:

"(g) A practitioner of the healing arts may instruct the pharmacist not to substitute a generic name drug in lieu of a brand name drug by including the words 'brand necessary' in the body of the prescription. When a prescription is a hard copy prescription drug order, such ~~Such~~ indication of brand necessary must be in the practitioner´s own handwriting and shall not be printed, applied by rubber stamp, or any such similar means."

SECTION 19.

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

SECTION 20.

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