The House Committee on Judiciary Non-civil offers the following substitute to SB 205:

A BILL TO BE ENTITLED
AN ACT

To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, so as to enact the "Prescription Medication Integrity Act"; to provide for a short title; to provide for definitions; to provide for pedigrees for prescription drugs; to provide for contingent effectiveness; to provide for enforcement; to provide for prohibited acts; to provide for penalties; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and pharmacies, is amended by inserting a new article at the end of such chapter to read as follows:

″ARTICLE 12

26-4-200.

This article shall be known and may be cited as the 'Prescription Medication Integrity Act.'

26-4-201.

As used in this article, the term:

(1) 'Authenticate' means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(2) 'Authorized distributor of record' means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer´s prescription drugs.

(3) 'Board' means the State Board of Pharmacy.

(4) 'Broker' has the same meaning as a third party logistics provider.

(5) 'Chain pharmacy warehouse' means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership or control.

(6) 'Co-licensed pharmaceutical products' means pharmaceutical products:

(A) That have been approved by the federal Food and Drug Administration; and

(B) Concerning which two or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

(7) 'Co-licensee' means a party to a co-licensed pharmaceutical product.

(8) 'Distribute' means to deliver a drug or device other than by administering or dispensing.

(9) 'Drop shipment arrangement' means the physical shipment of a prescription from a manufacturer, that manufacturer´s co-licensee, that manufacturer´s third-party logistics provider, or that manufacturer´s authorized distributor of record directly to a chain pharmacy warehouse, pharmacy buying cooperative warehouse, pharmacy, or other persons authorized under law to dispense or administer prescription drugs but wherein the sale and title for the prescription drug passes between a wholesale drug distributor and the party that directly receives the prescription drug.

(10) 'Facility' means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

(11) 'Manufacturer' means a person licensed or approved by the federal Food and Drug Administration ('FDA') to engage in the manufacture of drugs or devices, consistent with the FDA definition of 'manufacturer' under the regulations and interpreted guidances implementing the Prescription Drug Marketing Act.

(12) 'Manufacturer´s exclusive distributor' means an entity that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services for a manufacturer and takes title to that manufacturer´s prescription drug.

(13) 'Normal distribution channel' means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug (or from that manufacturer to that manufacturer´s co-licensed partner), (or from that manufacturer to that manufacturer´s third-party logistics provider), (or from that manufacturer to that manufacturer´s exclusive distributor) to (directly or by drop shipment) a wholesale distributor to a pharmacy, or to other designated persons authorized by law to dispense or administer such drug, including but not limited to:

(A) From a manufacturer to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse;

(B) From a manufacturer to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse;

(C) From a manufacturer to a third-party logistics provider, to a wholesale drug distributor, to a pharmacy;

(D) From a manufacturer to a third-party logistics provider, to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse;

(E) From a manufacturer to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member owner of the buying cooperative operating the warehouse;

(F) From a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(G) From a wholesale distributor to a pharmacy or designated persons authorized by law to dispense or administer such drug to a patient;

(H) From a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse´s intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(I) From a chain pharmacy warehouse to the chain pharmacy warehouse´s intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(J) From a manufacturer to a third-party logistics provider or the manufacturer´s exclusive distributor, to a wholesale drug distributor, to a pharmacy;

(K) From a manufacturer to a third-party logistics provider or the manufacturer´s exclusive distributor, to a wholesale drug distributor, to a chain pharmacy warehouse, to a pharmacy affiliated with the chain pharmacy warehouse;

(L) From a manufacturer to a third-party logistics provider or the manufacturer´s exclusive distributor, to a wholesale drug distributor, to a pharmacy buying cooperative warehouse, to a pharmacy that is a member owner of the buying cooperative operating the warehouse;

(M) From a manufacturer to a third-party logistics provider or the manufacturer´s exclusive distributor, to a wholesale drug distributor, to designated persons authorized by law to dispense or administer such drug to a patient;

(N) From a manufacturer to a third-party logistics provider or manufacturer´s authorized distributor of record, to a wholesale drug distributor, to one of the following wherein the prescription drug is delivered directly by way of a drop shipment arrangement:

(i) A pharmacy;

(ii) A chain pharmacy warehouse, to its intracompany pharmacy;

(iii) A pharmacy buying cooperative warehouse, to its member; or

(iv) Other designated persons authorized by law to dispense or administer such drug;

(O) In limited situations where a documented product shortage, back order, or emergency exists, from a manufacturer or that manufacturer´s third-party logistics provider or sole authorized distributor of record to an authorized distributor of record, to one other authorized distributor of record, to:

(i) A pharmacy;

(ii) A chain pharmacy warehouse, to its intracompany pharmacy;

(iii) A pharmacy buying cooperative warehouse, to its member; or

(iv) Other designated persons authorized by law to dispense or administer such drug;

(P) From a manufacturer directly to a prescriber, pharmacy, or hospital system to a patient or other designated persons authorized by law to dispense or administer such a drug to a patient; or

(Q) As prescribed by rules adopted by the board.

(14) 'Ongoing relationship' means an association that exists when a wholesale drug distributor, including any member of its affiliated group, as defined in Section 1504 of the Internal Revenue Code, of which the wholesale drug distributor is a member:

(A) Is listed on the manufacturer´s list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis; and

(B) Has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship.

(15) 'Pedigree' means a document or electronic file containing information that records each wholesale distribution of any given prescription drug.

(16) 'Pharmacy buying cooperative warehouse' means a permanent physical location that acts as a central warehouse for drugs and from which sales of drugs are made to a group of pharmacies that are member owners of the buying cooperative operating the warehouse. Pharmacy buying cooperative warehouses must be licensed as wholesale distributors.

(17) 'Prescription drug' means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law (including federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the federal Food, Drug and Cosmetic Act ('FFDCA').

(18) 'Repackage' means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug; provided, however, that this shall not apply to pharmacists in the dispensing of prescription drugs to the patient.

(19) 'Repackager' means a person who repackages.

(20) 'Third-party logistics provider' means an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a drug or have general responsibility to direct the sale or other disposition of the drug.

(21) 'Wholesale distributor' means any person engaged in wholesale distribution of drugs, including but not limited to repackagers; own label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers´ and distributors´ warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale distributions. This term shall not include manufacturers.

(22) 'Wholesale distribution' shall not include:

(A) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under common ownership or control of a corporate entity, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons including transfers of a prescription drug from retail pharmacy to retail pharmacy, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(C) The distribution of prescription drug samples by manufacturers´ representatives;

(D) Prescription drug returns when conducted by a retail pharmacy or by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. Section 203.23, except in cases where a pedigree is already required under the provisions of this article, in which case any return of that prescription drug to a wholesaler or manufacturer shall be documented on the same pedigree;

(E) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use, except that nothing contained herein shall be construed to prohibit the board from requiring that other records of these transactions shall be kept in accordance with law and regulation not found in this article;

(F) Retail pharmacies´ delivery of prescription drugs to a patient or patient´s agent pursuant to the lawful order of a licensed practitioner;

(G) The distribution of prescription drugs by third-party logistics providers working under contract of a prescription drug manufacturer;

(H)(i) The distribution by a manufacturer of the finished form of a prescription drug it manufactures; or

(ii) The distribution by a co-licensee of the finished form of a prescription drug if that co-licensee distributes that drug as a co-licensed product;

(I) Drop shipments of a prescription drug to a pharmacy, pharmacy buying cooperative warehouse, or chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient;

(J) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier´s usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(K) The sale or transfer from a retail pharmacy, pharmacy buying cooperative warehouse, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor; or

(L) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

26-4-202.

(a)(1) Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs which are not distributed through the normal distribution channel in accordance with rules and regulations adopted by the board.

(2) A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this Code section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(3) The board shall conduct a study to be completed no later than July 1, 2009, which shall include consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees which shall be no sooner than December 31, 2011, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply; provided, however, that no provision of this article shall be effective until such time as the General Assembly appropriates reasonable funds for administration of this article. Effective at a date established by the board, pedigrees may be implemented through an approved and

readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor, until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. This electronic tracking system will be deemed to be readily available only upon there being available a standardized system originating at the manufacturer and capable of being used on a wide scale across the entire pharmaceutical supply chain which includes manufacturers, wholesale distributors, and pharmacies. Consideration must be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person in possession of a pedigree for a prescription drug who is engaged in the wholesale distribution of a prescription drug, including repackagers but excluding the original manufacturer of the finished form of the prescription drug and any entity engaged in the activities listed in paragraph (9) of Code Section 26-4-201, and who attempts to further distribute that prescription drug shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, to acquisition and sale by any wholesale distributor or repackager, and to final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree shall include:

(1) The name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;

(2) The name and address of each location from which the prescription drug was shipped, if different from the owner´s;

(3) Transaction dates;

(4) Certification that each recipient, excluding retail or hospital pharmacies, has authenticated the pedigree;

(5) The name of the prescription drug;

(6) Dosage form and strength of the prescription drug;

(7) Size of the container;

(8) Number of containers;

(9) Lot number of the prescription drug; and

(10) The name of the manufacturer of the finished dosage form.

(d) Each pedigree shall be:

(1) Maintained by the wholesale distributor at its licensed location, unless given written authorization from the board to do otherwise, for three years from the date of sale or transfer; and

(2) Available for inspection, copying, or use at the licensed location upon a verbal request by the board or its designee.

(e) The board shall adopt rules and regulations, including a standard form, relating to the requirements of this article no later than 90 days after the effective date of this article.

(f) Pharmacies licensed pursuant to this chapter shall not be required to possess or maintain any pedigree issued pursuant to this Code section.

26-4-203.

(a) If the board finds that there is a reasonable probability that:

(1) A wholesale distributor, other than a manufacturer, has:

(A) Violated a provision of this article; or

(B) Falsified a pedigree, provided a falsified pedigree, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;

(2) The prescription drug at issue in subparagraph (B) of paragraph (1) of this subsection could cause serious, adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay,

the board shall issue an order requiring the appropriate person including the distributors or retailers of the prescription drug to immediately cease distribution of the prescription drug in or to this state.

(b) An order under subsection (a) of this Code section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten calendar days after the date of the issuance of the order, on the actions required by the order. If, after such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

26-4-204.

It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Selling, distributing, or transferring a prescription drug to a person that is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug;

(2) Failing to maintain or provide pedigrees as required by the board;

(3) Failing to obtain, transfer, or authenticate a pedigree as required by the board;

(4) Providing the board or any of its representatives or any federal official with false or fraudulent records, including, but not limited to falsified pedigrees, or making false or fraudulent statements regarding any matter within the provisions of this article;

(5) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug; and

(6) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the Food and Drug Administration, the manufacturing, repackaging, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution.

26-4-205.

(a) Notwithstanding Code Section 26-4-115, any person who engages without knowledge in the wholesale distribution of prescription drugs, including providing a falsified pedigree or other records, in violation of this article may be fined not more than $10,000.00.

(b) If a person engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, and acts in a grossly negligent manner in violation of this article, the person may be punished by imprisonment for not more than 15 years, fined not more than $50,000.00, or both.

(c) Notwithstanding Code Section 26-4-115, any person who knowingly engages in wholesale distribution of prescription drugs in violation of this article, including providing a falsified pedigree or other records, shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000.00, or both.″

SECTION 2.

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