

The Senate Health and Human Services Committee offered the following substitute to SB 205:

A BILL TO BE ENTITLED
AN ACT

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

7 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 **SECTION 1.**

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

12 "ARTICLE 12

13 26-4-200.

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

15 26-4-201.

16 As used in this article, the term:

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

19 (2) 'Board' means the State Board of Pharmacy.

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

23 (4) 'Co-licensed pharmaceutical products' means pharmaceutical products:

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

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

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

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

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

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

17 (9) 'Normal distribution channel' means a chain of custody for a prescription drug that
18 goes from a manufacturer of the prescription drug (or from that manufacturer to that
19 manufacturer's co-licensed partner), (or from that manufacturer to that manufacturer's
20 third-party logistics provider), (or from that manufacturer to that manufacturer's
21 exclusive distributor) to (directly or by drop shipment) a wholesale distributor to a
22 pharmacy, including but not limited to:

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (i) A pharmacy;

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

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

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

29 (i) A pharmacy;

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

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

32 (O) As prescribed by rules adopted by the board.

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

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

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

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

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

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

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

18 (15) 'Repackager' means a person who repackages.

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

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

29 (18) 'Wholesale distribution' shall not include:

30 (A) Intracompany sales of prescription drugs, meaning any transaction or transfer
31 between any division, subsidiary, parent, or affiliated or related company under
32 common ownership and control of a corporate entity;

33 (B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to
34 sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical
35 reasons including transfers of a prescription drug from retail pharmacy to retail
36 pharmacy;

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

- 1 (D) Prescription drug returns when conducted by a hospital, health care entity, retail
 2 pharmacy, or charitable institution in accordance with 21 C.F.R. Section 203.23;
- 3 (E) The sale of minimal quantities of prescription drugs by retail pharmacies to
 4 licensed practitioners for office use;
- 5 (F) Retail pharmacies' delivery of prescription drugs to a patient or patient's agent
 6 pursuant to the lawful order of a licensed practitioner;
- 7 (G) The distribution of prescription drugs by third-party logistics providers working
 8 under contract of a prescription drug manufacturer;
- 9 (H)(i) The distribution by a manufacturer of the finished form of a prescription drug
 10 it manufactures; or
- 11 (ii) The distribution by a co-licensee of the finished form of a prescription drug if that
 12 co-licensee distributes that drug as a co-licensed product;
- 13 (I) Drop shipments of a prescription drug to a pharmacy, pharmacy buying cooperative
 14 warehouse, or chain pharmacy warehouse, or other person authorized by law to
 15 dispense or administer such drug to a patient;
- 16 (J) The delivery of, or offer to deliver, a prescription drug by a common carrier solely
 17 in the common carrier's usual course of business of transporting prescription drugs, and
 18 such common carrier does not store, warehouse, or take legal ownership of the
 19 prescription drug; or
- 20 (K) The sale or transfer from a retail pharmacy, pharmacy buying cooperative
 21 warehouse, or chain pharmacy warehouse of expired, damaged, returned, or recalled
 22 prescription drugs to the original manufacturer or to a third party returns processor.

23 26-4-202.

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

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

32 (3) The board shall conduct a study to be completed no later than January 1, 2009,
 33 which shall include consultation with manufacturers, distributors, and pharmacies
 34 responsible for the sale and distribution of prescription drug products in this state. Based
 35 on the results of the study, the board shall establish a mandated implementation date for
 36 electronic pedigrees which shall be no sooner than December 31, 2011; provided,

1 however, that no provision of this article shall be effective until such time as the General
2 Assembly appropriates reasonable funds for administration of this article. Effective at
3 a date established by the board, pedigrees may be implemented through an approved and
4 readily available system that electronically tracks and traces the wholesale distribution
5 of each prescription drug starting with the sale by a manufacturer through acquisition and
6 sale by any wholesale distributor, until final sale to a pharmacy or other authorized
7 person administering or dispensing the prescription drug. This electronic tracking system
8 will be deemed to be readily available only upon there being available a standardized
9 system originating at the manufacturer and capable of being used on a wide scale across
10 the entire pharmaceutical supply chain which includes manufacturers, wholesale
11 distributors, and pharmacies. Consideration must be given to the large-scale
12 implementation of this technology across the supply chain and the technology must be
13 proven to have no negative impact on the safety and efficacy of the pharmaceutical
14 product. 'Track and trace' means the ability to locate a product in the supply chain and
15 determine its outbound distribution path.

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

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

- 27 (1) The name, address, telephone number, and, if available, e-mail address of each owner
28 of the prescription drug and each wholesale distributor of the prescription drug;
- 29 (2) The name and address of each location from which the prescription drug was
30 shipped, if different from the owner's;
- 31 (3) Transaction dates;
- 32 (4) Certification that each recipient has authenticated the pedigree;
- 33 (5) The name of the prescription drug;
- 34 (6) Dosage form and strength of the prescription drug;
- 35 (7) Size of the container;
- 36 (8) Number of containers;
- 37 (9) Lot number of the prescription drug; and

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

2 (d) Each pedigree shall be:

3 (1) Maintained by the wholesale distributor for three years from the date of sale or
4 transfer; and

5 (2) Available for inspection or use upon a request by the board.

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

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

10 26-4-203.

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

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

13 (A) Violated a provision of this article; or

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

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

18 (3) Other procedures would result in unreasonable delay,

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

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

27 26-4-204.

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

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

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

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

1 (4) Providing the board or any of its representatives or any federal official with false or
2 fraudulent records or making false or fraudulent statements regarding any matter within
3 the provisions of this article;

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

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

13 26-4-205.

14 (a) Notwithstanding Code Section 26-4-115, any person who engages without knowledge
15 in the wholesale distribution of prescription drugs in violation of this article may be fined
16 not more than \$10,000.00.

17 (b) If a person engages in wholesale distribution of prescription drugs in violation of this
18 article, and acts in a grossly negligent manner in violation of this article, the person may
19 be punished by imprisonment for not more than 15 years, or fined not more than
20 \$50,000.00, or both.

21 (c) Notwithstanding Code Section 26-4-115, any person who knowingly engages in
22 wholesale distribution of prescription drugs in violation of this article shall be guilty of a
23 felony and, upon conviction thereof, shall be punished by imprisonment for not more than
24 25 years, by fine not to exceed \$500,000.00, or both."

25 **SECTION 2.**

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