

Senate Bill 205

By: Senators Thomas of the 54th, Balfour of the 9th, Henson of the 41st, Wiles of the 37th, Unterman of the 45th and others

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 products.

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

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

- 1 (4) 'Co-licensed pharmaceutical products' means pharmaceutical products:  
2 (A) That have been approved by the federal Food and Drug Administration; and  
3 (B) Concerning which two or more parties have the right to engage in a business  
4 activity or occupation concerning the pharmaceutical products.
- 5 (5) 'Co-licensee' means a party to a co-licensed pharmaceutical product.
- 6 (6) 'Drop shipment arrangement' means the physical shipment of a prescription from a  
7 manufacturer, that manufacturer's third-party logistics provider, or that manufacturer's  
8 authorized distributor of record directly to a chain drug warehouse, pharmacy buying  
9 cooperative warehouse, pharmacy, or other persons authorized under law to dispense or  
10 administer prescription drugs but wherein the sale and title for the prescription drug  
11 passes between a wholesale drug distributor and the party that directly receives the  
12 prescription drug.
- 13 (7) 'Facility' means a facility of a wholesale distributor where prescription drugs are  
14 stored, handled, repackaged, or offered for sale.
- 15 (8) 'Manufacturer's exclusive distributor' means an entity that contracts with a  
16 manufacturer to provide or coordinate warehousing, distribution, or other services for a  
17 manufacturer and takes title to that manufacturer's prescription drug.
- 18 (9) 'Normal distribution channel' means a chain of custody for a prescription drug that  
19 goes from a manufacturer to a wholesale distributor to a pharmacy including but not  
20 limited to:
- 21 (A) From a manufacturer to a wholesale drug distributor, to a chain drug warehouse,  
22 to a pharmacy affiliated with the chain drug warehouse;
- 23 (B) From a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the  
24 chain drug warehouse;
- 25 (C) From a manufacturer to a third-party logistics provider, to a wholesale drug  
26 distributor, to a pharmacy;
- 27 (D) From a manufacturer to a third-party logistics provider, to a wholesale drug  
28 distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug  
29 warehouse;
- 30 (E) From a manufacturer to a wholesale drug distributor, to a pharmacy buying  
31 cooperative warehouse, to a pharmacy that is a member owner of the buying  
32 cooperative operating the warehouse;
- 33 (F) From a manufacturer to a third-party logistics provider or the manufacturer's  
34 exclusive distributor, to a wholesale drug distributor, to a pharmacy;
- 35 (G) From a manufacturer to a third-party logistics provider or the manufacturer's  
36 exclusive distributor, to a wholesale drug distributor, to a chain drug warehouse, to a  
37 pharmacy affiliated with the chain drug warehouse;

1 (H) From a manufacturer to a third-party logistics provider or the manufacturer's  
 2 exclusive distributor, to a wholesale drug distributor, to a pharmacy buying cooperative  
 3 warehouse, to a pharmacy that is a member owner of the buying cooperative operating  
 4 the warehouse;

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

8 (i) A pharmacy;

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

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

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

15 (i) A pharmacy;

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

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

18 (K) As prescribed by rules adopted by the board.

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

22 (A) Is listed on the manufacturer's list and the list is updated monthly; or

23 (B) Has a written agreement currently in effect with the manufacturer.

24 (11) 'Pedigree' means a document or electronic file containing information that records  
 25 each transaction of a prescription drug from sale by a pharmaceutical manufacturer, to  
 26 acquisition and sale by any wholesale distributor or repackager, to final sale to a  
 27 pharmacy or other person dispensing or administering the prescription drug.

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

33 (13) 'Prescription drug' means a drug which, under federal law, is required, prior to being  
 34 dispensed or delivered, to be labeled with either of the following statements: 'Caution:  
 35 federal law prohibits dispensing without prescription,' or 'Caution: federal law restricts  
 36 this drug to use by, or on the order of, a licensed veterinarian'; or a drug which is required  
 37 by any applicable federal or state law or rule to be dispensed pursuant only to a

1 prescription drug order or is restricted to use by practitioners only; or a controlled  
2 substance as defined in paragraph (6) of Code Section 26-4-5 or a dangerous drug as  
3 defined in paragraph (7) of Code Section 26-4-5.

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

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

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

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

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

19 (A) Intracompany sales of prescription drugs by a chain drug warehouse, meaning any  
20 transaction or transfer between any division, subsidiary, parent, or affiliated or related  
21 company under common ownership and control of a corporate entity;

22 (B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to  
23 sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical  
24 reasons including transfers of a prescription drug from retail pharmacy to retail  
25 pharmacy;

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

27 (D) Prescription drug returns when conducted by a hospital, health care entity, retail  
28 pharmacy, or charitable institution in accordance with 21 C.F.R. Section 203.23;

29 (E) The sale of minimal quantities of prescription drugs by retail pharmacies to  
30 licensed practitioners for office use;

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

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

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

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

3 26-4-202.

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

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

12 (3) The board shall conduct a study to be completed no later than January 1, 2008,  
13 which shall include consultation with manufacturers, distributors, and pharmacies  
14 responsible for the sale and distribution of prescription drug products in this state. Based  
15 on the results of the study, the board shall establish a mandated implementation date for  
16 electronic pedigrees which shall be no sooner than December 31, 2008; provided,  
17 however, that no provision of this article shall be effective until such time as the General  
18 Assembly appropriates reasonable funds for administration of this article.

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

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

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

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

34 (3) Transaction dates;

35 (4) Certification that each recipient has authenticated the pedigree;

36 (5) The name of the prescription drug;

- 1 (6) Dosage form and strength of the prescription drug;  
 2 (7) Size of the container;  
 3 (8) Number of containers;  
 4 (9) Lot number of the prescription drug; and  
 5 (10) The name of the manufacturer of the finished dosage form.
- 6 (d) Each pedigree shall be:  
 7 (1) Maintained by the wholesale distributor for three years from the date of sale or  
 8 transfer; and  
 9 (2) Available for inspection or use upon a request by the board.
- 10 (e) The board shall adopt rules and regulations, including a standard form, relating to the  
 11 requirements of this article no later than 90 days after the effective date of this article.
- 12 (f) Pharmacies licensed pursuant to this chapter shall not be required to possess or  
 13 maintain any pedigree issued pursuant to this Code section.

14 26-4-203.

- 15 (a) If the board finds that there is a reasonable probability that:  
 16 (1) A wholesale distributor, other than a manufacturer, has:  
 17 (A) Violated a provision of this article; or  
 18 (B) Falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged,  
 19 handled, or held a counterfeit prescription drug intended for human use;  
 20 (2) The prescription drug at issue in subparagraph (B) of paragraph (1) of this subsection  
 21 could cause serious, adverse health consequences or death; and  
 22 (3) Other procedures would result in unreasonable delay,  
 23 the board shall issue an order requiring the appropriate person including the distributors or  
 24 retailers of the prescription drug to immediately cease distribution of the prescription drug  
 25 in or to this state.
- 26 (b) An order under subsection (a) of this Code section shall provide the person subject to  
 27 the order with an opportunity for an informal hearing, to be held not later than ten days  
 28 after the date of the issuance of the order, on the actions required by the order. If, after  
 29 such a hearing, the board determines that inadequate grounds exist to support the actions  
 30 required by the order, the board shall vacate the order.

31 26-4-204.

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

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

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

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

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

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

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

18 26-4-205.

19 (a) Notwithstanding Code Section 26-4-115, any person who engages in the wholesale  
20 distribution of prescription drugs in violation of this article shall be guilty of a felony and,  
21 upon conviction thereof, shall be punished by imprisonment for not more than 15 years, by  
22 fine not to exceed \$50,000.00, or both.

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

27 **SECTION 2.**

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