

The House Committee on Health and Human Services offers the following substitute to HB 907:

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 11

13 26-4-190.

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

15 26-4-191.

16 As used in this article, the term:

17 (1) 'Board' means the State Board of Pharmacy.

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

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

1 (4) 'Normal distribution channel' means a chain of custody for a prescription drug that
2 goes from a manufacturer to a wholesale distributor to a pharmacy including but not
3 limited to:

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

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

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

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

13 (E) As prescribed by rules adopted by the board.

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

18 (6) 'Prescription drug' means a drug which, under federal law, is required, prior to being
19 dispensed or delivered, to be labeled with either of the following statements: 'Caution:
20 federal law prohibits dispensing without prescription' or 'Caution: federal law restricts
21 this drug to use by, or on the order of, a licensed veterinarian'; or a drug which is required
22 by any applicable federal or state law or rule to be dispensed pursuant only to a
23 prescription drug order or is restricted to use by practitioners only; or a controlled
24 substance as defined in paragraph (6) of Code Section 26-4-5 or a dangerous drug as
25 defined in paragraph (7) of Code Section 26-4-5.

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

29 (8) 'Repackager' means a person who repackages.

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

34 (10) 'Wholesale distributor' means any person engaged in wholesale distribution of
35 drugs, including but not limited to repackagers; own label distributors; private label
36 distributors; jobbers; brokers; warehouses, including manufacturers' and distributors'
37 warehouses and wholesale drug warehouses; independent wholesale drug traders; and

1 retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale
2 distributions. This term shall not include manufacturers.

3 (11) 'Wholesale distribution' shall not include:

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

7 (B) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to
8 sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical
9 reasons including transfers of a prescription drug from retail pharmacy to retail
10 pharmacy;

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

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

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

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

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

20 26-4-192.

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

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

29 (3) The board shall conduct a study to be completed no later than January 1, 2007,
30 which shall include consultation with manufacturers, distributors, and pharmacies
31 responsible for the sale and distribution of prescription drug products in this state. Based
32 on the results of the study, the board shall establish a mandated implementation date for
33 electronic pedigrees which shall be no sooner than December 31, 2007; provided,
34 however, that no provision of this article shall be effective until such time as the General
35 Assembly appropriates reasonable funds for administration of this article.

1 (b) Each person in possession of a pedigree for a prescription drug who is engaged in the
2 wholesale distribution of a prescription drug, including repackagers but excluding the
3 original manufacturer of the finished form of the prescription drug, and who attempts to
4 further distribute that prescription drug shall affirmatively verify before any distribution
5 of a prescription drug occurs that each transaction listed on the pedigree has occurred.

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

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

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

15 (3) Transaction dates;

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

17 (5) The name of the prescription drug;

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

19 (7) Size of the container;

20 (8) Number of containers;

21 (9) Lot number of the prescription drug; and

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

23 (d) Each pedigree shall be:

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

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

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

29 26-4-193.

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

31 (1) A wholesale distributor has:

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

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

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

1 (3) Other procedures would result in unreasonable delay,
2 the board shall issue an order requiring the appropriate person, including the
3 manufacturers, distributors, or retailers of the prescription drug, to immediately cease
4 distribution of the prescription drug in or to this state.

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

10 26-4-194.

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

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

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

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

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

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

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

30 26-4-195.

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

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

5 **SECTION 2.**

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