

Senate Bill 1004

Sponsored by Senator SCHRADER

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced**.

Requires manufacturer, wholesale drug outlet and pharmacy to create and maintain record of each sale, trade or transfer of prescription drug except to final consumer. Requires wholesale drug outlets and pharmacies that resell prescription drugs to wholesale drug outlets to verify prior sales of prescription drugs.

Prescribes requirements for registration and renewal of registration of wholesale drug outlets.

Requires wholesale drug outlets, including retail pharmacies that conduct wholesale distribution, to sell, distribute or transfer each calendar month minimum of 95 percent of total sales of prescription drugs to pharmacies or other persons with authority to dispense or administer prescription drugs.

Prohibits establishment of accounts for purchase of prescription drugs unless account bears names of certain persons associated with entity authorized to purchase prescription drugs.

Requires certain persons associated with wholesale drug outlets to submit fingerprints for nationwide criminal records check prior to registration or renewal of registration of wholesale drug outlet.

Requires wholesale drug outlets to furnish bond prior to registration or renewal of registration.

Prescribes testing and other requirements of designated representative of wholesale drug outlet prior to registration or renewal of registration.

Prescribes penalties.

A BILL FOR AN ACT

Relating to wholesale drug outlets; creating new provisions; and amending ORS 689.005 and 689.995.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.005 is amended to read:

689.005. As used in this chapter:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner or the authorized agent thereof; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Approved continuing pharmacy education program" means those seminars, classes, meetings, workshops and other educational programs on the subject of pharmacy approved by the board.

(3) "Board of pharmacy" or "board" means the State Board of Pharmacy.

(4) "Continuing pharmacy education" means professional, pharmaceutical post-graduate education in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the disease state.

(5) "Continuing pharmacy education unit" means the unit of measurement of credits for approved continuing education courses and programs.

(6) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device other than by administration from one person to another, whether or not for a consideration.

(7) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

1 reagent or other similar or related article, including any component part or accessory, which is re-
2 quired under federal or state law to be prescribed by a practitioner and dispensed by a pharmacist.

3 (8) "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pur-
4 suant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent
5 administration to or use by a patient or other individual entitled to receive the prescription drug.

6 (9) "Distribute" means the delivery of a drug other than by administering or dispensing.

7 (10) "Drug" means:

8 (a) Articles recognized as drugs in the official United States Pharmacopoeia, official National
9 Formulary, official Homeopathic Pharmacopoeia, other drug compendium or any supplement to any
10 of them;

11 (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of dis-
12 ease in a human or other animal;

13 (c) Articles (other than food) intended to affect the structure or any function of the body of
14 humans or other animals; and

15 (d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c)
16 of this subsection.

17 (11) "Drug order" means a written order, in a hospital or other inpatient care facility, for an
18 ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by
19 other means of communication from a practitioner, that is immediately reduced to writing by a
20 pharmacist, licensed nurse or other practitioner.

21 (12) "Drug outlet" means any pharmacy, nursing home, shelter home, convalescent home, ex-
22 tended care facility, drug abuse treatment center, penal institution, hospital, family planning clinic,
23 student health center, retail store, wholesaler, manufacturer or mail-order vendor with facilities lo-
24 cated within or out of this state that is engaged in dispensing, delivery or distribution of drugs
25 within this state.

26 (13) "Drug room" means a secure and lockable location within an inpatient care facility that
27 does not have a licensed pharmacy.

28 (14) "Electronically transmitted" or "electronic transmission" means a communication sent or
29 received through technological apparatuses, including computer terminals or other equipment or
30 mechanisms linked by telephone or microwave relays, or any similar apparatus having electrical,
31 digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

32 (15) "Institutional drug outlet" means hospitals and inpatient care facilities where medications
33 are dispensed to another health care professional for administration to patients served by the hos-
34 pitals or facilities.

35 (16) "Intern" means any person who has completed the junior or third academic year of a course
36 of study at an approved college of pharmacy and is licensed with the board as an intern.

37 (17) "Internship" means a professional and practical experience program approved by the board
38 under the supervision of a licensed pharmacist registered with the board as a preceptor.

39 (18) "Itinerant vendor" means all persons who sell or otherwise distribute nonprescription drugs
40 by passing from house to house, or by haranguing the people on the public streets or in public
41 places, or who use the customary devices for attracting crowds and therewith recommending their
42 wares and offering them for sale.

43 (19) "Labeling" means the process of preparing and affixing of a label to any drug container
44 exclusive, however, of the labeling by a manufacturer, packer or distributor of a nonprescription
45 drug or commercially packaged legend drug or device. Any such label shall include all information

1 required by federal and state law or regulation.

2 (20) "Manufacture" means the production, preparation, propagation, compounding, conversion
3 or processing of a device or a drug, either directly or indirectly by extraction from substances of
4 natural origin or independently by means of chemical synthesis or by a combination of extraction
5 and chemical synthesis and includes any packaging or repackaging of the substances or labeling or
6 relabeling of its container, except that this term does not include the preparation or compounding
7 of a drug by an individual for their own use or the preparation, compounding, packaging or labeling
8 of a drug:

9 (a) By a practitioner as an incident to administering or dispensing of a drug in the course of
10 professional practice; or

11 (b) By a practitioner or by the practitioner's authorization under supervision of the practitioner
12 for the purpose of or as an incident to research, teaching or chemical analysis and not for sale.

13 (21) "Manufacturer" means a person engaged in the manufacture of drugs.

14 (22) "Nonprescription drug outlet" means shopkeepers and itinerant vendors registered under
15 ORS 689.305.

16 (23) "Nonprescription drugs" means drugs which may be sold without a prescription and which
17 are prepackaged for use by the consumer and labeled in accordance with the requirements of the
18 statutes and regulations of this state and the federal government.

19 (24) "Person" means an individual, corporation, partnership, association or any other legal en-
20 tity.

21 (25) "Pharmacist" means an individual licensed by this state to engage in the practice of phar-
22 macy.

23 (26) "Pharmacy" means a place that meets the requirements of rules of the board, is licensed
24 and approved by the board where the practice of pharmacy may lawfully occur and includes
25 apothecaries, drug stores, dispensaries, hospital outpatient pharmacies, pharmacy departments and
26 prescription laboratories but does not include a place used by a manufacturer or wholesaler.

27 (27) "Pharmacy technician" means a person registered by the State Board of Pharmacy who
28 assists the pharmacist in the practice of pharmacy pursuant to rules of the board.

29 (28) "Practitioner" means a person licensed and operating within the scope of such license to
30 prescribe, dispense, conduct research with respect to or administer drugs in the course of profes-
31 sional practice or research:

32 (a) In this state; or

33 (b) In another state or territory of the United States not residing in Oregon and registered un-
34 der the federal Controlled Substances Act.

35 (29) "Preceptor" means a pharmacist licensed and in good standing, registered by the board to
36 supervise the internship training of a licensed intern.

37 [(30) "Prescription drug" or "legend drug" means a drug which is:]

38 [(a) Required by federal law, prior to being dispensed or delivered, to be labeled with either of the
39 following statements:]

40 [(A) "Caution: Federal law prohibits dispensing without prescription"; or]

41 [(B) "Caution: Federal law restricts this drug to use by or on the order of a licensed
42 veterinarian"; or]

43 [(b) Required by any applicable federal or state law or regulation to be dispensed on prescription
44 only or is restricted to use by practitioners only.]

45 **(30)(a) "Prescription drug" or "legend drug" means a drug required by federal law to be**

1 **dispensed only by prescription.**

2 **(b) "Prescription drug" or "legend drug" includes, but is not limited to:**

3 **(A) Biological products, except as provided in paragraph (c) of this subsection; and**

4 **(B) Finished dosage forms and bulk drug substances subject to section 503(b) of the**
 5 **Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).**

6 **(c) "Prescription drug" or "legend drug" does not include:**

7 **(A) Blood or blood components intended for transfusion; or**

8 **(B) Biological products that are medical devices.**

9 (31) "Prescription" or "prescription drug order" means a written, oral or electronically trans-
 10 mitted direction, given by a practitioner authorized to prescribe drugs, for the preparation and use
 11 of a drug. When the context requires, "prescription" also means the drug prepared under such
 12 written, oral or electronically transmitted direction.

13 (32) "Retail drug outlet" means a place used for the conduct of the retail sale, administering or
 14 dispensing or compounding of drugs or chemicals or for the administering or dispensing of pre-
 15 scriptions and licensed by the board as a place wherein the practice of pharmacy may lawfully oc-
 16 cur.

17 (33) "Shopkeeper" means a business establishment, open to the general public, for the sale of
 18 nonlegend drugs, in the original and unbroken package, properly labeled according to state and
 19 federal laws, in conformity with the rules of the board.

20 (34) "Unit dose" means a sealed single-unit container so designed that the contents are admin-
 21 istered to the patient as a single dose, direct from the container. Each unit dose container must bear
 22 a separate label, be labeled with the name and strength of the medication, the name of the man-
 23 ufacturer or distributor, an identifying lot number and, if applicable, the expiration date of the
 24 medication.

25 (35) "Wholesale drug outlet" means any person [*who imports, stores, distributes or sells for resale*
 26 *any drugs including legend drugs and nonprescription drugs.*] **engaged in the wholesale distrib-**
 27 **ution of prescription drugs, including, but not limited to:**

28 **(a) Repackagers;**

29 **(b) Own-label distributors;**

30 **(c) Private-label distributors;**

31 **(d) Jobbers;**

32 **(e) Brokers;**

33 **(f) Warehouses, including manufacturers' and distributors' warehouses, chain drug**
 34 **warehouses and wholesale drug warehouses;**

35 **(g) Independent wholesale drug traders; and**

36 **(h) Retail pharmacies that conduct wholesale distribution.**

37 [(36) "Class I wholesaler" means any person operating or maintaining a wholesale distribution
 38 center, wholesale business or any other business in which drugs, medicinal chemicals, or poisons are
 39 sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally li-
 40 censed drug outlets or persons.]

41 [(37) "Class II wholesaler" means any person operating or maintaining a wholesale distribution
 42 center, wholesale business or any other business in which nonprescription drugs are offered for sale
 43 at wholesale to a drug outlet legally authorized to resell.]

44 **SECTION 2. Sections 3 to 10 of this 2005 Act are added to and made a part of ORS**
 45 **chapter 689.**

1 **SECTION 3.** The State Board of Pharmacy shall require, in addition to any other criteria
 2 under ORS 689.305 or 689.315, the following from each applicant for a wholesale drug outlet
 3 registration or renewal of registration:

4 (1) Name, business address and telephone number of the applicant;

5 (2) All current or former trade or business names used by the applicant;

6 (3) Name, address and telephone number of the contact person for each location or fa-
 7 cility used by the applicant for the storage or distribution of prescription drugs;

8 (4) Identity of the wholesale drug outlet as a sole proprietorship, partnership or corpo-
 9 ration and, if a corporation, the state of incorporation;

10 (5) The name of each partner or the name and title of each corporate officer or director
 11 of the wholesale drug outlet;

12 (6) A list of all licenses, registrations or permits issued by any other state to the appli-
 13 cant that authorize the purchase or possession of prescription drugs by the applicant; and

14 (7) The name of the manager, the next four highest ranking employees, all affiliated
 15 parties and the designated representative of the wholesale drug outlet. For each person
 16 identified in this paragraph, all of the following information must be provided:

17 (a) Place of residence for the past seven years.

18 (b) Date and place of birth.

19 (c) Occupations, job titles, names and addresses of places of employment and corporate
 20 offices held during the past seven years.

21 (d) A statement regarding whether the person was the subject of any proceeding for the
 22 revocation or suspension of any license, registration or permit related to manufacturing,
 23 distributing, delivering, dispensing, administering or storing drugs during the past seven
 24 years and, if so, the nature and disposition of the proceeding.

25 (e) A statement regarding whether the person has been enjoined by a court of competent
 26 jurisdiction from violating any federal or state law regulating the possession, control or dis-
 27 tribution of prescription drugs and, if so, a copy of the injunction and information on the
 28 current status of the proceeding.

29 (f) A statement describing any involvement by the person during the past seven years
 30 with any business that manufactures, administers, prescribes, distributes, dispenses or
 31 stores prescription drugs, and a description of any lawsuits in which the business was named
 32 a party. For purposes of this paragraph, "involvement" includes financial investment in a
 33 business, but does not include ownership of stock in a publicly traded company or a mutual
 34 fund.

35 (g) A description of any felony criminal offense for which the person was found guilty.
 36 If a criminal conviction is under appeal, a copy of the notice of appeal must be submitted
 37 with the application, and, within 15 days after the disposition of the appeal, a copy of the
 38 disposition must be submitted to the board.

39 (h) A photograph of the person taken within 30 days preceding submission of the appli-
 40 cation for registration or renewal of registration.

41 (8) A wholesale drug outlet shall obtain a registration for each location or facility that
 42 stores or distributes prescription drugs.

43 (9) All registered wholesale drug outlets must report to the board, in a form and manner
 44 prescribed by the board, any change in the information submitted to the board under this
 45 section.

1 (10) The board by rule shall determine the information to be provided under this section.

2 **SECTION 4.** The State Board of Pharmacy may not issue or renew a wholesale drug
 3 outlet registration unless the designated representative of the applicant meets all of the
 4 following criteria:

5 (1) Is at least 18 years of age.

6 (2) Has been employed full-time for at least three years in a pharmacy or wholesale drug
 7 outlet in a capacity related to the dispensing and distribution of prescription drugs and
 8 recordkeeping of the sales of prescription drugs.

9 (3) Has received a score of 75 percent or higher on an examination approved by the board
 10 on federal and state laws governing wholesale distribution of prescription drugs. The desig-
 11 nated representative must retake the examination and receive a score of 75 percent or
 12 higher each time the applicant applies for renewal of registration if the designated repre-
 13 sentative is to continue in that capacity for the applicant.

14 (4) Is employed full-time in a managerial level position by the applicant.

15 (5) Is actively involved in and is aware of the daily operation of the wholesale drug outlet.

16 (6) Is physically present at the wholesale drug outlet during regular business hours.

17 (7) Is serving as the designated representative for only one applicant at a time.

18 (8) Has not been convicted of any offense relating to wholesale or retail distribution of
 19 prescription drugs or controlled substances.

20 (9) Has not been convicted of any felony under local, state or federal law.

21 **SECTION 5.** (1) The State Board of Pharmacy shall require each wholesale drug outlet
 22 applying for registration or renewal of registration to furnish a full set of fingerprints from
 23 each person required to submit information pursuant to section 3 of this 2005 Act. The fin-
 24 gerprints shall be used to conduct a nationwide criminal records check. The board shall
 25 submit completed fingerprint cards to the Department of State Police. The Department of
 26 State Police is authorized to submit the fingerprint cards to the Federal Bureau of Investi-
 27 gation for a nationwide criminal records check. The board may use information obtained
 28 from the nationwide criminal records check to determine the person's eligibility for licensing
 29 or renewal or in the conduct of investigations under ORS 676.165 or 677.320.

30 (2) Notwithstanding the provisions of ORS 192.410 to 192.505 relating to public records,
 31 the fingerprints and any photographs, records or reports compiled under this section are
 32 confidential and exempt from public inspection, except:

33 (a) As ordered by a court; or

34 (b) For access by the person who is the subject of the fingerprints, photographs, records
 35 or reports.

36 **SECTION 6.** (1) The State Board of Pharmacy shall require every wholesale drug outlet
 37 applying for registration or renewal of registration to submit a bond of at least \$_____
 38 or other equivalent means of security established by the board by rule.

39 (2) The bond or security shall be used solely for the purpose of paying any fine, penalty,
 40 fee or cost assessed by the board against the applicant for registration or renewal of regis-
 41 tration that the applicant fails to pay within 30 days after the fine, penalty, fee or cost be-
 42 comes final.

43 (3) The board may make a claim against the bond or security for a period not to exceed
 44 one year after the registration ceases to be valid.

45 **SECTION 7.** (1) At least 95 percent of the total amount of dollars a wholesale drug outlet

1 receives each month for the sale, distribution or transfer of prescription drugs must be to
2 pharmacies or other persons with authority to dispense or administer prescription drugs.

3 (2)(a) A wholesale drug outlet may not purchase or otherwise receive a prescription drug
4 from a pharmacy unless the prescription drug was originally purchased by the pharmacy
5 from the wholesale drug outlet.

6 (b) A wholesale drug outlet may not pay a pharmacy for a prescription drug, in cash or
7 credit, an amount greater than the amount originally paid by the pharmacy to the wholesale
8 drug outlet.

9 **SECTION 8.** A manufacturer or wholesale drug outlet subject to ORS 689.305:

10 (1) May not sell or otherwise distribute or dispense prescription drugs except to a person
11 registered by the State Board of Pharmacy under ORS 689.305 and at the premises listed on
12 the registration of the person registered under ORS 689.305.

13 (2) May sell or otherwise distribute prescription drugs to a person registered by the board
14 under ORS 689.305 provided:

15 (a) The identity and registration of the person is established; and

16 (b) The transfer of prescription drugs is limited to what is necessary to meet the imme-
17 diate needs of a particular patient of the registered person.

18 **SECTION 9.** A manufacturer or wholesale drug outlet may not accept payment, or allow
19 the use of credit to establish an account, for the purchase of prescription drugs from any
20 person other than the owner of record, the chief executive officer or the chief financial of-
21 ficer of an entity authorized by the State Board of Pharmacy to purchase prescription drugs.
22 An account established by a manufacturer or wholesale drug outlet for the purchase of pre-
23 scription drugs must bear the name of the purchasing entity.

24 **SECTION 10.** (1) As used in this section:

25 (a) "Authenticate" or "authentication" means verification, before distribution of a pre-
26 scription drug, that each transaction listed on a pedigree has occurred.

27 (b) "Pedigree" means a record of each sale, trade or transfer of a prescription drug from
28 manufacture through final sale to a pharmacy or other entity for dispensing or administer-
29 ing.

30 (2) A person, including a manufacturer, repackager or pharmacy, that sells, trades or
31 transfers a prescription drug other than to a final consumer shall retain a pedigree of the
32 sale, trade or transfer.

33 (3) A person that sells, trades or transfers a prescription drug other than to a final
34 consumer shall provide a copy of the pedigree to the person purchasing or receiving the
35 prescription drug, and shall affirmatively verify before distribution that each transaction
36 listed on the pedigree has occurred.

37 (4) A sale, trade or transfer of a prescription drug between licensees with a common
38 ownership or to meet emergency needs is not subject to this section.

39 (5) For each sale, trade or transfer required by this section to be recorded, the pedigree
40 shall be in a form adopted by the State Board of Pharmacy by rule and shall contain the
41 following information:

42 (a) Name, address, telephone number and, if available, electronic mail address of each
43 purchaser of the prescription drug and of each wholesale drug outlet that takes possession
44 of but not title to the prescription drug;

45 (b) Signature of each purchaser of the prescription drug and of each wholesale drug

1 **outlet that takes possession of but not title to the prescription drug;**

2 (c) **Name and address of each location from which the prescription drug was shipped;**

3 (d) **Date of each sale, trade or transfer;**

4 (e) **Certification that each recipient of the prescription drug has authenticated the**
5 **pedigree;**

6 (f) **Name of each prescription drug;**

7 (g) **Dosage form and strength of each prescription drug;**

8 (h) **Size of each container;**

9 (i) **Number of containers;**

10 (j) **Lot number of each prescription drug; and**

11 (k) **Names of the manufacturers of the finished dosage forms.**

12 (6) **Each person required by this section to produce or receive a pedigree shall maintain**
13 **the pedigree for three years.**

14 **SECTION 11.** ORS 689.995 is amended to read:

15 689.995. (1) Violation of any provision of this chapter or of any rule of the State Board of
16 Pharmacy is a misdemeanor.

17 (2) Failure to comply with any notice, citation or subpoena issued by the board under ORS
18 689.135 (13) is a misdemeanor. Each day during which the violation continues is a separate offense.

19 (3) Refusal to furnish information required under this chapter or willfully furnishing false in-
20 formation, is a misdemeanor.

21 (4) Any attempt to secure or the securing of registration or licensure for any person under any
22 certificate, license or permit authorized by this chapter by making or causing to be made any false
23 representations is a misdemeanor.

24 (5) **Violation of any provisions of sections 3, 4, 7, 8, 9 or 10 of this 2005 Act is punishable**
25 **by a fine not to exceed \$500,000 or imprisonment for life, or both.**

26