

House Bill 2669

Sponsored by Representative KENY-GUYER; Representative SCHOUTEN (Pre-session filed.)

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**.

Authorizes State Board of Pharmacy to inspect pharmacy to determine whether pharmacy compounds drugs. Defines "compound." Directs board to register outsourcing facility that complies with requirements established by rule and to inspect registered outsourcing facilities. Defines "outsourcing facility." Directs board to consider certain factors in determining whether drug is misbranded or mislabeled.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

1
2 Relating to pharmaceutical drugs; creating new provisions; amending ORS 689.135 and 689.505; and
3 prescribing an effective date.

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

5 **SECTION 1. Sections 2 and 3 of this 2019 Act are added to and made a part of ORS**
6 **chapter 689.**

7 **SECTION 2. (1) As used in this section, "compound" has the meaning given that term in**
8 **ORS 689.505.**

9 **(2) In addition to an inspection authorized under ORS 689.135, the State Board of Phar-**
10 **macy may inspect a pharmacy for the purpose of determining whether the pharmacy is one**
11 **in which drugs are compounded.**

12 **(3) The board shall:**

13 **(a) Maintain records of any inspections conducted pursuant to subsection (2) of this**
14 **section.**

15 **(b) Ensure that persons performing inspections under subsection (2) of this section have**
16 **appropriate training related to the sterile compounding of drugs.**

17 **(c) Inspect twice per year a pharmacy that the board determines is a pharmacy that**
18 **compounds drugs.**

19 **(4) The board may:**

20 **(a) Publish on a website maintained by or on behalf of the board the name of a pharmacy**
21 **in which drugs are compounded in violation of any rules adopted under this subsection or in**
22 **violation of any provision of this chapter.**

23 **(b) Adopt rules to carry out this section.**

24 **SECTION 3. (1) As used in this section:**

25 **(a) "Compound" has the meaning given that term in ORS 689.505.**

26 **(b) "Outsourcing facility" means a pharmacy that compounds sterile drugs.**

27 **(2) The State Board of Pharmacy shall register an outsourcing facility that meets the**
28 **requirements of the board established by rule. Rules adopted under this section must:**

29 **(a) Consider the requirements of federal law for outsourcing facilities.**

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 **(b) Require an outsourcing facility to report data to the board, in a manner similar to**
2 **that required under federal law, about the compound sterile drugs produced at the out-**
3 **sourcing facility.**

4 **(3) The board shall inspect, at least annually, an outsourcing facility to ensure compli-**
5 **ance with requirements established pursuant to subsection (2) of this section.**

6 **(4) The board shall publish on a website operated by or on behalf of the board the data**
7 **reported by outsourcing facilities to the board pursuant to subsection (2) of this section.**

8 **(5) The board:**

9 **(a) Shall adopt rules to establish a process to register outsourcing facilities and fees for**
10 **registration under this section.**

11 **(b) May adopt other rules as necessary to carry out this section.**

12 **SECTION 4. (1) As used in this subsection, "cosmetic":**

13 **(a) Means an item intended to be applied to any part of the human body for the purpose**
14 **of cleaning, beautifying or altering the appearance of the human body.**

15 **(b) Does not include soap.**

16 **(2) A person may not market, sell or offer for sale, in this state or another jurisdiction,**
17 **a cosmetic that the person knows or reasonably should know is adulterated or does not**
18 **comply with requirements related to labeling adopted by the State Board of Pharmacy by**
19 **rule.**

20 **(3) The board shall adopt rules to carry out this section.**

21 **SECTION 5. ORS 689.135 is amended to read:**

22 689.135. (1) The State Board of Pharmacy shall exercise the duties, powers and authority nec-
23 essary to enforce this chapter and to enforce board rules adopted pursuant to this chapter, including
24 but not limited to the following:

25 (a) Annual printing and circulation of copies of any changes in the laws relating to pharmacy,
26 controlled substances, drugs and poisons and the rules adopted to enforce the laws, and establish-
27 ment of reasonable charges for the copies.

28 (b) Appointment of advisory committees.

29 (2) The board may join professional organizations and associations organized exclusively to
30 promote the improvement of the standards of the practice of pharmacy for the protection of the
31 health and welfare of the public and whose activities assist and facilitate the work of the board.

32 (3) In addition to any statutory requirements, the board may require surety bonds as it deems
33 necessary to guarantee the performance and discharge of the duties of any officer or employee re-
34 ceiving and disbursing funds.

35 (4) The executive director of the board shall keep the seal of the board and shall affix it only
36 in the manner prescribed by the board.

37 (5) The board shall determine within 30 days prior to the beginning of each state fiscal year the
38 fees to be collected for:

39 (a) Examinations and reexaminations.

40 (b) A pharmacist license.

41 (c) A pharmacist license acquired through reciprocity.

42 (d) An intern license.

43 (e) A duplicate pharmacist certificate.

44 (f) Late renewal of a pharmacist license.

45 (g) Certification of an approved provider of continuing education courses.

1 (h) Registration of a drug outlet other than a pharmacy and renewal of the registration.

2 (i) Initial registration of a pharmacy or an institutional drug outlet.

3 (j) Annual renewal of a pharmacy or an institutional drug outlet registration.

4 (k) Late renewal of a pharmacy or an institutional drug outlet registration.

5 (L) Registration of a nonprescription drug outlet.

6 (m) Late renewal of a nonprescription drug outlet registration.

7 (n) Reinspection.

8 (o) Late renewal of registration of a drug outlet, other than a pharmacy or an institutional drug
9 outlet.

10 **(p) Registration of an outsourcing facility.**

11 (6) All moneys received under ORS 435.010 to 435.130 and 453.185 and this chapter shall be paid
12 into the State Treasury and placed to the credit of the State Board of Pharmacy Account to be used
13 only for the administration and enforcement of ORS 435.010 to 435.130 and this chapter.

14 (7) The board may receive and expend funds, in addition to its biennial appropriation, from
15 parties other than the state, provided:

16 (a) The moneys are awarded for the pursuit of a specific objective that the board is authorized
17 to accomplish by this chapter, or that the board is qualified to accomplish by reason of its juris-
18 diction or professional expertise;

19 (b) The moneys are expended for the pursuit of the objective for which they are awarded;

20 (c) Activities connected with or occasioned by the expenditures of the funds do not interfere
21 with or impair the performance of the board's duties and responsibilities and do not conflict with
22 the exercise of the board's powers as specified by this chapter;

23 (d) The moneys are kept in a separate, special state account; and

24 (e) Periodic reports are made to the Governor concerning the board's receipt and expenditure
25 of the moneys.

26 (8) The board may assign to each drug outlet under its jurisdiction, a uniform state number,
27 coordinated where possible with all other states that adopt the same uniform numbering system.

28 (9) The board or its authorized representatives shall have the power to investigate and gather
29 evidence concerning alleged violations of the provisions of this chapter or of the rules of the board.

30 (10) The president and vice president of the board may administer oaths in connection with the
31 duties of the board.

32 (11) The books, registers and records of the board as made and kept by the executive director,
33 or under the supervision of the executive director, subject to the direction of the board, are prima
34 facie evidence of the matter recorded in the books, registers and records, in any court of law.

35 (12) The board may administer oaths, issue notices and subpoenas in the name of the board,
36 enforce subpoenas in the manner authorized by ORS 183.440, hold hearings and perform such other
37 acts as are reasonably necessary to carry out its duties under this chapter.

38 (13)(a) Notwithstanding anything in this chapter to the contrary, whenever a duly authorized
39 representative of the board finds or has probable cause to believe that any drug or device is
40 adulterated, misbranded or a new drug, as defined in Section 201(p) of the Federal Food, Drug and
41 Cosmetic Act, for which there is no approval in effect pursuant to Section 505(b) of the federal Act
42 nor an approved notice of claimed investigational exemption pursuant to Section 505(i) of the federal
43 Act, or otherwise rendered unsafe for use as a result of fire, flood or other natural disaster, the
44 representative shall affix to such drug or device a tag or other appropriate marking giving notice
45 that such article is or is suspected of being adulterated, misbranded, or otherwise rendered unsafe

1 and has been detained or embargoed and warning all persons not to remove or dispose of such ar-
 2 ticle by sale or otherwise until provision for removal or disposal is given by the board, its agent or
 3 the court. No person shall remove or dispose of such embargoed drug or device by sale or otherwise
 4 without the permission of the board or its agent or, after summary proceedings have been instituted,
 5 without permission from the court.

6 (b) When a drug or device detained or embargoed under paragraph (a) of this subsection has
 7 been declared by such representative to be adulterated, misbranded or a new drug, or rendered un-
 8 safe, the board shall, as soon as practical thereafter, petition the judge of the circuit court in whose
 9 jurisdiction the article is detained or embargoed for an order for condemnation of such article. If
 10 the judge determines that the drug or device so detained or embargoed is not adulterated or mis-
 11 branded or rendered unsafe, the board shall direct the immediate removal of the tag or other
 12 marking.

13 (c) If the court finds the detained or embargoed drug or device is adulterated or misbranded or
 14 rendered unsafe, such drug or device, after entry of the judgment, shall be destroyed at the expense
 15 of the owner under the supervision of a board representative and all court costs and fees, storage
 16 and other proper expense shall be borne by the owner of such drug or device. When the
 17 adulteration or misbranding can be corrected by proper labeling or processing of the drug or device,
 18 the court, after entry of the judgment and after such costs, fees and expenses have been paid and
 19 a good and sufficient bond has been posted, may direct that such drug or device be delivered to the
 20 owner thereof for such labeling or processing under the supervision of a board representative. Ex-
 21 pense of such supervision shall be paid by the owner. Such bond shall be returned to the owner of
 22 the drug or device on representation to the court by the board that the drug or device is no longer
 23 in violation of the embargo and the expense of supervision has been paid.

24 (d) It is the duty of the Attorney General to whom the board reports any violation of this sub-
 25 section to cause appropriate proceedings to be instituted in the proper court without delay and to
 26 be prosecuted in the manner required by law. Nothing in this subsection shall be construed to re-
 27 quire the board to report violations whenever the board believes the public's interest will be ade-
 28 quately served in the circumstances by a suitable written notice or warning.

29 (14) Except as otherwise provided to the contrary, the board shall exercise all of its duties,
 30 powers and authority in accordance with ORS chapter 183.

31 **SECTION 6.** ORS 689.505 is amended to read:

32 689.505. (1)(a) Except as specifically provided by law, *[no]* a person *[shall]* **may not** distribute
 33 or dispense any drug without affixing to the authorized container a clear and legible label, either
 34 printed or written, *[bearing]* **that bears:**

35 (A) The name of the drug *[and]*;

36 (B) The name and place of business of the person distributing or dispensing the drug*[,]*; and

37 (C) Any other information required by state law or rules or federal law or regulations under
 38 whose supervision the drug is delivered or dispensed.

39 (b) *[Labeling requirements regarding any drug may be changed or exemption therefrom granted*
 40 *by the State Board of Pharmacy in the form of a special permit]* If the **State Board of Pharmacy**
 41 determines that a change **in** or exemption **to drug labeling requirements** is in the best interest
 42 of public health and safety, **the board may:**

43 (A) **Change the drug labeling requirements; or**

44 (B) **Grant an exemption to the drug labeling requirements in the form of a special**
 45 **permit.**

1 (2)(a) [No] A manufacturer or wholesaler subject to ORS 689.305 [shall] **may not** sell or other-
 2 wise distribute, or offer to sell or otherwise distribute, any drug for use in a:

3 (A) Parcel, package or container **that does** not [bearing] **bear** a label specifying the name, ac-
 4 tive ingredients or contents, quality and quantity of the drug.

5 (B) Misbranded parcel, package or container.

6 (b) A parcel, package or container is misbranded:

7 (A) If its labeling is false or misleading in any particular.

8 (B) Unless it bears a label containing the name and business address of the manufacturer,
 9 packer, distributor or wholesaler, and an accurate statement of the quantity of the drug in terms
 10 of weight, measure or numerical count, exclusive of wrappers, cartons, containers or other materials
 11 packed with such drug.

12 (C) In case it contains controlled substances which the board finds and by rule designates after
 13 reasonable notice and opportunity for hearing to be habit forming, unless it bears the statement
 14 "Warning--May Be Habit Forming."

15 (D) Unless it bears a label with adequate directions for the safe use of the drug for specified
 16 conditions, and adequate warning against use in those pathological conditions or by children where
 17 such use may be dangerous to the health or welfare of a user.

18 (E) Unless it bears a label with true representations of the intended uses of the drug and no
 19 false claims or representations are made of the drug in accompanying literature or advertising.

20 (3) This section does not apply to parcels, packages or containers containing:

21 (a) Drugs prepared and packaged solely for use by a pharmacist in compounding prescriptions
 22 or for dispensing in dosage unit form upon a prescription, except that such parcels, packages or
 23 containers must bear the name and business address of the manufacturer and, if different, the name
 24 and business address of the distributor of the drug, and the legend "Caution: Federal Law Prohibits
 25 Dispensing Without Prescription" or an equivalent legend.

26 (b) Drugs intended solely for use in the professional diagnosis of disease, except that such par-
 27 cels, packages or containers shall bear the statement "Diagnostic Reagent--For Professional Use
 28 Only."

29 (c) Coloring agents, emulsifiers, excipients, flavorings, lubricants, preservatives and other like
 30 inactive ingredients used in the manufacture of drugs.

31 (4) The board shall by rule exempt from any labeling or packaging requirement of this section
 32 drugs [which] **that** are, in accordance with the practice of the trade, to be processed, labeled or
 33 repacked in substantial quantities at establishments other than those where originally processed or
 34 packed. [However, such] **The drugs described in this subsection [must] may** not be adulterated or
 35 misbranded upon removal from such processing, labeling or repacking establishment.

36 (5) A pharmacist or pharmacy intern [shall] **may** not dispense, on the prescription of a practi-
 37 tioner, any drug without affixing to the **drug** container [thereof] a clear and legible label. The label
 38 may be printed or written. Except as provided in subsection (6) of this section, the pharmacist or
 39 pharmacy intern shall state or cause to be stated on the label the following:

40 (a) The name of the drug. If the dispensed drug does not have a brand name, the prescription
 41 label [shall] **must** indicate the generic name of the drug dispensed along with the name of the drug
 42 distributor or manufacturer, [its] **the drug's** quantity per unit and the directions for its use stated
 43 in the prescription. However, if the drug is a compound, the quantity per unit need not be stated.

44 (b) The name of the practitioner prescribing the drug.

45 (c) The name and place of business of the pharmacist or the name and place of business of the

1 pharmacy for which the pharmacist or pharmacy intern is acting.

2 (d) The name of the patient, unless the drug is prescribed to a partner of a patient as defined
3 in ORS 676.350 in accordance with rules adopted under ORS 676.350 authorizing the practice of ex-
4 pedited partner therapy.

5 (e) When applicable and as determined by the [State Board of Pharmacy] **board**, an expiration
6 date after which the patient should not use the drug.

7 (6) If the prescribing practitioner so directs, the prescription label [shall] **may** not state the
8 name and quantity per unit of the drug.

9 (7) The [State Board of Pharmacy] **board** shall determine those drugs [which] **that** must bear
10 an expiration date under subsection (5)(e) of this section.

11 [(8) As used in this section, “compound” means a drug containing two or more medically active
12 ingredients.]

13 [(9)] (8) [No] A person [shall] **may not** deliver or dispense any drug for use by the ultimate
14 consumer without labeling the drug container as required in this section.

15 [(10)] (9) In addition to the labeling requirements imposed by subsections (1) to [(9)] (8) of this
16 section, the board may impose by rule requirements for drug code imprints on solid dose legend
17 drugs.

18 (10) **If a drug is alleged to be mislabeled or misbranded in violation of this section, the**
19 **board shall consider, in determining whether the drug was mislabeled or misbranded, the**
20 **following:**

21 (a) **Any representations made regarding potential impacts of the use of the drug as di-**
22 **rected by the label; and**

23 (b) **The extent to which any representations made misguide the user of the drug with**
24 **respect to the impact of the use of the drug as directed by the label.**

25 (11) **As used in this section, “compound” means a drug containing two or more medically**
26 **active ingredients.**

27 **SECTION 7. (1) Sections 2 to 4 of this 2019 Act and the amendments to ORS 689.135 and**
28 **689.505 by sections 5 and 6 of this 2019 Act become operative on January 1, 2020.**

29 (2) **The State Board of Pharmacy may take any action before the operative date specified**
30 **in subsection (1) of this section that is necessary to enable the board to exercise, on and**
31 **after the operative date specified in subsection (1) of this section, all of the duties, functions**
32 **and powers conferred on the board by sections 2 to 4 of this 2019 Act and the amendments**
33 **to ORS 689.135 and 689.505 by sections 5 and 6 of this 2019 Act.**

34 **SECTION 8. This 2019 Act takes effect on the 91st day after the date on which the 2019**
35 **regular session of the Eightieth Legislative Assembly adjourns sine die.**

36