

Senate Bill 763

Sponsored by Senator PATTERSON, Representative SALINAS, Senator LINTHICUM, Representative HUDSON; Senator GORSEK, Representatives CAMPOS, GRAYBER, NERON, NOSSE, PRUSAK, SANCHEZ, SCHOUTEN, WITT

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**.

Provides that person may not engage in business as pharmaceutical representative without obtaining license from Director of Department of Consumer and Business Services. Specifies application requirements and procedures, required qualifications of licensee and basis on which director may issue, renew or reinstate license. Prescribes certain duties of and prohibits certain actions by licensee. Enables director to punish violations of Act by suspending, revoking or refusing to renew or reinstate license.

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

1 Relating to licensing pharmaceutical representatives; and prescribing an effective date.

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

SECTION 1. As used in sections 1 to 9 of this 2021 Act:

4 (1) **"Business entity" means a corporation, limited liability company, partnership, limited**
5 **liability partnership, association or other legal entity that is incorporated, organized or au-**
6 **thorized to engage in business in this state.**

7 (2) **"Compensation" means a salary, wage, commission, bonus, concession, franchise or**
8 **any other pecuniary benefit a person receives for engaging in business as a pharmaceutical**
9 **representative.**

10 (3) **"Health care provider" means a person that is licensed, certified or otherwise au-**
11 **thorized under the laws of this state to prescribe, provide or dispense pharmaceutical pro-**
12 **ducts to patients for the purposes of diagnosis, treatment or care of disease, injury or**
13 **congenital conditions including, but not limited to, a person who is:**

14 (a) **A physician or physician's assistant;**

15 (b) **A nurse practitioner;**

16 (c) **A psychiatrist;**

17 (d) **A pharmacist; or**

18 (e) **A hospital, clinic or pharmacy.**

19 (4) **"Licensee" means a person that holds a valid and unexpired license to engage in**
20 **business as a pharmaceutical representative that the person obtained under section 4 of this**
21 **2021 Act.**

22 (5) **"Person" means an individual or a business entity.**

23 (6) **"Pharmaceutical product" means any biological or chemical product designed, manu-**
24 **factured, prescribed and dispensed for the purpose of treating or preventing disease, physical**
25 **or mental illness, physical discomfort, a chronic or congenital condition or related symp-**
26 **toms.**

27 **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 (7) “Pharmaceutical representative” means a person that meets the description in sec-
2 tion 2 of this 2021 Act of a person that engages in business as a pharmaceutical represen-
3 tative.

4 **SECTION 2.** (1) A person may not engage in business as a pharmaceutical representative
5 unless the person is a licensee. Except as provided in subsection (2) of this section, a person
6 engages in business as a pharmaceutical representative if for compensation the person en-
7 gages in, purports to engage in or offers to engage in:

8 (a) Making marketing or sales presentations, whether in person or by remote communi-
9 cation, to a health care provider:

10 (A) With the intention of inducing or persuading the health care provider to purchase a
11 pharmaceutical product, or to prescribe or recommend a pharmaceutical product to the
12 health care provider’s patients or clients; or

13 (B) That have the effect of inducing or persuading the health care provider to purchase
14 a pharmaceutical product, or to prescribe or recommend a pharmaceutical product to the
15 health care provider’s patients or clients;

16 (b) Negotiating pricing and terms and conditions for sales of a pharmaceutical product
17 to a health care provider;

18 (c) Selling or offering a pharmaceutical product for sale to a health care provider;

19 (d) Acting as a consultant or providing a service to a health care provider with regard
20 to a pharmaceutical product;

21 (e) Giving advice, counsel or opinion to a health care provider with respect to the fea-
22 tures, benefits, effects, advantages or disadvantages of a pharmaceutical product;

23 (f) Providing information about a pharmaceutical product to a health care provider in any
24 other manner; or

25 (g) Acting in another capacity that the Director of the Department of Consumer and
26 Business Services by rule determines is engaging in business as a pharmaceutical represen-
27 tative.

28 (2) A person does not engage in business as a pharmaceutical representative if the person
29 provides information about, testifies or answers questions concerning, or discusses the fea-
30 tures, benefits, effects, advantages or disadvantages of, a pharmaceutical product in the
31 context of an academic presentation, a research study that is not conducted or funded by the
32 person’s employer or an affiliate of the person’s employer, a hearing or proceeding before a
33 governmental agency, an official government proceeding to consider approving the pharma-
34 ceutical product for manufacture, distribution or sale or in a similar or related context that
35 the director specifies by rule.

36 **SECTION 3.** (1) An applicant for a license to engage in business as a pharmaceutical
37 representative shall submit to the Director of the Department of Consumer and Business
38 Services, on a form, in a format and using a method that the director specifies by rule, an
39 application that:

40 (a) Lists the applicant’s name, residence and business address, previous experience en-
41 gaging in business as a pharmaceutical representative, present occupation, occupation during
42 the previous year and the names of the applicant’s employers for the previous five years;

43 (b) Lists the street address of the applicant’s principal place of business;

44 (c) Lists any assumed business name under which the applicant intends to engage in
45 business as a pharmaceutical representative;

1 (d) Specifies the portion of the applicant's time that the applicant will devote to engaging
2 in business as a pharmaceutical representative; and

3 (e) Includes any other information the director requires by rule.

4 (2) An applicant that is a business entity, in addition to providing the information speci-
5 fied in subsection (1) of this section in an application for a license to engage in business as
6 a pharmaceutical representative, shall:

7 (a) List the names and addresses of each director, member and officer of the business
8 entity, and any person that owns, directly or indirectly, more than 10 percent of any class
9 of equity security of the business entity; and

10 (b) Designate each individual who is responsible for ensuring that the business entity
11 complies with sections 1 to 9 of this 2021 Act and rules the director adopts under sections 1
12 to 9 of this 2021 Act and who will otherwise exercise the powers that the license confers on
13 the licensee.

14 (3) The applicant shall pay to the Department of Consumer and Business Services as part
15 of an application under this section a fee in an amount that the director specifies by rule
16 that does not exceed \$750. Unless the director by rule specifies otherwise, the fee is not
17 refundable.

18 **SECTION 4.** (1) The Director of the Department of Consumer and Business Services may
19 issue a license for a person to engage in business as a pharmaceutical representative in this
20 state if the director finds that the person:

21 (a) Submitted a complete and accurate application in accordance with section 3 of this
22 2021 Act;

23 (b) Paid all required fees to the director and to any other entity the director specifies
24 by rule;

25 (c) Met the qualifications set forth in section 5 of this 2021 Act; and

26 (d) Has not engaged in conduct that would subject the person to discipline under section
27 8 of this 2021 Act.

28 (2)(a) The director may renew a license the director issues under this section if the
29 licensee:

30 (A) Pays all fees the director by rule requires for the renewal;

31 (B) Demonstrates, if the licensee is an individual, that the licensee has satisfactorily
32 completed continuing education requirements in subjects that the director specifies by rule;

33 (C) Has not engaged in any conduct that would subject the licensee to discipline under
34 section 8 of this 2021 Act; and

35 (D) Satisfies any other requirement the director by rule establishes for renewing a li-
36 cense under this subsection.

37 (b) The director may renew a license that has expired within one year after the expira-
38 tion date if:

39 (A) The director did not revoke the former licensee's license or did not refuse to renew
40 the license for failing the condition stated in paragraph (a)(C) of this subsection;

41 (B) The director determines, by examination or otherwise, that the former licensee has
42 the knowledge required to qualify for licensure under section 5 of this 2021 Act;

43 (C) The former licensee pays double the amount of the fee the director specified in ac-
44 cordance with section 3 (3) of this 2021 Act; and

45 (D) The former licensee otherwise satisfies all applicable requirements for renewal.

1 (c) A former licensee may renew a license that has expired during a period of suspension
2 as provided in paragraph (b) of this subsection.

3 (d) A person that does not renew a license as provided in paragraph (a) or (b) of this
4 subsection may obtain a license only as provided in subsection (1) of this section.

5 (3)(a) A license that the director issues under subsection (1) of this section expires on
6 the last day of the month in which the anniversary of the date on which the director issued
7 the license occurs, unless the director specifies a different date by rule or order.

8 (b) A license that the director renews as provided in subsection (2) of this section expires
9 two years after the renewal date, unless the director specifies a different date by rule or
10 order.

11 (c) A licensee may not assign or transfer a license the director issues under this section
12 to any other person.

13 (4) The director may reinstate a licensee's license under the following circumstances:

14 (a) If the director revoked the license, the director may reinstate the license if the
15 licensee satisfies all of the conditions that the director prescribes for reinstatement; and

16 (b) If a licensee has voluntarily surrendered a license, the director may reinstate the li-
17 cense without requiring the former licensee to take an examination otherwise required for
18 the license if the former licensee applies for the license as provided in section 3 of this 2021
19 Act within two years after surrendering the previous license and demonstrates that the
20 former licensee has satisfied any continuing education requirements that would have applied
21 had the former licensee renewed the previous license.

22 (5) If the director has suspended a license, the director may modify or lift the suspension
23 at a time certain or upon the licensee's satisfying the conditions the director prescribes for
24 modifying or lifting the suspension.

25 **SECTION 5.** (1) An individual who applies for a license to engage in business as a phar-
26 maceutical representative shall:

27 (a) Establish a residence or place of business in or from which the applicant intends to
28 engage in business in this state before submitting an application;

29 (b) Have at least one year of experience performing the duties of a pharmaceutical rep-
30 resentative under the supervision of a licensee or have equivalent education or qualifications
31 that the Director of the Department of Consumer and Business Services specifies by rule;
32 and

33 (c) Pass an examination that the director by rule recognizes as adequately testing the
34 applicant's qualifications, competence and knowledge of:

35 (A) Ethical standards that emphasize honesty, transparency, good faith and fair dealing;

36 (B) State and federal laws that apply to pharmaceutical marketing and sales, including
37 knowledge of the requirements of sections 1 to 9 of this 2021 Act;

38 (C) Situations that require notifications to regulatory authorities and whistleblower pro-
39 tections that apply to such situations; and

40 (D) Any other qualifications, competence or knowledge the director deems necessary to
41 qualify for licensure.

42 (2) A business entity that applies for a license to engage in business as a pharmaceutical
43 representative must establish an office in this state that is managed by an individual who is
44 a licensee.

45 (3) In addition to the requirements set forth in subsection (1) or (2) of this section, as

1 appropriate, an applicant must satisfy any other requirement the director specifies by rule.

2 (4)(a) Except as provided in paragraph (b) of this subsection, the director may agree or
3 contract with another jurisdiction, regulatory body, private vendor or other person to ad-
4 minister any required examinations and to collect documentation and any fees that the di-
5 rector by rule specifies that the jurisdiction, regulatory body, vendor or person may collect
6 from an applicant.

7 (b) The director may not contract for the purposes described in paragraph (a) of this
8 subsection with a person that:

9 (A) Employs a pharmaceutical representative in any capacity; or

10 (B) Otherwise has a material conflict of interest that would prevent the person from
11 administering an examination described in subsection (1)(c) of this section in an impartial
12 and disinterested manner.

13 (c) The director, before executing an agreement or contract described in paragraph (a)
14 of this subsection, shall require each prospective contractor to disclose all potential conflicts
15 of interest of the type described in paragraph (b) of this subsection. For the purposes of this
16 paragraph, a material conflict of interest includes providing any funding to a person that
17 administers an examination described in subsection (1)(c) of this section or any education
18 or preparatory course for such an examination.

19 **SECTION 6.** (1) A licensee shall:

20 (a) Maintain a principal place of business in or from which the licensee engages in busi-
21 ness as a pharmaceutical representative. The principal place of business may be the
22 licensee's residence, but the principal place of business must be accessible to the public.

23 (b) Keep at the licensee's place of business all of the usual and customary records for the
24 business in which the licensee engages and must make the records available to the Director
25 of the Department of Consumer and Business Services for inspection during business hours.
26 The licensee shall keep the records of each business transaction for three years after the
27 conclusion of the transaction.

28 (c) Provide or make available to the director copies of the records described in subsection
29 (2) of this section at the director's request and in the manner the director prescribes, if the
30 licensee's principal place of business is outside this state.

31 (2)(a) In addition to the requirements set forth in subsection (1) of this section, a licensee
32 not later than November 1 of each year shall submit to the director on a form the director
33 provides a report that discloses for the previous 12 months:

34 (A) How many health care providers the licensee contacted or interacted with for the
35 purpose of marketing or selling a pharmaceutical product;

36 (B) The specialties or areas of practice of the health care providers;

37 (C) The method, location and duration of the contact or interaction;

38 (D) The specific pharmaceutical products that the licensee marketed, sold or offered for
39 sale; and

40 (E) Whether the licensee offered or provided product samples, gifts, consideration or in-
41 ducements to the health care provider and the value of any such samples, consideration, gifts
42 or inducements.

43 (b) The licensee shall keep the report described in paragraph (a) of this subsection as
44 part of the business records described in subsection (1)(b) of this section.

45 (c) A report a licensee submits under this subsection is a public record, but the director

1 before disclosing a report shall redact any information that personally identifies a licensee.

2 **SECTION 7. (1)(a) A licensee shall notify the Director of the Department of Consumer**
3 **and Business Services not later than 30 days after:**

4 (A) The licensee opens or closes a place of business in this state or changes the location
5 or contact information for the licensee's residence or any of the licensee's places of business;

6 (B) The licensee begins or stops using or changes an assumed business name under which
7 the licensee engages in business as a pharmaceutical representative;

8 (C) A government agency or regulator in this or another state has taken a final admin-
9 istrative action against the licensee;

10 (D) The licensee receives notice of an initiation or prosecution of criminal charges
11 against the licensee in any United States jurisdiction for any felony or a misdemeanor that
12 involves fraud, dishonesty or a breach of trust; or

13 (E) The licensee's authority to act for a business entity begins or terminates.

14 (b) In the notice a licensee submits under paragraph (a) of this subsection, the licensee
15 shall:

16 (A) Update any information that has changed from the time the licensee submitted an
17 application for a license or submitted a previous notice under this section; and

18 (B) Include any relevant documents that describe, support, are evidence of or otherwise
19 illustrate the contents of the notice, including but not limited to copies of complaints, in-
20 formations or indictments, motions, orders, consents and consent decrees, judgments and
21 any other relevant records or legal documents.

22 (2) Not later than December 31 of each year, a licensee that is a business entity shall
23 notify the director of any change during the previous calendar year in the licensee's direc-
24 tors, members or officers, or other persons that own, directly or indirectly, more than 10
25 percent of any class of equity security of the licensee.

26 (3) The director by rule may establish a different period within which a licensee must
27 notify the director under subsection (1) or (2) of this section.

28 **SECTION 8. (1) A licensee or an applicant for a license to engage in business as a phar-**
29 **maceutical representative may not:**

30 (a) Act in an incompetent or untrustworthy manner.

31 (b) Falsify or act dishonestly with respect to an application for a license or an amend-
32 ment to the license or with respect to an examination related to obtaining, renewing or
33 reinstating a license.

34 (c) Commit an offense that results in a conviction in any United States jurisdiction for
35 any felony or a misdemeanor that involves fraud, dishonesty or a breach of trust. For the
36 purpose of this paragraph, the record of a conviction is conclusive evidence of the conviction.

37 (d) Materially misrepresent the features, benefits, effects, advantages or disadvantages
38 or price of, available discounts for, or other information about a pharmaceutical product or
39 otherwise engage in deceptive or misleading practices when marketing or selling a pharma-
40 ceutical product, including concealing, suppressing, omitting or misstating any material
41 facts.

42 (e) Use a designation or title or otherwise represent that the licensee or applicant has a
43 license to practice medicine, nursing, dentistry, optometry, pharmacy or otherwise engage
44 in business as a health care provider unless the licensee or applicant does in fact have such
45 a license.

1 (f) Offer or provide compensation, a payment, merchandise, travel, lodgings or other ac-
2 commodations or any other valuable consideration or inducement directly to a health care
3 provider in exchange for the health care provider's agreement to purchase, recommend or
4 prescribe a pharmaceutical product, unless the consideration or inducement is a rebate or
5 discount on a purchase and the pharmaceutical representative makes substantially the same
6 offer to all of the pharmaceutical representative's customers.

7 (g) Attend or participate in an examination of a patient without the patient's informed
8 and affirmative consent.

9 (h) Fail to disclose as part of a marketing or sales presentation or other contact with a
10 health care provider the wholesale cost of a pharmaceutical product or the availability of a
11 generic alternative to the pharmaceutical product in response to an inquiry from a health
12 care provider.

13 (i) Fail to display the licensee's license during each separate interaction with a health
14 care provider for the purpose of marketing or selling a pharmaceutical product.

15 (j) Commit an act that results in another federal or state jurisdiction or an agency or
16 instrumentality of the jurisdiction canceling, suspending, revoking or refusing to renew a li-
17 cense or other evidence of authority to act as a pharmaceutical representative. For the
18 purpose of this paragraph, the record of the cancellation, suspension, revocation or refusal
19 is conclusive evidence of the cancellation, suspension, revocation or refusal.

20 (k) Fail to comply with continuing education requirements that apply to the licensee or
21 applicant, unless the Director of the Department of Consumer and Business Services has
22 waived the requirements.

23 (L) Act dishonestly, fraudulently or deceptively in a business that is not related to en-
24 gaging in business as a pharmaceutical representative.

25 (m) Fail to pay state income tax or to comply with an administrative or court order that
26 directs the licensee or applicant to pay state income tax that remains unpaid.

27 (n) Otherwise engage in a fraudulent or dishonest practice in the course of engaging in
28 business as a pharmaceutical representative that causes injury or loss to a health care pro-
29 vider or a member of the public.

30 (2) A health care provider may report a licensee's violation of a provision of subsection
31 (1) of this section to the director. The director shall investigate any such reports and take
32 appropriate disciplinary action when the director determines disciplinary action is appropri-
33 ate.

34 (3)(a) If a licensee or an applicant for a license to engage in business as a pharmaceutical
35 representative engages in an action or practice prohibited under subsection (1) of this sec-
36 tion, the director by order or otherwise may:

37 (A) Refuse to issue a license to an applicant to engage in business as a pharmaceutical
38 representative; or

39 (B) Suspend, revoke or refuse to renew a licensee's license.

40 (b) Before taking a disciplinary action against a licensee under paragraph (a) of this
41 subsection, the director shall notify the licensee and offer the licensee an opportunity for a
42 hearing in accordance with ORS chapter 183.

43 (4) The director may take a disciplinary action described in subsection (3) of this section
44 if the director finds that:

45 (a) A director, member or officer of a licensee that is a business entity, or another per-

1 son that directly or indirectly has the power to direct the management, control or activities
 2 of the business entity, engaged in an action prohibited under subsection (1) of this section;
 3 or

4 (b) The Director of the Department of Consumer and Business Services erred in approv-
 5 ing, issuing, renewing or reinstating a license under section 4 of this 2021 Act.

6 (5)(a) For a violation of a prohibition described in subsection (1) of this section and in lieu
 7 of taking a disciplinary action against a licensee under subsection (3) of this section, the di-
 8 rector may set a period of probation with respect to a license to engage in business as a
 9 pharmaceutical representative. In setting the probationary period, the director shall specify
 10 conditions that a licensee must meet in order to end the probationary period.

11 (b) The director may set the probationary period to begin at the time the director issues,
 12 renews, amends or reinstates a license.

13 (c) Before setting a period of probation for a licensee under paragraph (a) of this sub-
 14 section, the director shall notify the licensee and offer the licensee an opportunity for a
 15 hearing in accordance with ORS chapter 183.

16 (d) During any probationary period, the director may take any disciplinary action de-
 17 scribed in subsection (3) of this section.

18 **SECTION 9.** The Director of the Department of Consumer and Business Services shall:

19 (1) Establish by rule requirements for continuing education that each licensee must sat-
 20 isfy as a condition for continuation of the license.

21 (2) Prepare and submit to an interim committee of the Legislative Assembly with over-
 22 sight over health care not later than December 31 of each year a report that aggregates and
 23 summarizes the information the director receives from licensees in the previous 12 months
 24 under section 6 (2) of this 2021 Act and that recommends any legislation or other actions the
 25 director deems necessary to better effectuate the purposes of sections 1 to 9 of this 2021 Act.

26 **SECTION 10.** (1) Sections 1 to 9 of this 2021 Act become operative on January 1, 2022.

27 (2) The Director of the Department of Consumer and Business Services may adopt rules
 28 and take any other action before the operative date specified in subsection (1) of this section
 29 that is necessary to enable the director, on and after the operative date specified in sub-
 30 section (1) of this section, to undertake and exercise all of the duties, functions and powers
 31 conferred on the director by sections 1 to 9 of this 2021 Act.

32 **SECTION 11.** This 2021 Act takes effect on the 91st day after the date on which the 2021
 33 regular session of the Eighty-first Legislative Assembly adjourns sine die.

34