

B-Engrossed Senate Bill 763

Ordered by the Senate June 18
Including Senate Amendments dated April 16 and June 18

Sponsored by Senator PATTERSON, Representatives SALINAS, HUDSON; Senators GOLDEN, 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.

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*] **professional educational requirements for** 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[,] **or** revoking [*or refusing to renew or reinstate*] license **and by imposing civil penalty of not less than \$1,000 and not more than \$3,000 for violation of Act.**

Takes effect on 91st day following adjournment sine die.

A BILL FOR AN ACT

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

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

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

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

9 (A) **A physician or physician's assistant;**

10 (B) **A nurse practitioner;**

11 (C) **A psychiatrist;**

12 (D) **A pharmacist; or**

13 (E) **A hospital, clinic or pharmacy.**

14 (b) **"Licensee" means a person that holds a valid and unexpired license issued under this**
15 **section.**

16 (c) **"Pharmaceutical product" means a medication that may be legally dispensed only with**
17 **a valid prescription from a health care provider.**

18 (d) **"Pharmaceutical representative" means a person that markets or promotes pharma-**
19 **ceutical products to health care providers.**

20 (2)(a) **A person may not engage in business as a pharmaceutical representative without**
21 **first obtaining a license, unless the person engages in business as a pharmaceutical repre-**
22 **sentative in this state for fewer than 15 days during each calendar year.**

23 (b) **As a condition of applying for and receiving a license under this section, an applicant**
24 **shall complete a professional education course that the Director of the Department of Con-**

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 **sumer and Business Services specifies by rule.**

2 **(3)(a) An applicant for a license to engage in business as a pharmaceutical representative**
3 **shall submit to the director on a form and with the contents the director specifies by rule:**

4 **(A) The applicant's full name, residence address, residence telephone number, business**
5 **address and business telephone number;**

6 **(B) A description of the business in which the applicant will engage;**

7 **(C) A license fee of \$750;**

8 **(D) Documentation that shows that the applicant has completed the professional educa-**
9 **tion course described in subsection (2)(b) of this section; and**

10 **(E) Any other information the director reasonably requires.**

11 **(b) Except as provided in subsection (8) of this section, the director shall issue a license**
12 **to an applicant or renew a license for a licensee unless the director determines that the ap-**
13 **plicant or licensee has not complied with the requirements of paragraph (a) of this sub-**
14 **section.**

15 **(c) A license the director issues under this section is valid until the end of the calendar**
16 **year in which the director issues the license.**

17 **(d) A licensee may not transfer a license the director issues under this section.**

18 **(e) A licensee shall report to the director in writing any changes to the information the**
19 **licensee submitted under paragraph (a) of this subsection, and any material changes the**
20 **licensee made in the licensee's business operations, within four days after the change in the**
21 **information occurs. The director by rule may specify changes that constitute material**
22 **changes in the licensee's business operations.**

23 **(4) A licensee may renew a license by submitting an application as provided in subsection**
24 **(3)(a) of this section, except that in lieu of the documentation required under subsection**
25 **(3)(a)(D) of this section, the applicant must submit documentation that shows that the ap-**
26 **plicant during the previous year completed at least five hours of continuing education in**
27 **accordance with requirements the director specifies by rule.**

28 **(5)(a) The director shall specify by rule the contents of a course of professional education**
29 **necessary to complete an application for a license under this section and the contents of a**
30 **course of continuing education necessary to renew a license under this section. The educa-**
31 **tion may include training in:**

32 **(A) Ethics;**

33 **(B) Pharmacology;**

34 **(C) Laws and rules that apply to pharmaceutical marketing; and**

35 **(D) Any other subjects related to pharmaceutical marketing that the director deems**
36 **necessary.**

37 **(b) The director may designate and publish a list of persons that provide professional**
38 **education that meets the director's specifications under this section. An applicant or a**
39 **licensee may not receive professional education from the applicant's or licensee's employer.**

40 **(6)(a) At the director's request or at intervals the director specifies by rule, a licensee**
41 **shall provide to the director the following information:**

42 **(A) Documentation that shows that the licensee has completed education required under**
43 **this section;**

44 **(B) A list of health care providers within this state that the licensee contacted since the**
45 **director's last request or during the previous calendar year, as appropriate;**

1 (C) The number of times the licensee contacted each health care provider;

2 (D) The location and duration of the licensee's contact with each health care provider;

3 (E) Which pharmaceutical products the licensee promoted;

4 (F) Whether the licensee provided the health care provider with any product samples,
5 materials or gifts and, if so, the monetary value of the samples, materials or gifts; and

6 (G) Whether and how the licensee otherwise compensated the health care provider for
7 contact with the licensee.

8 (b) The director by rule may specify a form and contents for the disclosures required
9 under this subsection.

10 (7) A licensee may not:

11 (a) Engage in any deceptive or misleading marketing of a pharmaceutical product, in-
12 cluding knowingly concealing, suppressing, omitting, misrepresenting or misstating material
13 facts concerning or related to a pharmaceutical product;

14 (b) Use a title or designation that could reasonably lead a health care provider or an
15 employee of a health care provider to believe that the licensee is a health care provider if
16 the licensee is not licensed as a health care provider or otherwise authorized to provide
17 health care services; or

18 (c) Attend an examination of a patient without the patient's consent.

19 (8)(a) The director may suspend or revoke a license for a violation of a provision of this
20 section and, in addition to and not in lieu of a suspension or revocation, may impose a civil
21 penalty in an amount not less than \$1,000 and not more than \$3,000 for each violation. Each
22 day during which a violation continues constitutes a separate violation. The director shall
23 impose any civil penalties in accordance with ORS 183.745.

24 (b) The director may not reinstate a license that the director suspended or revoked until
25 the licensee has remedied all violations and has paid all applicable fees and civil penalties the
26 director imposed.

27 (c) The director may not for a period of two years after revoking a license under this
28 section for any cause reinstate or renew the license or issue a new license to a licensee
29 whose license the director revoked.

30 **SECTION 2.** (1) Section 1 of this 2021 Act becomes operative on January 1, 2022.

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

36 **SECTION 3.** Notwithstanding any other law limiting expenditures, the amount of \$698,944
37 is established for the biennium beginning July 1, 2021, as the maximum limit for payment of
38 expenses from fees, moneys or other revenues, including Miscellaneous Receipts, but ex-
39 cluding lottery funds and federal funds, collected or received by the Department of Consumer
40 and Business Services for the program set forth in section 1 of this 2021 Act.

41 **SECTION 4.** This 2021 Act takes effect on the 91st day after the date on which the 2021
42 regular session of the Eighty-first Legislative Assembly adjourns sine die.