SB 763-1
(LC 1996)
3/26/21 (TSB/ps)

Requested by Senator PATTERSON

PROPOSED AMENDMENTS TO
SENATE BILL 763

On page 1 of the printed bill, delete lines 4 through 27 and delete pages 2 through 8 and insert:

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

"(1) 'Business entity' means a corporation, limited liability company, partnership, limited liability partnership, association or other legal entity that is incorporated, organized or authorized to engage in business in this state.

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

"(3) 'Health care provider' means a person that is licensed, certified or otherwise authorized under the laws of this state to prescribe, provide or dispense pharmaceutical products to patients for the purposes of diagnosis, treatment or care of disease, injury or congenital conditions including, but not limited to, a person who is:

"(a) A physician or physician's assistant;

"(b) A nurse practitioner;

"(c) A psychiatrist;

"(d) A pharmacist; or

"(e) A hospital, clinic or pharmacy.

"(4) 'Licensee' means a person that holds a valid and unexpired li-

cense to engage in business as a pharmaceutical representative that the person obtained under section 4 of this 2021 Act.

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

"(6) 'Pharmaceutical product' means any biological or chemical product designed, manufactured, prescribed and dispensed for the purpose of treating or preventing disease, physical or mental illness, physical discomfort, a chronic or congenital condition or related symptoms.

"(7) 'Pharmaceutical representative' means a person that meets the description in section 2 of this 2021 Act of a person that engages in business as a pharmaceutical representative.

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

"(a) Making marketing or sales presentations, whether in person or by remote communication, to a health care provider:

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

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

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

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

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

"(e) Giving advice, counsel or opinion to a health care provider with respect to the features, benefits, effects, advantages or disadvantages of a pharmaceutical product;

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

"(g) Acting in another capacity that the Director of the Department of Consumer and Business Services by rule determines is engaging in business as a pharmaceutical representative.

"(2) A person does not engage in business as a pharmaceutical representative if the person provides information about, testifies or answers questions concerning, or discusses the features, benefits, effects, advantages or disadvantages of, a pharmaceutical product in the context of an academic presentation, a research study that is not conducted or funded by the person's employer or an affiliate of the person's employer, a hearing or proceeding before a governmental agency, an official government proceeding to consider approving the pharmaceutical product for manufacture, distribution or sale or in a similar or related context that the director specifies by rule.

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

"(a) Lists the applicant's name, residence and business address, previous experience engaging in business as a pharmaceutical representative, present occupation, occupation during the previous year and the names of the applicant's employers for the previous five years;

"(b) Lists the street address of the applicant's principal place of

business;

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

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

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

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

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

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

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

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

"(a) Submitted a complete and accurate application in accordance

with section 3 of this 2021 Act;

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

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

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

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

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

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

"(C) Satisfies any other requirement the director by rule establishes for renewing a license under this subsection.

"(b) The director may renew a license that has expired within one year after the expiration date if:

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

"(B) The former licensee pays double the amount of the fee the director specified in accordance with section 3 (3) of this 2021 Act; and

"(C) The former licensee otherwise satisfies all applicable requirements for renewal.

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

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

"(3)(a) A license that the director issues under subsection (1) of this section expires on the last day of the month in which the anniversary

of the date on which the director issued the license occurs, unless the director specifies a different date by rule or order.

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

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

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

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

"(b) If a licensee has voluntarily surrendered a license, the director may reinstate the license if the former licensee applies for the license as provided in section 3 of this 2021 Act within two years after surrendering the previous license.

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

"SECTION 5. (1) An individual who applies for a license to engage in business as a pharmaceutical representative shall:

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

"(b) Have qualifications that the Director of the Department of Consumer and Business Services specifies by rule.

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

"(3) In addition to the requirements set forth in subsection (1) or (2) of this section, as appropriate, an applicant must satisfy any other requirement the director specifies by rule.

"SECTION 6. (1) A licensee shall:

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

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

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

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

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

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

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

"(D) The specific pharmaceutical products that the licensee mar-

keted, sold or offered for sale; and

"(E) Whether the licensee offered or provided product samples, gifts, consideration or inducements to the health care provider and the value of any such samples, consideration, gifts or inducements.

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

"(c) A report a licensee submits under this subsection is a public record, but the director before disclosing a report shall redact any information that personally identifies a licensee.

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

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

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

"(C) A government agency or regulator in this or another state has taken a final administrative action against the licensee;

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

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

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

"(A) Update any information that has changed from the time the

licensee submitted an application for a license or submitted a previous notice under this section; and

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

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

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

"SECTION 8. (1) A licensee or an applicant for a license to engage in business as a pharmaceutical representative may not:

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

"(b) Falsify or act dishonestly with respect to an application for a license or an amendment to the license.

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

"(d) Materially misrepresent the features, benefits, effects, advantages or disadvantages or price of, available discounts for, or other information about a pharmaceutical product or otherwise engage in deceptive or misleading practices when marketing or selling a pharmaceutical product, including concealing, suppressing, omitting or

misstating any material facts.

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

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

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

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

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

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

suspension, revocation or refusal.

"(k) Act dishonestly, fraudulently or deceptively in a business that is not related to engaging in business as a pharmaceutical representative.

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

"(m) Otherwise engage in a fraudulent or dishonest practice in the course of engaging in business as a pharmaceutical representative that causes injury or loss to a health care provider or a member of the public.

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

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

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

"(B) Suspend, revoke or refuse to renew a licensee's license; or

"(C) Impose a civil penalty in accordance with ORS 183.745 in an amount the director specifies by rule.

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

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

"(a) A director, member or officer of a licensee that is a business entity, or another person that directly or indirectly has the power to direct the management, control or activities of the business entity, engaged in an action prohibited under subsection (1) of this section; or

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

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

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

"(c) Before setting a period of probation for a licensee under paragraph (a) of this subsection, the director shall notify the licensee and offer the licensee an opportunity for a hearing in accordance with ORS chapter 183.

"(d) During any probationary period, the director may take any disciplinary action described in subsection (3) of this section.

"SECTION 9. The Director of the Department of Consumer and Business Services shall prepare and submit to an interim committee of the Legislative Assembly with oversight over health care not later than December 31 of each year a report that aggregates and summarizes the information the director receives from licensees in the previous 12 months under section 6 (2) of this 2021 Act and that recommends any legislation or other actions the director deems nec-

essary to better effectuate the purposes of sections 1 to 9 of this 2021 Act.

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

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

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