HOUSE OF REPRESENTATIVES
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

H.B. NO. 1804 H.D. 1

A BILL FOR AN ACT

RELATING TO PHARMACEUTICAL REPRESENTATIVES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The Hawaii Revised Statutes is amended by adding a new chapter to be appropriately designated and to read as follows:

"CHAPTER

PHARMACEUTICAL REPRESENTATIVES

§ -1 Definitions. For purposes of this chapter:

"Department" means the department of commerce and consumer affairs.

"Director" means the director of commerce and consumer affairs.

"Health care professional" means a physician licensed under chapter 453 or other health care practitioner who is licensed in the State to provide health care services or to prescribe pharmaceutical or biologic products.

"Pharmaceutical" means a medication that may be legally dispensed only with a valid prescription from a health care professional.

"Pharmaceutical representative" means a person who markets or promotes pharmaceuticals to health care professionals.

§ -2 Pharmaceutical representative program. There is established a pharmaceutical representative program within the department to be administered by the director.

§ -3 Powers and duties of the director. In addition to any other powers and duties authorized by law, the director shall have the power and duties to:

(1) Adopt, amend, or repeal rules in accordance with chapter 91 to carry out the purposes of this chapter;

(2) Issue and renew registrations pursuant to this chapter and deny or refuse to renew registrations for failure to comply with this chapter; and

(3) Administer, coordinate, and enforce this chapter.

§ -4 Registration required; application. (a) No person shall act or conduct business as a pharmaceutical representative in the State without first registering with the department pursuant to this chapter unless the person acts or conducts business in the State as a pharmaceutical representative for fewer than fifteen days per calendar year.

(b) Each person seeking to register as a pharmaceutical representative shall file with the department on a form prescribed by the director. The application shall include:

(1) The applicant's full name, residence address, residence telephone number, business address, and business telephone number;

(2) An affirmation that the applicant has completed the continuing education requirements in accordance with section -7 prior to submitting the application; and

(3) Any other information the director may reasonably require.

The application shall be accessible on the department's website.

(c) Registration shall expire on December 31 of each odd-numbered year.

(d) No transfer of ownership shall be allowed on any registration issued under this chapter.

§ -5 Renewal of registration. Each pharmaceutical representative shall renew the representative's registration by December 31 of each odd-numbered year. When renewing a registration, a pharmaceutical representative shall submit to the director:

(1) An application for renewal on a form prescribed by the director that shall be accessible on the department's website;

(2) An affirmation that the pharmaceutical representative has completed the continuing education requirements in accordance with section -7;

(3) Proof that the pharmaceutical representative has paid all assessed penalties, if any;

(4) The required renewal fee; and

(5) Any other information that the director may reasonably require.

§ -6 **Fees.** No applicant or registrant shall be issued a certificate of registration unless the appropriate fees have been paid. The director shall establish the amount of all fees by rules adopted pursuant to chapter 91. Fees collected pursuant to this chapter shall be deposited to the credit of the compliance resolution fund established pursuant to section 26-9(o).

§ -7 **Continuing education.** (a) The department shall approve continuing education courses and establish continuing education requirements pursuant to chapter 91.

(b) All pharmaceutical representatives shall complete one continuing education course prior to submitting an application for registration. All pharmaceutical representatives shall complete a minimum of five credit hours before renewing their registration.

(c) The department may designate or publish a list of institutions that provide approved continuing education courses. The department may designate the courses that satisfy the continuing education requirements under this section. The continuing education courses may include training in the areas of ethics, pharmacology, laws and rules applicable to pharmaceutical marketing, and other areas that the department may designate by rule. No provider of a continuing education course may be an employer of pharmaceutical representatives.

§ -8 Disclosure. (a) Upon request, a pharmaceutical representative shall provide the following information to the department:

(1) The number of times the pharmaceutical representative contacted health care professionals in the State;

(2) The location and duration of contact;

(3) The pharmaceuticals promoted to a health care professional;

(4) Whether product samples, materials, or gifts of any value were provided to the health care professional, and the value of the product samples, materials, or gifts; and

(5) Whether and how the health care professional was compensated for contact with the pharmaceutical representative.

The director may prescribe by rule regular time intervals for the disclosure of the information listed in paragraphs (1) through (5); provided that the time intervals shall be no greater than the period between license renewals. A model disclosure form may be issued to facilitate compliance with the disclosure requirements of this subsection.

(b) Any material change to the information submitted on an application for registration or any material changes made to a registered pharmaceutical representative's personal or business operations or any information provided under this chapter shall be reported in writing to the department within four business days of the change.

§ -9 **Ethical standards.** A pharmaceutical representative shall not:

(1) Engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact; or

(2) Use a title or designation that could reasonably lead a health care professional or an employee or representative of a health care professional to believe that the pharmaceutical representative is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health care occupation unless the pharmaceutical representative holds such a license.

The director shall establish additional ethical standards for pharmaceutical representatives by rule adopted pursuant to chapter 91.

§ -10 **Suspension; revocation.** The director may suspend or revoke a registration for any violation of this chapter, chapter 436B, or any rule adopted by the director pursuant to

this chapter. No suspended or revoked registration shall be reinstated unless the violations related to the suspension or revocation have been remedied and all assessed penalties and fees have been paid. No person whose pharmaceutical representative registration has been revoked shall be granted another registration pursuant to this chapter for a period of two years from the date of the revocation.

§ -11 Penalties. Any person violating any provision of this chapter shall be fined not less than $1,000, but not more than $3,000 for each violation. Each day of a continued violation shall constitute a separate and distinct violation.

§ -12 Rules. The director shall adopt rules pursuant to chapter 91 that the director deems necessary for the effective administration and enforcement of this chapter."

SECTION 2. There is appropriated out of the general revenues of the State of Hawaii the sum of $ or so much thereof as may be necessary for fiscal year 2020-2021 to be deposited into the compliance resolution fund.

SECTION 3. There is appropriated out of the compliance resolution fund the sum of $ or so much thereof as may be necessary for fiscal year 2020-2021 to implement the

registration of pharmaceutical representatives as required by this Act.

The sum appropriated shall be expended by the department of commerce and consumer affairs for the purposes of this Act.

SECTION 4. If any provision of this Act, or the application thereof to any person or circumstance, is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

SECTION 5. This Act shall take effect on July 1, 2050; provided that sections 2 and 3 shall take effect on July 1, 2020.

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Report Title:
Pharmaceutical Representatives; Registration; Appropriation

Description:
Requires pharmaceutical representatives to register with DCCA. Creates a program within DCCA for the administration and enforcement of pharmaceutical representative registrations. Appropriates funds. Effective 7/1/2050. (HD1)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.