



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

3 § -2 **Pharmaceutical representative program.** There is  
4 established a pharmaceutical representative program within the  
5 department to be administered by the director.

6 § -3 **Powers and duties of the director.** In addition to  
7 any other powers and duties authorized by law, the director  
8 shall have the power and duties to:

- 9 (1) Adopt, amend, or repeal rules in accordance with  
10 chapter 91 to carry out the purposes of this chapter;  
11 (2) Issue and renew registrations pursuant to this chapter  
12 and deny or refuse to renew registrations for failure  
13 to comply with this chapter; and  
14 (3) Administer, coordinate, and enforce this chapter.

15 § -4 **Registration required; application.** (a) No person  
16 shall act or conduct business as a pharmaceutical representative  
17 in the State without first registering with the department  
18 pursuant to this chapter unless the person acts or conducts  
19 business in the State as a pharmaceutical representative for  
20 fewer than fifteen days per calendar year.



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

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

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

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

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

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

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

17 **§ -5 Renewal of registration.** Each pharmaceutical  
18 representative shall renew the representative's registration by  
19 December 31 of each odd-numbered year. When renewing a  
20 registration, a pharmaceutical representative shall submit to  
21 the director:



- 1 (1) An application for renewal on a form prescribed by the  
2 director that shall be accessible on the department's  
3 website;
- 4 (2) An affirmation that the pharmaceutical representative  
5 has completed the continuing education requirements in  
6 accordance with section -7;
- 7 (3) Proof that the pharmaceutical representative has paid  
8 all assessed penalties, if any;
- 9 (4) The required renewal fee; and
- 10 (5) Any other information that the director may reasonably  
11 require.

12 § -6 Fees. No applicant or registrant shall be issued a  
13 certificate of registration unless the appropriate fees have  
14 been paid. The director shall establish the amount of all fees  
15 by rules adopted pursuant to chapter 91. Fees collected  
16 pursuant to this chapter shall be deposited to the credit of the  
17 compliance resolution fund established pursuant to section  
18 26-9(o).

19 § -7 Continuing education. (a) The department shall  
20 approve continuing education courses and establish continuing  
21 education requirements pursuant to chapter 91.



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

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

15 § -8 Disclosure. (a) Upon request, a pharmaceutical  
16 representative shall provide the following information to the  
17 department:

- 18 (1) The number of times the pharmaceutical representative  
19 contacted health care professionals in the State;  
20 (2) The location and duration of contact;



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

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

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

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

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



1           §   -9   **Ethical standards.**   (a)   A pharmaceutical

2 representative shall not:

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

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

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

19           §   -10   **Suspension; revocation.**   The director may suspend  
20 or revoke a registration for any violation of this chapter,  
21 chapter 436B, or any rule adopted by the director pursuant to



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

8 § -11 Penalties. Any person violating any provision of  
 9 this chapter shall be fined not less than \$1,000, but not more  
 10 than \$3,000 for each violation. Each day of a continued  
 11 violation of this chapter shall constitute a separate and  
 12 distinct violation.

13 § -12 Rules. The director shall adopt rules pursuant to  
 14 chapter 91 that the director deems necessary for the effective  
 15 administration and enforcement of this chapter."

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

20 SECTION 3. There is appropriated out of the compliance  
 21 resolution fund the sum of \$ or so much thereof as may





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1 be necessary for fiscal year 2020-2021 to implement the  
 2 registration of pharmaceutical representatives as required by  
 3 this Act.

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

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

12 SECTION 5. This Act shall take effect upon its approval;  
 13 provided that sections 2 and 3 shall take effect on July 1,  
 14 2020.

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INTRODUCED BY:

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JAN 16 2020



# H.B. NO. 1804

**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.

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