H.B. NO. <sup>1804</sup> H.D. <sup>2</sup>

#### A BILL FOR AN ACT

RELATING TO PHARMACEUTICAL REPRESENTATIVES.

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

1	SECTION 1. The Hawaii Revised Statutes is amended by
2	adding a new chapter to be appropriately designated and to read
3	as follows:
4	"CHAPTER
5	PHARMACEUTICAL REPRESENTATIVES
6	<b>§ -1 Definitions.</b> For purposes of this chapter:
7	"Department" means the department of commerce and consumer
8	affairs.
9	"Director" means the director of commerce and consumer
10	affairs.
11	"Health care professional" means a physician licensed under
12	chapter 453 or other health care practitioner who is licensed in
13	the State to provide health care services or to prescribe
14	pharmaceutical or biologic products.
15	"Pharmaceutical" means a medication that may be legally
16	dispensed only with a valid prescription from a health care
17	professional.



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	<b>§ -4 Registration required; application.</b> (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.

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1	(b)	Each person seeking to register as a pharmaceutical
2	represent	ative shall file with the department on a form
3	prescribe	d 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 appli	cation 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	registrat	ion issued under this chapter.
17	S	-5 Renewal of registration. Each pharmaceutical
18	represent	ative shall renew the representative's registration by
19	December	31 of each odd-numbered year. When renewing a
20	registrat	ion, a pharmaceutical representative shall submit to
21	the direc	tor:



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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	S	-6 Fees. No applicant or registrant shall be issued a
13	certifica	te 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	complianc	e resolution fund established pursuant to section
18	26-9(0).	
19	§	-7 Continuing education. (a) The department shall

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

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

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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 direc	tor may prescribe by rule regular time intervals for		
11	the discl	osure of the information listed in paragraphs (1)		
12	through (	5); provided that the time intervals shall be no		
13	greater t	greater than the period between license renewals. A model		
14	disclosur	e form may be issued to facilitate compliance with the		
15	disclosur	e requirements of this subsection.		
16	(b)	Any material change to the information submitted on an		
17	applicati	on for registration or any material changes made to a		
18	registere	d pharmaceutical representative's personal or business		
19	operation	s or any information provided under this chapter shall		
20	be report	ed in writing to the department within four business		

21 days of the change.

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1	S	-9 Ethical standards. A pharmaceutical representative
2	shall no	t:
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 dire	ctor shall establish additional ethical standards for
17	pharmace	utical representatives by rule adopted pursuant to
18	chapter	91.
19	S	-10 Suspension; revocation. The director may suspend
20	or revok	e a registration for any violation of this chapter,

21 chapter 436B, or any rule adopted by the director pursuant to

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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 S -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 shall constitute a separate and distinct violation. 12 S -12 Rules. The director shall adopt rules pursuant to 13 chapter 91 that the director deems necessary for the effective 14 administration and enforcement of this chapter." 15 SECTION 2. There is appropriated out of the general 16 revenues of the State of Hawaii the sum of \$ or so 17 much thereof as may be necessary for fiscal year 2020-2021 to be 18 deposited into the compliance resolution fund. 19 SECTION 3. There is appropriated out of the compliance resolution fund the sum of \$ or so much thereof as may 20 21 be necessary for fiscal year 2020-2021 to implement the



registration of pharmaceutical representatives as required by
 this Act.

3 The sum appropriated shall be expended by the department of 4 commerce and consumer affairs for the purposes of this Act. 5 SECTION 4. If any provision of this Act, or the 6 application thereof to any person or circumstance, is held 7 invalid, the invalidity does not affect other provisions or 8 applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions 9 10 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.



#### 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. (HD2)

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

