

JAN 23 2020

A BILL FOR AN ACT

RELATING TO PHARMACY BENEFIT MANAGERS.

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

1 SECTION 1. The legislature finds that:

2 (1) The program under section 340B of the Public Health
3 Service Act (42 U.S.C. 256b) ("340B Program") enables
4 health care settings that serve a disproportionate
5 share of underserved patient populations ("covered
6 entities") to stretch scarce resources as far as
7 possible, reaching more patients and providing more
8 comprehensive services than without such program;

9 (2) The 340B Program provides covered entities with a
10 discount from drug manufacturers on covered outpatient
11 drugs they purchase to meet the health care needs of
12 the community;

13 (3) Covered entities that qualify for participation under
14 the 340B Program meet rigorous eligibility criteria,
15 proving they are safety net health care providers for
16 many underserved patients;



- 1 (4) Such discounts are provided to covered entities rather
2 than directly to individual patients;
- 3 (5) The discounts described in paragraph (2) provided
4 through the 340B Program enable covered entities to
5 deliver comprehensive services to the communities they
6 serve, which may include providing free or discounted
7 drugs to vulnerable populations, although providing
8 free or discounted drugs to patients is not the sole
9 purpose of the program;
- 10 (6) The 340B Program is also designed to help covered
11 entities promote health for underserved communities
12 and patients, regardless of a particular patient's
13 insurance status or inability to pay;
- 14 (7) Savings from the 340B Program are used by covered
15 entities to reach more patients and provide more
16 comprehensive services, and covered entities are in
17 the best position to assess the use of their savings
18 for community needs;
- 19 (8) Drugs purchased under the 340B Program account for a
20 small proportion of overall drug spending and the



1 discounts described in paragraph (2) provided through
2 the 340B Program are not funded by taxpayers;

3 (9) Manufacturer rebate money may cause pharmacy benefit
4 managers to favor more costly brand-name drugs over
5 generic or lower-cost, therapeutically equivalent
6 brand-name drugs and the business practices of
7 pharmacy benefit managers generally lack transparency;

8 (10) Mergers between pharmacy benefit managers and
9 pharmaceutical manufacturers and large pharmacy chains
10 have also occurred which have raised numerous
11 concerns; and

12 (11) Some of the biggest concerns are potential conflicts
13 of interest, inhibiting competition in the dispensing
14 of prescription drugs, actual increased out-of-pocket
15 costs for consumers, denying consumer choice, and
16 determining whether patients and covered entities have
17 received the discounts and other price concessions
18 negotiated by the program on their behalf.

19 Currently, pharmacy benefit managers in Hawaii are required
20 to register with the insurance commissioner pursuant to chapter
21 431S, Hawaii Revised Statutes, and are subject to certain



1 transparency laws set forth in section 326-108, Hawaii Revised
2 Statutes. However, the existing laws lack an appropriate
3 enforcement mechanism or incentive for pharmacy benefit managers
4 to comply with the disclosure of maximum allowable cost lists,
5 as required by section 326-108, Hawaii Revised Statutes. This
6 lack of oversight and transparency regarding the business
7 operations of pharmacy benefit managers has generated numerous
8 questions. The legislature finds that there is a need for the
9 industry to fully disclose how much it is actually saving
10 consumers and what portion of those savings are actually passed
11 along to consumers by more strictly regulating pharmacy benefit
12 managers.

13 SECTION 2. Section 431S-1, Hawaii Revised Statutes, is
14 amended as follows:

15 1. By adding ten new definitions to be appropriately
16 inserted and to read:

17 "340B covered entity" shall have the meaning as in section
18 2566(a)(4) of title 42 of the United States Code.

19 "Claim" means a request from a covered entity or contract
20 pharmacy to be reimbursed for the cost of filling or refilling a



1 prescription for a drug or for providing a medical supply or
2 service.

3 "Contract pharmacy" means a pharmacy operating under
4 contract with a 340B covered entity to provide dispensing
5 services to the 340B covered entity as described in 75 Federal
6 Register 10,272 published on March 5, 2010.

7 "Enrollee" means an individual who has enrolled for
8 coverage in a health benefit plan for which a pharmacy benefit
9 manager has contracted with the insurer to reimburse claims
10 submitted to covered entities or contract pharmacies for the
11 costs for drugs prescribed for the individual.

12 "Insurer" means an insurance company, a health maintenance
13 organization, or a hospital and medical service corporation.

14 "Out-of-pocket cost" means the amount paid by an enrollee
15 under the enrollee's coverage, including deductibles,
16 copayments, coinsurance or other expenses as prescribed by the
17 insurance commissioner by rule.

18 "Pharmacist services" means products, good, and services,
19 or any combination or products, goods, and services, provided as
20 part of the practice of pharmacy as defined in Chapter 461-1.



1 "Rebate" means a discount or other price concession, or a
2 payment that is:

- 3 (1) Based on a utilization of a prescription drug; and
4 (2) Paid by a manufacturer or third-party, directly or
5 indirectly to a pharmacy benefit manager after a claim
6 has been processed and paid at the covered entity or
7 contract pharmacy.

8 "Spread pricing" means the model of prescription drug
9 pricing in which the pharmacy benefit manager charges a health
10 benefit plan a contracted price for prescription drugs, and the
11 contracted price for prescription drugs differs from the amount
12 the pharmacy benefit manager directly or indirectly pays the
13 covered entity or contract pharmacy for pharmacy services.

14 "Third-party" means a person, business, or entity other
15 than a pharmacy benefit manager that is not an enrollee or
16 insured in a health benefit plan."

17 2. By amending the definition of "covered entity" to read:

18 "Covered entity" means:

- 19 (1) A health benefits plan regulated under chapter 87A;
20 health insurer regulated under article 10A of
21 chapter 431; mutual benefit society regulated under



1 article 1 of chapter 432; or health maintenance
2 organization regulated under chapter 432D; provided
3 that a "covered entity" under this paragraph shall not
4 include a health maintenance organization regulated
5 under chapter 432D that owns or manages its own
6 pharmacies;

7 (2) A health program administered by the State in the
8 capacity of a provider of health coverage; or

9 (3) An employer, labor union, or other group of persons
10 organized in the State that provides health coverage
11 to covered persons employed or residing in the
12 State[-]; and

13 (4) The same as it means in section 2566(a)(4) of title 42
14 of the United States Code.

15 "Covered entity" shall not include any plans issued for coverage
16 for federal employees or specified disease or limited benefit
17 health insurance as provided by section 431:10A-607."

18 3. By amending the definition of "pharmacy benefit
19 manager" to read:

20 ""Pharmacy benefit manager" means [any]:



- 1 (1) Any person that performs pharmacy benefit management,
2 including but not limited to a person or entity in a
3 contractual or employment relationship with a pharmacy
4 benefit manager to perform pharmacy benefit management
5 for a covered entity[-]; and
- 6 (2) A person, business, or other entity that contracts
7 with pharmacies on behalf of an insurer to perform ,
8 pharmacy benefit management, including but not limited
9 to:
- 10 (A) Contracting directly or indirectly with
11 pharmacies to provide prescription drugs to
12 enrollees or other covered individuals;
- 13 (B) Administering a prescription drug benefit;
- 14 (C) Processing or paying pharmacy claims;
- 15 (D) Creating or updating prescription drug
16 formularies;
- 17 (E) Making or assisting in making prior
18 authorizations on prescription drugs;
- 19 (F) Administering rebates on prescription drugs; or
- 20 (G) Establishing a network to provide pharmacist
21 services for health benefit plans."



1 "Pharmacy benefit manager" shall not include the department of
2 human services."

3 SECTION 3. Chapter 431S, Hawaii Revised Statutes, is
4 amended by adding three new sections to be appropriately
5 designated and to read as follows:

6 "§431S-A Pharmacy benefit managers; duties. A pharmacy
7 benefit manager registered under chapter 431S-3 shall:

8 (1) Comply with the requirements of chapter 328-106;

9 (2) Not reimburse a covered entity differently than any
10 other pharmacy that contracts with a pharmacy benefit
11 manager based on the covered entity's participation in
12 the 340B program or otherwise discriminate against
13 such covered entity with respect to the terms of any
14 reimbursement, including terms related to the level
15 and amount of reimbursement;

16 (3) Not reimburse a covered entity or contract pharmacy
17 for a drug on a maximum allowable cost basis, unless
18 the pharmacy benefit manager strictly complies with
19 the requirements of chapter 328-106;

20 (4) Not penalize a covered entity or contract pharmacy
21 for, or otherwise directly or indirectly prevent, a



1 covered entity or contract pharmacy from informing an
2 enrollee of the difference between the out-of-pocket
3 cost to the enrollee to purchase a prescription drug
4 using the enrollee's pharmacy benefit and the
5 pharmacy's usual and customary charge for the
6 prescription drug;

7 (5) Not conduct spread pricing; and

8 (6) Not retroactively deny or reduce a claim for
9 reimbursement of the cost of services after the claim
10 has been adjudicated by the pharmacy benefit manager
11 unless the:

12 (A) Adjudicated claim was submitted fraudulently;

13 (B) Pharmacy benefit manager's payment on the
14 adjudicated claim was incorrect because the
15 covered entity or contract pharmacy had already
16 been paid for the services;

17 (C) Services were improperly rendered by the covered
18 entity or contract pharmacy; or

19 (D) Covered entity or contract pharmacy agrees to the
20 denial or reduction prior to the pharmacy benefit
21 manager notifying the covered entity or contract



1 pharmacy that the claim had been denied or
2 reduced.

3 Paragraph (6) may not be construed to limit pharmacy claim
4 audits under section 431S-C. This section does not apply to
5 retail drugs that are reimbursed by the State on a fee-for-
6 service basis pursuant to a state plan approved under Title XIX
7 of the Social Security Act.

8 **§431S-B Pharmacy benefit managers; quarterly reports**

9 **required.** (a) A pharmacy benefit manager shall report to the
10 insurance commissioner on a quarterly basis for each insurer or
11 third-party the following information:

12 (1) The aggregate amount of rebates received by the
13 pharmacy benefit manager;

14 (2) The aggregate amount of rebates distributed to the
15 appropriate insurer or third-party;

16 (3) The aggregate amount of rebates passed on to the
17 enrollees of each insurer or third-party at the point
18 of sale that reduced the enrollees' applicable
19 deductible, copayment, coinsurance, or other cost-
20 sharing amount;



1 (4) The individual and aggregate amount paid by the
2 insurer or third-party to the pharmacy benefit manager
3 for pharmacist services itemized by pharmacy, by
4 product, and by goods and services; and

5 (5) The individual and aggregate amount a pharmacy benefit
6 manager paid for pharmacist services itemized by
7 pharmacy, by product, and by goods and services.

8 (b) The report required under subsection (a) is:

9 (1) Proprietary and confidential under chapter
10 431:2-209(e)(3); and

11 (2) Not subject to the Freedom of Information Act of 1967,
12 or Uniform Information Practices Act pursuant to the
13 exception found at chapter 92F-13(4).

14 §431S-C Pharmacy benefit manager; program integrity. The
15 insurance commissioner may commence audits of an insurer or
16 pharmacy benefit manager that reimburses a covered entity or its
17 contract pharmacy for drugs that are subject to an agreement
18 under section 431S-A to ensure the integrity of the program
19 including the level and amount of reimbursement, on the basis
20 that the covered entity participates in the program under
21 section 431S-A."



1 SECTION 4. Section 431S-3, Hawaii Revised Statutes, is
2 amended to read as follows:

3 " ~~[§431S-3]~~ **Registration required.** (a) Notwithstanding
4 any law to the contrary, no person shall act or operate as a
5 pharmacy benefit manager without first obtaining a valid
6 registration issued by the commissioner pursuant to this
7 chapter.

8 (b) Each person seeking to register as a pharmacy benefit
9 manager shall file with the commissioner an application on a
10 form prescribed by the commissioner. The application shall
11 include:

12 (1) The name, address, official position, and professional
13 qualifications of each individual who is responsible
14 for the conduct of the affairs of the pharmacy benefit
15 manager, including all members of the board of
16 directors; board of trustees; executive commission;
17 other governing board or committee; principal
18 officers, as applicable; partners or members, as
19 applicable; and any other person who exercises control
20 or influence over the affairs of the pharmacy benefit
21 manager;



- 1 (2) The name and address of the applicant's agent for
2 service of process in the State; and
- 3 (3) A nonrefundable application fee [~~of \$140.~~] not to
4 exceed two hundred dollars."

5 SECTION 5. Section 431S-4, Hawaii Revised Statutes, is
6 amended to read as follows:

7 " ~~[+] §431S-4~~ **Annual renewal requirement.** (a) Each
8 pharmacy benefit manager shall renew its registration by
9 March 31 each year.

10 (b) When renewing its registration, a pharmacy benefit
11 manager shall submit to the commissioner the following:

- 12 (1) An application for renewal on a form prescribed by the
13 commissioner; and
- 14 (2) A renewal fee [~~of \$140.~~] not to exceed two hundred
15 dollars.

16 (c) Failure on the part of a pharmacy benefit manager to
17 renew its registration as provided in this section shall result
18 in a penalty of \$140 and may cause the registration to be
19 revoked or suspended by the commissioner until the requirements
20 for renewal have been met."



1 SECTION 6. Section 431S-5, Hawaii Revised Statutes, is
2 amended to read as follows:

3 "[+]§431S-5[+] Penalty. Any person who acts as a pharmacy
4 benefit manager in this State without first being registered
5 pursuant to this chapter shall be subject to a fine of [~~\$500 for~~
6 ~~each violation.~~] not less than one thousand dollars per day for
7 the period the pharmacy benefit manager is found to be in
8 violation of this chapter."

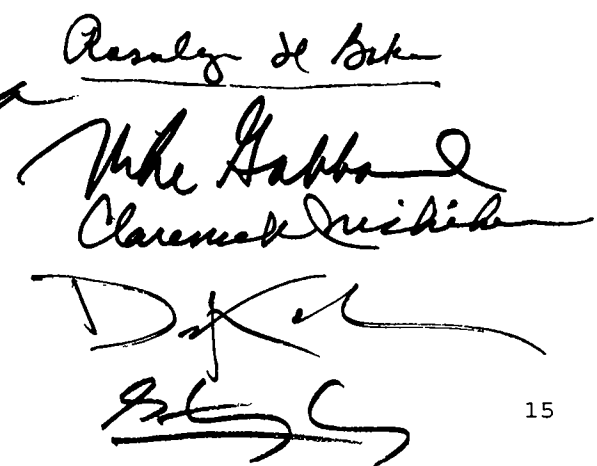
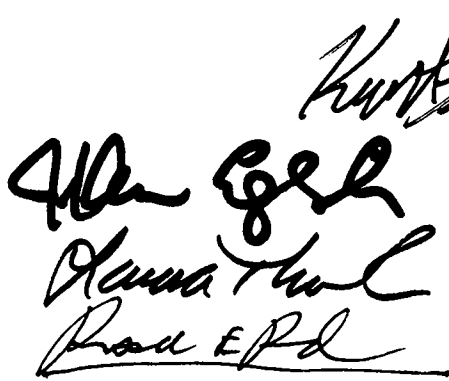
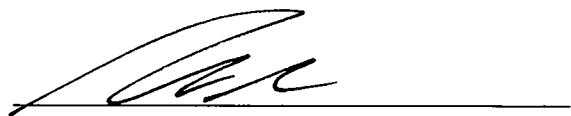
9 SECTION 7. In codifying the new sections added by
10 section 2 of this Act, the revisor of statutes shall substitute
11 appropriate section numbers for the letters used in designating
12 the new sections in this Act.

13 SECTION 8. Statutory material to be repealed is bracketed
14 and stricken. New statutory material is underscored.

15 SECTION 9. This Act shall take effect on July 1, 2021.

16

INTRODUCED BY:



S.B. NO. 3095

Report Title:

Consumer Protection; Pharmacy Benefit Managers

Description:

Ensures the community health system remains financially viable in the face of healthcare value transformation; ensures access to quality and affordable prescription drugs by vulnerable populations served by community health centers, special needs clinics and other nonprofit healthcare entities covered by the federal 340B pharmacy program.

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