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A BILL FOR AN ACT

RELATING TO PHARMACY BENEFIT MANAGERS.

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

1	SECI	TON 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 eligi1bility 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



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discounts described in paragraph (2) provided through 1 the 340B Program are not funded by taxpayers; 2 Manufacturer rebate money may cause pharmacy benefit 3 (9) managers to favor more costly brand-name drugs over 4 5 generic or lower-cost, therapeutically equivalent brand-name drugs and the business practices of 6 7 pharmacy benefit managers generally lack transparency; Mergers between pharmacy benefit managers and 8 (10)9 pharmaceutical manufacturers and large pharmacy chains have also occurred which have raised numerous 10 11 concerns; and Some of the biggest concerns are potential conflicts 12 (11)of interest, inhibiting competition in the dispensing 13 of prescription drugs, actual increased out-of-pocket 14 costs for consumers, denying consumer choice, and 15 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 431S, Hawaii Revised Statutes, and are subject to certain 21



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

13 SECTION 2. Section 431S-1, Hawaii Revised Statutes, is14 amended as follows:

15 1. By adding ten new definitions to be appropriately16 inserted and to read:

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

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



prescription for a drug or for providing a medical supply or 1 2 service. "Contract pharmacy" means a pharmacy operating under 3 contract with a 340B covered entity to provide dispensing 4 services to the 340B covered entity as described in 75 Federal 5 Register 10,272 published on March 5, 2010. 6 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 submitted to covered entities or contract pharmacies for the 10 costs for drugs prescribed for the individual. 11 "Insurer" means an insurance company, a health maintenance 12 organization, or a hospital and medical service corporation. 13 "Out-of-pocket cost" means the amount paid by an enrollee 14 15 under the enrollee's coverage, including deductibles, 16 copayments, coinsurance or other expenses as prescribed by the 17 insurance commissioner by rule. "Pharmacist services" means products, good, and services, 18 19 or any combination or products, goods, and services, provided as part of the practice of pharmacy as defined in Chapter 461-1. 20



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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 feder	al employees or specified disease or limited benefit
17	health in	surance as provided by section 431:10A-607."
18	3.	By amending the definition of "pharmacy benefit
19	manager"	to read:
20	" " Ph	armacy benefit manager" means [any] <u>:</u>



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1	(1)	Any	person that performs pharmacy benefit management,
2		incl	uding but not limited to a person or entity in a
3		cont	ractual or employment relationship with a pharmacy
4		bene	fit manager to perform pharmacy benefit management
5		for	a covered entity[-]; and
6	(2)	А ре	rson, business, or other entity that contracts
7		with	pharmacies on behalf of an insurer to perform
8		phar	macy benefit management, including but not limited
9		<u>to:</u>	
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		<u>(C)</u>	Processing or paying pharmacy claims;
15		(D)	Creating or updating prescription drug
16			formularies;
17		<u>(E)</u>	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."



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1	"Pharmacy benefit manager" shall not include the department of			
2	human services."			
3	SECT	SECTION 3. Chapter 431S, Hawaii Revised Statutes, is		
4	amended b	y adding three new sections to be appropriately		
5	designate	d and to read as follows:		
6	" <u>§</u> 43	15-A Pharmacy benefit managers; duties. A pharmacy		
7	benefit m	anager 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		cover	ed entity or contract pharmacy from informing an
2		enrol	lee 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		pharm	acy's usual and customary charge for the
6		presc	ription drug;
7	(5)	Not c	conduct spread pricing; and
8	(6)	Not r	etroactively deny or reduce a claim for
9		reimb	oursement of the cost of services after the claim
10		has b	een adjudicated by the pharmacy benefit manager
11		unles	s 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



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1	pl	narmacy that the claim had been denied or
2	re	educed.
3	Paragraph (6) may	y not be construed to limit pharmacy claim
4	audits under sect	tion 431S-C. This section does not apply to
5	retail drugs that	are reimbursed by the State on a fee-for-
6	service basis pu	rsuant to a state plan approved under Title XIX
7	of the Social Sec	curity Act.
8	§431S-B Pha	armacy benefit managers; quarterly reports
9	required. (a)	A pharmacy benefit manager shall report to the
10	insurance commiss	sioner on a quarterly basis for each insurer or
11	third-party the	following information:
12	(1) The age	gregate amount of rebates received by the
13	pharmac	cy benefit manager;
14	(2) The age	gregate amount of rebates distributed to the
15	approp	riate insurer or third-party;
16	(3) The age	gregate amount of rebates passed on to the
17	enrolle	ees of each insurer or third-party at the point
18	of sale	e that reduced the enrollees' applicable
19	deduct	ible, copayment, coinsurance, or other cost-
20	sharing	g amount;



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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	<u>§431</u>	S-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 sec	tion 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 4	31S-A."



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SECTION 4. Section 431S-3, Hawaii Revised Statutes, is 1 2 amended to read as follows: "[+] §431S-3[+] Registration required. (a) Notwithstanding 3 any law to the contrary, no person shall act or operate as a 4 pharmacy benefit manager without first obtaining a valid 5 6 registration issued by the commissioner pursuant to this 7 chapter. Each person seeking to register as a pharmacy benefit 8 (b) manager shall file with the commissioner an application on a 9 form prescribed by the commissioner. The application shall 10 11 include: The name, address, official position, and professional 12 (1)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 officers, as applicable; partners or members, as 18 19 applicable; and any other person who exercises control or influence over the affairs of the pharmacy benefit 20 21 manager;



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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.] <u>not to</u>
4	exceed two hundred dollars."
5	SECTION 5. Section 431S-4, Hawaii Revised Statutes, is
6	amended to read as follows:
7	"[-[]§4315-4[]] 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 th
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."



SECTION 6. Section 431S-5, Hawaii Revised Statutes, is 1 amended to read as follows: 2 3 "[**[**]**§431S-5**[**]**] **Penalty.** Any person who acts as a pharmacy benefit manager in this State without first being registered 4 pursuant to this chapter shall be subject to a fine of [\$500 for 5 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 appropriate section numbers for the letters used in designating 11 the new sections in this Act. 12 13 SECTION 8. Statutory material to be repealed is bracketed 14 and stricken. New statutory material is underscored. SECTION 9. This Act shall take effect on July 1, 2021. 15 16 INTRODUCED BY: JAN 2 3 2020 2020-0844 HB SMA.doc 15

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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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