
A BILL FOR AN ACT

RELATING TO THE REPEAL OF SECTION 328-106, HAWAII REVISED
STATUTES.

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

1 SECTION 1. The department of health has historically
2 regulated the safety and integrity of food, drugs, and cosmetics
3 to protect the health of Hawaii's residents and visitors
4 pursuant to the authority provided in chapter 328, Hawaii
5 Revised Statutes. The department's regulatory purview with
6 respect to pharmaceuticals under chapter 328, Hawaii Revised
7 Statutes, is analogous to that of the Federal Food and Drug
8 Administration under the Federal Food, Drug, and Cosmetic Act
9 (title 21 United States Code sections 321 et seq.). The Federal
10 Food and Drug Administration exercises its regulatory authority
11 to ensure the efficacy and overall safety of prescription drugs,
12 but not to control their cost or the business practices of the
13 insurance companies and independent pharmacies that supply them.

14 Section 328-106, Hawaii Revised Statutes, requires the
15 department of health to police the insurance industry, a task
16 for which it is not well-suited. Section 328-106, Hawaii
17 Revised Statutes, requires pharmacy benefit managers to maintain

H.B. NO. 1083

1 certain information related to the cost of prescription drugs
2 and provide a process for a contracting pharmacy to appeal the
3 maximum allowable cost for reimbursement. Regulatory oversight
4 of what was intended as a price control function, however, is
5 not within the department of health's area of expertise.
6 Additionally, section 328-106, Hawaii Revised Statutes, does not
7 provide an adequate remedy for violations, rather it only
8 prescribes certain aspects of an appeal process to be utilized
9 by the pharmacy benefit managers who nonetheless retain
10 exclusive control over both the administration of the appeal
11 process itself and of any decision ultimately rendered.

12 Therefore, the legislature finds that section 328-106,
13 Hawaii Revised Statutes, is inconsistent with the purpose of
14 chapter 328 generally and does not achieve a meaningful balance
15 in the contractual relationship between pharmacy benefit
16 managers and pharmacies. The regulatory burden this section
17 places on the department of health is outside the scope of the
18 department of health's mission to protect public health.
19 Regulation of the insurance industry's process for reimbursement
20 to pharmacies of prescription drug costs, and of the contractual
21 relationship between them, is likely more effectively achieved

H.B. NO. 1083

1 by other means. As a result, the legislature finds that repeal
2 of section 328-106, Hawaii Revised Statutes, is appropriate.

3 The purpose of this Act is to repeal section 328-106,
4 Hawaii Revised Statutes, which requires the department of health
5 to regulate business practices between private entities engaged
6 in the selling, billing, and reimbursement of pharmaceuticals.

7 SECTION 2. Section 328-106, Hawaii Revised Statutes, is
8 repealed.

9 ~~["§328-106] Pharmacy benefit manager; maximum allowable~~
10 ~~cost. (a) A pharmacy benefit manager that reimburses a~~
11 ~~contracting pharmacy for a drug on a maximum allowable cost~~
12 ~~basis shall comply with the requirements of this section.~~

13 ~~(b) The pharmacy benefit manager shall include the~~
14 ~~following in the contract information with a contracting~~
15 ~~pharmacy:~~

16 ~~(1) Information identifying any national drug pricing~~
17 ~~compendia; or~~

18 ~~(2) Other data sources for the maximum allowable cost~~
19 ~~list.~~

20 ~~(c) The pharmacy benefit manager shall make available to a~~
21 ~~contracting pharmacy, upon request, the most up to date maximum~~
22 ~~allowable cost price or prices used by the pharmacy benefit~~

H.B. NO. 1083

1 ~~manager for patients served by the pharmacy in a readily~~
2 ~~accessible, secure, and usable web based or other comparable~~
3 ~~format.~~

4 ~~(d) A drug shall not be included on a maximum allowable~~
5 ~~cost list or reimbursed on a maximum allowable cost basis unless~~
6 ~~all of the following apply:~~

7 ~~(1) The drug is listed as "A" or "B" rated in the most~~
8 ~~recent version of the Orange Book or has a rating of~~
9 ~~"NR", "NA", or similar rating by a nationally~~
10 ~~recognized reference;~~

11 ~~(2) The drug is generally available for purchase in this~~
12 ~~State from a national or regional wholesaler; and~~

13 ~~(3) The drug is not obsolete.~~

14 ~~(e) The pharmacy benefit manager shall review and make~~
15 ~~necessary adjustments to the maximum allowable cost of each drug~~
16 ~~on a maximum allowable cost list at least once every seven days~~
17 ~~using the most recent data sources available, and shall apply~~
18 ~~the updated maximum allowable cost list beginning that same day~~
19 ~~to reimburse the contracted pharmacy until the pharmacy benefit~~
20 ~~manager next updates the maximum allowable cost list in~~
21 ~~accordance with this section.~~

H.B. NO. 1083

1 ~~(f) The pharmacy benefit manager shall have a clearly~~
2 ~~defined process for a contracting pharmacy to appeal the maximum~~
3 ~~allowable cost for a drug on a maximum allowable cost list that~~
4 ~~complies with all of the following:~~

5 ~~(1) A contracting pharmacy may base its appeal on one or~~
6 ~~more of the following:~~

7 ~~(A) The maximum allowable cost for a drug is below~~
8 ~~the cost at which the drug is available for~~
9 ~~purchase by similarly situated pharmacies in this~~
10 ~~State from a national or regional wholesaler, or~~

11 ~~(B) The drug does not meet the requirements of~~
12 ~~subsection (d);~~

13 ~~(2) A contracting pharmacy shall be provided no less than~~
14 ~~fourteen business days following receipt of payment~~
15 ~~for a claim to file the appeal with the pharmacy~~
16 ~~benefit manager;~~

17 ~~(3) The pharmacy benefit manager shall make a final~~
18 ~~determination on the contracting pharmacy's appeal no~~
19 ~~later than fourteen business days after the pharmacy~~
20 ~~benefit manager's receipt of the appeal;~~

21 ~~(4) If the maximum allowable cost is upheld on appeal, the~~
22 ~~pharmacy benefit manager shall provide to the~~

H.B. NO. 1083

1 ~~contracting pharmacy the reason therefor and the~~
2 ~~national drug code of an equivalent drug that may be~~
3 ~~purchased by a similarly situated pharmacy at a price~~
4 ~~that is equal to or less than the maximum allowable~~
5 ~~cost of the drug that is the subject of the appeal,~~
6 ~~and~~

7 ~~(5) If the maximum allowable cost is not upheld on appeal,~~
8 ~~the pharmacy benefit manager shall adjust, for the~~
9 ~~appealing contracting pharmacy, the maximum allowable~~
10 ~~cost of the drug that is the subject of the appeal,~~
11 ~~within one calendar day of the date of the decision on~~
12 ~~the appeal and allow the contracting pharmacy to~~
13 ~~reverse and rebill the appealed claim.~~

14 ~~(g) A contracting pharmacy shall not disclose to any third~~
15 ~~party the maximum allowable cost list and any related~~
16 ~~information it receives, either directly from a pharmacy benefit~~
17 ~~manager or through a pharmacy services administrative~~
18 ~~organization or similar entity with which the pharmacy has a~~
19 ~~contract to provide administrative services for that pharmacy."]~~

20 SECTION 3. Statutory material to be repealed is bracketed
21 and stricken.

H.B. NO. 1083

1 SECTION 4. This Act shall take effect upon its approval.

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INTRODUCED BY: *Tom*

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BY REQUEST

JAN 23 2023

H .B. NO. 1083

Report Title:

Section 328-106, Hawaii Revised Statutes; Repeal

Description:

Repeals unenforceable and ineffective provisions from chapter 328, Hawaii Revised Statutes.

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

JUSTIFICATION SHEET

DEPARTMENT: Health.

TITLE: A BILL FOR AN ACT RELATING TO THE REPEAL OF SECTION 328-106, HAWAII REVISED STATUTES.

PURPOSE: Abolish the Department of Health's statutory obligation to regulate certain aspects of the drug cost reimbursement mechanisms that exist contractually between pharmacy benefit managers and individual pharmacies.

MEANS: Repeal section 328-106, Hawaii Revised Statutes (HRS).

JUSTIFICATION: Section 328-106, HRS, provides the Department of Health the authority to regulate the process by which health care providers, through their pharmacy benefit managers, control the process of reimbursement to pharmacies of prescription drug costs.

Specifically, section 328-106, HRS, requires pharmacy benefit managers (PBMs), typically employed with health insurance companies, to provide pharmacies information on lower cost sources of pharmaceuticals and to have a clearly defined process by which contracted pharmacies can challenge the amount of reimbursement for those costs.

The oversight of financial transactions between PBMs and pharmacies is beyond the scope of the rest of chapter 328, HRS, and does not further the Department of Health's mission to protect public health. The public and the department are not well-served by the appearance that the department is in the business of regulating the insurance industry and the price of prescription drugs, something section 328-106, HRS, simply does not do. Even if section 106 were recodified and placed in a different chapter, and the responsibility of enforcing it transferred to another

department, its practical value as currently written, is negligible. It requires only an appeal process that is solely at the discretion of the PBM and does not support an equitable outcome. For example, if the PBM denies a pharmacy's claim of insufficient reimbursement and provides certain follow up information, with no additional remuneration to the pharmacy, there is no violation of section 328-106, HRS, because the amount of reimbursement is not prescribed in any way.

Consequently, the Department of Health recommends repeal of this section entirely as opposed to amendment or recodification in a different chapter of the HRS.

Impact on the public: None. Section 328-106, HRS, does not serve its intended purpose and is ineffective.

Impact on the department and other agencies: Repeal of section 328-106, HRS, will relieve the department of health of the regulatory burden of trying to implement a price control mechanism that does not function as intended. Additionally, this measure will return the department's attention to chapter 328's core function - to protect public health and the safety of food, drugs, and cosmetics.

GENERAL FUND: N/A.

OTHER FUNDS: N/A.

PPBS PROGRAM
DESIGNATION:

OTHER AFFECTED
AGENCIES: N/A.

EFFECTIVE DATE: Upon approval.