



STATE OF HAWAII
DEPARTMENT OF HEALTH
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**Testimony in SUPPORT of SB1381 SD1
RELATING TO THE REPEAL OF SECTION 328-106, HAWAII REVISED
STATUTES.**

REP. DELLA AU BELATTI, CHAIR
HOUSE COMMITTEE ON HEALTH & HOMELESSNESS

Hearing Date: March 22, 2023

Room Number: 016

1 **Fiscal Implications:** N/A.

2 **Department Testimony:** The Department of Health (DOH) supports the repeal of section 328-
3 106, Hawaii Revised Statutes (HRS), which created a parallel but ineffective and unenforceable
4 regulatory mechanism for pharmacy benefit managers.

5 Section 328-106, HRS, established an appeals process for pharmacies that dispense prescription
6 medications pursuant to a contract with a health plan based on the “maximum allowable charge”
7 payment model. If the pharmacy can demonstrate a financial loss for a specific transaction due
8 to an untimely cost list adjustment by the health plan, and the health plan concurs, the health plan
9 is obligated to refund the loss. If the health plan does not concur, the plan shall permit the
10 pharmacy to rebill the claim at the current cost, though not necessarily guaranteeing higher
11 reimbursement.

12 The department, in good faith, attempted to process an appeal in 2020. The pharmacy benefit
13 manager, communicating through the local health plan, provided information that documented
14 their response within the mandatory 14 days, a clear rationale for denying the appeal based on the
15 price of the drug in question was within the current market price range, and recertified the denial.
16 Informal review by the Department of the Attorney General confirmed that section 328-106,
17 HRS, was met, i.e., the health plan provided for a clear appeals process within 14 days.

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1 Pharmacy benefit manager regulation is a [nation-wide topic](#) for which [model legislation](#) exists.
2 Enacted in Hawaii in 2015, section 328-106, HRS, leveraged what was thought to be an
3 innovative approach, i.e., MAC-based appeals, but industry quickly adapted, rendering the
4 appeals process hollow. Section 328-106, HRS, offers Hawaii’s pharmacies no realistic or
5 substantive relief from the volatile price fluctuations of the prescription drug market, and diverts
6 resources and attention away from more substantive approaches. It is worth noting that the
7 [model PBM regulation legislation](#), published by the National Academy for State Health Policy,
8 does not include any reference to MAC.

9 Competing Regulatory Systems

10 [Chapter 431S, HRS, “Pharmacy Benefit Managers,”](#) established a regulatory framework
11 including clear definitions and rule-making authority specific to pharmacy benefit managers.

12 By contrast, chapter 328, HRS, to which section 106 is appended, is the Hawaii Food, Drug, and
13 Cosmetics Act, which is a supplement to Federal Food, Drug, and Cosmetic Act (USC, Title 21)
14 that oversees the safety of food, drugs, medical devices, and cosmetics. Assuring an appeals
15 process between private entities is not within scope nor expertise of DOH, and was not the
16 intention of the Legislature when enacting this chapter.

17 Inappropriate Oversight of Private Contracts

18 Section 328-106, HRS, applies only to pharmacy benefit managers and pharmacies, both of
19 which are private entities, in contractual relationships with each other to provide health care and
20 reimbursement for health care. The Department of Health’s has no authority, created by section
21 328-106 or any other statute, to enforce agreements between private contracted parties for
22 financial transactions. Disputes over contractually obligated reimbursement should be enforced
23 by the courts.

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1 No Public Health Threat

2 There is no imminent or long-term threat to public health or the environment created by
3 contractual agreement based on MAC, nor the appeal of such.

4 Ineffective Appeals Mechanism

5 The regulatory feature of section 328-106, HRS, is that the pharmacy benefit manager “shall
6 have a clearly defined process for a contracting pharmacy to appeal the maximum allowable
7 costs” in a timely manner. The pharmacy benefit manager, typically a business incorporated in
8 another state that is transacting business across state lines, has sole authority under this section to
9 uphold or deny an appeal, where denials incur a financial cost to the pharmacy benefit manager.
10 DOH, nor any state agency has legal jurisdiction over an out-of-state business for regulatory
11 purposes.

12 Insufficient Enforcement Capacity

13 DOH staff lack expertise in healthcare financing, risk management, retail pharmacy operations,
14 and forensic accounting to meaningfully administer this section. Moreover, chapter 328 does not
15 authorize DOH to compel cooperation with an investigation if they are not part of the physical
16 custody of drug products, such as pharmacy benefit managers. Although a DOH inspector may
17 enter a retail premises inspect the condition in which pharmaceuticals are stored for purposes of
18 patient and product safety, pursuant to the intent of chapter 328, HRS, the department can not
19 compel a pharmacy benefit manager to turn over data from claims management systems.

20 The public policy debate on regulation of pharmacy benefit managers is the prerogative of the
21 Legislature. However, there is no value to section 328-106 because it is unenforceable and with
22 no practical benefit to the pharmacy. Compliance is achieved by a PBM simply by having a
23 clear appeals process that lasts no more than 14 days, regardless of the outcome to the pharmacy.

24 Thank you for the opportunity to testify.