



STATE OF HAWAII
DEPARTMENT OF HEALTH
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**Testimony in SUPPORT of SB1381 SD1 HD1
RELATING TO THE REPEAL OF SECTION 328-106, HAWAII REVISED
STATUTES.**

REP. KYLE T. YAMASHITA, CHAIR
HOUSE COMMITTEE ON FINANCE

Hearing Date: March 30, 2023

Room Number: 329

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 an ineffective and unenforceable regulatory
4 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 being within the current market price range, and recertified the
16 denial. Informal review by the Department of the Attorney General confirmed that section 328-
17 106, HRS, was met, i.e., the health plan provided for a clear appeals process within 14 days.

18

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 This regulatory action is unenforceable and ineffective regardless of chapter or agency and
10 should be repealed.

11 Inappropriate Chapter

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

17 Insufficient Regulatory Powers and Expertise

18 DOH staff lack expertise in healthcare financing, risk management, retail pharmacy operations,
19 and forensic accounting to meaningfully administer this section. Moreover, chapter 328 does not
20 compel cooperation with an investigation because the PBM’s legal entity never has physical
21 custody of drug products and are out of state, beyond the jurisdiction of HRS.

22 A DOH inspector may enter a retail site, for example a chain pharmacy at a suburban strip mall,
23 and conduct an unannounced inspection of the condition in which pharmaceuticals are stored for
24 purposes of patient and product safety, pursuant to of chapter 328, HRS. The inspector may also
25 require the pharmacy to immediately hand over paperwork like shipping manifests and order
26 forms, under threat of a fine or other sanction. However, because PBMs deal exclusively with

1 online financial transactions, chapter 328, HRS, does not authorize DOH to seize electronic
2 records, let alone those served from an out-of-state data center.

3 Inappropriate Oversight of Private Contracts

4 Section 328-106, HRS, applies only to pharmacy benefit managers and pharmacies, both of
5 which are private entities, in contractual relationships with each other to provide health care and
6 reimbursement for health care. Disputes over contractually obligated reimbursement should be
7 enforced by the courts.

8 No Public Health Threat

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

11 Ineffective Appeals Mechanism

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

19 Once more, this regulatory action is unenforceable and ineffective regardless of chapter or
20 agency and should be repealed.

21 The public policy debate on regulation of pharmacy benefit managers is the prerogative of the
22 Legislature. However, there is no value to section 328-106 because there is no practical benefit
23 to the pharmacy.

24 Thank you for the opportunity to testify.

SB-1381-HD-1

Submitted on: 3/28/2023 4:39:58 PM

Testimony for CPC on 3/30/2023 2:00:00 PM

Submitted By	Organization	Testifier Position	Testify
Ronald Taniguchi, Pharm.D.	Individual	Oppose	Written Testimony Only

Comments:

DOH offloading a responsibility due to incompetence & lack of resources is not surprising. If DOH understands the core issues, it would advise/recommend which agency can pick up regulating and enforcing the statutes. Suggesting HRS Chapter 431S is a competing regulatory system is a joke. As written, 431S performs a bookkeeping function and little else. "No Public Health Threat? How is closing of independent pharmacies, particularly in rural areas, and large chain pharmacies reducing their staffing to the bare minimum over the past 10 years viewed? Do better than this.

Mahalo