JOSH GREEN, M.D.
GOVERNOR

SYLVIA LUKE
LIEUTENANT GOVERNOR

JADE T. BUTAY
DIRECTOR

WILLIAM G. KUNSTMAN
DEPUTY DIRECTOR

STATE OF HAWAIʻI
KA MOKUʻĀINA O HAWAIʻI
DEPARTMENT OF LABOR AND INDUSTRIAL RELATIONS
KA ʻOIHANA PONO LIMAHANA

February 17, 2026

To: The Honorable Jackson D. Sayama, Chair,
The Honorable Mike Lee, Vice Chair, and
Members of the House Committee on Labor

Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Place: Conference Room 309, State Capitol

From: Jade T. Butay, Director
Department of Labor and Industrial Relations (DLIR)

**Re: H.B. 2164 RELATING TO WORKERS' COMPENSATION**

## I. OVERVIEW OF PROPOSED LEGISLATION

The **DLIR strongly supports** this measure that provides a clear definition of compounded prescription drugs and helps prevent inflated pricing that burdens both injured workers and employers. The Department also suggests an amendment to limit the availability of compounded drugs in the workers' compensation system by specifying allowing compounded drugs only from 503A facilities, which operate under state pharmacy boards and may compound medications only for identified individual patients

HB2164 proposes to amend §386-21.7(f) by:

- Providing a definition of a "compounded prescription drug" that aligns state law with federal standards for pharmacy compounding.

## II. CURRENT LAW

§386-21.7 (a) provides that notwithstanding any other provision to the contrary, immediately after a work injury is sustained by an employee and so long as reasonably needed, the employer shall furnish to the employee all prescription drugs as the nature of the injury requires.

§386-21.7 (c) states that payment for compounded prescription drugs shall be the sum of one hundred forty per cent of the average wholesale price by gram weight of each underlying prescription drug contained in the compounded prescription drug.

Subsection (c) furthermore provides that for compounded prescription drugs, the average wholesale price is defined as the price set by the original manufacturer of each underlying prescription drug, as identified by its National Drug Code (NDC) and as published in the *Red Book* on the date the compounding occurs. This pricing applies unless the employer, carrier, or an entity acting on their behalf has a direct contract with the provider or the provider's assignee for a lower amount.

§386-21.7 (d) states that all pharmaceutical claims submitted for repackaged, relabeled, or compounded prescription drugs must include the National Drug Code of the original manufacturer. If the original manufacturer of the underlying drug product used in a repackaged, relabeled, or compounded prescription drug is not provided or is unknown, reimbursement shall be set at one hundred forty percent of the average wholesale price for the original manufacturer's National Drug Code, as listed in the *Red Book* for the prescription drug most closely related to the underlying drug product.

§386-21.7(e) sets forth that, notwithstanding any other provision in this section, equivalent generic drug products must be substituted for brand-name pharmaceuticals unless the prescribing physician certifies that no substitution should be made because the injured employee's condition does not tolerate an equivalent generic drug product.

§386-21.7(f) provides that for the purposes of this section, "equivalent generic drug product" has the same meaning as provided in §328-91.

HAR §12-15-55 *Drugs, supplies and materials* subsection (a) provides that charges for prescribed drugs, supplies, or materials furnished to an injured employee must be separately listed and certified by the provider, or a duly authorized representative, confirming that the items were required and prescribed for the industrial injury.

§328-91 "Equivalent generic drug product" is defined as a drug product approved by the director as substitutable by pharmacists and included in the Hawaii list of equivalent generic drug products and interchangeable biological products.

§328-1 "Prescription drug" means: (1) Any drug required by federal or state statutes, regulations, or rules to be dispensed only upon a prescription, including finished dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Act; or (2) Any drug product compounded or prepared pursuant to a practitioner's order.

## III. COMMENTS ON THE HOUSE BILL

The Department fully supports this measure. The fundamental intent of Hawai'i's workers' compensation law is to ensure that injured workers receive appropriate, individualized medical care that promotes recovery and a safe return to work. Prescription drugs are a critical component of this care, and in certain cases, compounded prescription drugs are essential when FDA-approved medications are not suitable due to allergies, dosage requirements, or other clinical considerations.

Patient-specific compounding ensures that medications are tailored to the unique needs of each injured worker, supporting both patient safety and effective treatment outcomes. This individualized approach reflects the original purpose of the law, to provide care that is necessary and reasonable for the specific injury and patient. The lack of clarity has led to inconsistent interpretations and inflated billing practices, undermining the law's intent. By adopting the federal definition under section 503A, this bill ensures compounded drugs are prepared only for an identified individual patient based on a valid prescription, with professional oversight by licensed pharmacists and physicians.

The Department has experienced a significant increase in billing disputes over the past few years involving compounded drugs with inflated pricing from section 503B outsourcing facilities and similar bulk manufacturing operations. These facilities prioritize mass production rather than patient-specific compounding, which contradicts the individualized care principle of Hawaii's workers' compensation law. Bulk compounding models have consistently been linked to inflated costs and lack of cost control, further undermining the integrity of the system.

Section 1 Purpose of HB2164 references only Section 503A facilities, but Title 21 includes both 503A and 503B facilities. Therefore, to remain aligned with the intent of the measure that compounded medications in Hawai‘i are prepared only for identified individual patients under appropriate professional oversight, the DLIR suggests 503A facilities exclusively should be permitted under Hawai‘i's compounded drug provisions.

Whereas 503A facilities operate under state pharmacy boards and may compound medications only for identified individual patients, 503B outsourcing facilities, by contrast, are FDA registered manufacturers that may compound in bulk without patient specific prescriptions. Amending this measure to prohibit the use of compounded drugs from 503B outsourcing facilities will fully address the source of the inflated billing practices currently occurring in the workers' compensation system.

This measure strengthens Hawai‘i's workers' compensation system by reaffirming its core purpose to provide individualized, patient-centered care that supports recovery and safety. The DLIR's suggested amendment strengthens that stated purpose and effectiveness of HB2164.

For these reasons, the Department is in **strong support** of this measure.

**JOSH GREEN, M. D.**
GOVERNOR
KE KIAʻĀINA

**SYLVIA LUKE**
LT. GOVERNOR
KA HOPE KIAʻĀINA

**BRENNA H. HASHIMOTO**
DIRECTOR
KA LUNA HOʻOKELE

**BRIAN K. FURUTO**
DEPUTY DIRECTOR
KA HOPE LUNA HOʻOKELE

**STATE OF HAWAIʻI | KA MOKUʻĀINA O HAWAIʻI**
**DEPARTMENT OF HUMAN RESOURCES DEVELOPMENT**
**KA ʻOIHANA HOʻOMŌHALA LIMAHANA**
235 S. BERETANIA STREET
HONOLULU, HAWAIʻI 96813-2437

Statement of
**BRENNA H. HASHIMOTO**
Director, Department of Human Resources Development

Before the
**HOUSE COMMITTEE ON LABOR**
Tuesday, February 17, 2026
9:00AM
State Capitol, Conference Room 309

In consideration of
**HB2164, RELATING TO WORKERS' COMPENSATION**

Chair Sayama, Vice Chair Lee, and members of the committee:

The Department of Human Resources Development (HRD) opposes HB2164.

The purpose of HB2164 is to align state law with federal standards for pharmacy compounding by codifying the federal definition of a "compounded drug".

HRD opposes the measure for the following reasons:

- The U.S. Food and Drug Administration (FDA) does not approve compounded drugs. As a result, the FDA does not review compounded drugs for safety, effectiveness, or quality before marketing.

  The FDA describes drug compounding as a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

- HRD has a fiduciary duty to administer the State of Hawaii's Executive Branch's self-insured workers' compensation program using public funds. As currently written, the bill narrows the definition of "compounded prescription drug", allowing certain non-FDA-approved compounds to be dispensed by physicians. Because

there are no definitive regulations in the Hawaii Workers' Compensation Medical Fee Schedule that address the specific costs of compounds, current ethical and safety protections that help ensure proper costs may be compromised. This could expose employers to higher expenses that bypass reasonable reimbursement limits.

- HRS §386-21.7 already provides an effective framework that balances the needs of injured workers while maintaining cost controls for employers. The existing statutory language broadly covers prescription drugs, including compounds, making the measure unnecessary.

- SB2751's proposed definition excludes drugs compounded in outsourcing facilities such as 503A and 503B. While these facilities are FDA-registered, their products are not FDA-approved and are subjected to the reimbursement guidelines referenced in HRS §386-21.7(c), which caps payments at 140% of the average wholesale price (AWP) based on gram weight of the underlying prescription drug. Excluding outsourcing facilities go against the law's intent to promote patient safety, regulatory consistency, and cost predictability, creating loopholes for higher costs.

Should this bill move forward, HRD respectfully requests amendments to the current draft.

On page 2, line 10, add new sections (f) and (g) to read as follows:

"(f) Physician dispensing of prescription drugs shall be allowed for thirty days following the industrial injury. Thereafter, all prescription drugs shall be obtained through the employer's pharmacy benefit manager.

(g) Prescription drugs not approved by the Food and Drug Administration, such as compounds, shall be identified as compounds when listed on the treatment plan and when billed, and be supported by a statement of medical necessity documenting the case of medical need for a compound drug over an over the counter or prescription drug of similar therapeutic effect approved by the Food and Drug Administration. Failure to identify a compound on a treatment plan or when billed shall make the payment for the drug non-reimbursable."

On page 2, line 10, revise the current subsection (f) as follows:

"(h) Compounded prescription drug" means a drug product that **combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient, compounded by a licensed pharmacist, licensed physician, or in a 503A and503B, or any other type of similar, FDA-approved, compounding facility as defined by the Food, Drug, and Cosmetic Act (21 U.S.C. 353a).**"

We are available to answer any questions or provide further information as needed.

HAWAII INSURERS COUNCIL
A trade association of property and casualty insurance companies

P. O. Box 893315
Mililani, Hawaii 96789
Telephone (808) 997-5876

**Alison H. Ueoka**
President

# TESTIMONY OF MILIA LEONG

COMMITTEE ON LABOR
Representative Jackson D. Sayama, Chair
Representative Mike Lee, Vice Chair

Tuesday, February 17, 2026
9:00 a.m.

## HB 2164

Chair Sayama, Vice Chair Lee, and members of the Committee on Labor, my name is Milia Leong, Executive Claims Administrator for HEMIC Insurance Managers, Inc., and Chair of the Workers' Compensation Policy Committee for Hawaii Insurers Council. The Hawaii Insurers Council is a non-profit trade association of property and casualty insurance companies licensed to do business in Hawaii. Member companies underwrite approximately forty percent of all property and casualty insurance premiums in the state.

Hawaii Insurers Council (HIC) **supports** this bill which would clarify who may produce compounds and that the compound must be for a specific patient.

We ask that the phrase, "…or a licensed physician,…" be deleted from Page 2, line 15 of the bill because this would eliminate any potential conflict of interest if the physician who makes the compound is also writing the prescription for the same compound.

In addition, HIC has had the opportunity to review the comments of the Department prior to this hearing and we fully support their position that compounds should be patient-specific and produced for the individual based on a prescription with oversight by licensed pharmacists and physicians. HB 2164 codifies this by adopting the federal definition under section 503A.

Thank you for the opportunity to testify.

SOLERA | IMS

841 Bishop Street, Suite 2250 | Honolulu, Hawaii 96813

Statement of

**KRIS KADZIELAWA**

Managing Director, Solera Integrated Medical Solutions

Before the

**HOUSE COMMITTEE ON LABOR**

Rep. Jackson D. Sayama, Chair Rep. Mike Lee, Vice Chair

Tuesday, February 17, 2026

9:00AM

State Capitol, Conference Room 309

In consideration of

**HB2164 RELATING TO WORKERS' COMPENSATION**

**TESTIMONY IN OPPOSITION TO HB2164**

Aloha Chair Sayama, Vice Chair Lee, and Members of the Committee:

My name is Kris Kadzielawa, and I am the Managing Director of Solera Integrated Medical Solutions, a medical payment integrity technology and services provider dedicated to ensuring fair, efficient, and transparent processes within Hawaii's workers' compensation system for insurers, employers, government agencies, and healthcare providers. For over 33 years, we have partnered with employers, claims teams, and government agencies to combat medical fraud and abuse. Currently, the big issue of contention stems from physician dispensing practices that inflate costs through repackaged or compounded drugs,

often at 10–100 times the price of standard therapeutic equivalents. These practices divert resources from injured workers' recovery and burden employers with unnecessary expenses.

I appreciate the opportunity to testify in **opposition** to HB2164 as introduced, while offering constructive amendments that protect the safety of the injured worker, reign in the current, inflated prescription drug costs, and minimize drug-related Bill Disputes at DLIR. These proposed amendments represent a thoughtful, balanced solution that protects patient safety, closes loopholes, and delivers significant cost savings. We urge the House to adopt this approach.

Hawaii's existing framework under **HRS §386-21.7** is reasonable, fair, and effective. It broadly covers all prescription drugs — including compounds produced under either section 503A or 503B of the Federal Food, Drug, and Cosmetic Act — and has worked well for all stakeholders except those who continually develop novel products and aggressive billing tactics to circumvent its safeguards.

HB2164 would narrow the definition of "compounded prescription drug" to only those produced in a state-licensed pharmacy or by a licensed physician under patient-specific 503A standards. This exclusion of 503B outsourcing facilities which bulk-manufacture compounds would create a dangerous and costly loophole and run contrary to federal law.

Under federal law, the definition of a compounded drug hinges on the **process of compounding itself**—combining, mixing, or altering ingredients to create a customized medication not commercially available in an FDA-approved form—rather than the entity producing it, the location of production, or the intended recipient. This principle is enshrined in the FDCA, as amended by the Drug Quality and Security Act of 2013. Federal regulations explicitly treat 503B outsourcing facilities as **compounders** producing **compounded drugs**:

- 21 CFR §207.1 defines an "outsourcing facility" as "a **compounder** that has elected to register with FDA under section 503B…"
- 21 CFR §216.24 prohibits certain substances from being "compounded under the exemptions provided by section 503A(a) **or section 503B(a)**," treating both categories identically.
- 21 CFR §207.13(k) further refers to 503B facilities as entities that "**compound drugs** in conformance with section 503B."

The FDA's own application of cGMP regulations (21 CFR Parts 210 and 211) to 503B facilities confirms they engage in compounding. Excluding 503B products from Hawaii's

reimbursement safeguards would allow bulk-produced compounds to bypass **HRS §386-21.7(c)** limits, undermining patient safety and cost predictability.

I advocate that injured workers are far better served receiving FDA-approved prescription and FDA-approved over-the-counter (OTC) medications directly from a retail pharmacy. Studies consistently show that topical pain compounds are not superior to FDA-approved OTC topicals. FDA-approved topical creams sell for as little as $24 per 3 ounces versus $2,400 or more for compounded versions that the FDA has never evaluated for safety or effectiveness.

Therefore, we respectfully request this Committee adopt the following amendments to HB2164:

1. **Include both 503A and 503B (and any future compounding facilities) in the definition.** Amend subsection (f) to read: "'Compounded prescription drug' means a drug product that is compounded in a 503A or 503B, or any other type of FDA-registered, compounding facility." This ensures all non-FDA-approved compounds remain subject to the existing cost controls and prevents future schemes that might skirt definitions.
2. **Limit physician dispensing to 30 days post-injury.** Add a new subsection: "Physician dispensing shall be allowed for 30 days following the industrial injury. Thereafter, all prescription drugs shall be obtained through the employer's Pharmacy Benefit Manager." This single, targeted reform is the most effective way to eliminate long-term abuse of inflated AWPs, promote PBM oversight and FDA approved, generic/OTC utilization, remove more than 90% of the bill-dispute burden on the Department of Labor, and save the State **$3–5 million annually with another $8-10 million of savings to insurers**. Without it, passage of HB2164 and other similar measures will add an additional **$3–5 million per year** to the workers' compensation budget over the next 24 months and require the Department to process double the current volume of bill disputes.
3. **Require preapproval for non-FDA-approved drugs.** Add a new subsection: "Non-FDA-approved prescription drugs, such as compounds, shall be identified as compounds when listed on the treatment plan and when billed, and be supported by a statement of medical necessity documenting the case of medical need for a compound drug over an FDA-approved OTC or prescription drug of similar therapeutic effect. Failure to identify a compound on a treatment plan or when billed shall make it non-reimbursable." This adds accountability and ensures that compound prescribing is truly necessary rather than profit driven.

In my 33 years in the medical bill audit and payment integrity business, I have not encountered a single issue of contention regarding prescription drug bills outside the practice of physician dispensing. On the other hand, physician dispensers have attempted numerous strategies to bypass the cost controls in the current statute. Hawaii's existing law is broad, fair, and works flawlessly for everyone except those who continue to invent novel ways around it. For example, HRS ties prescription drug reimbursement to the Average Wholesale Price (AWP) published in Redbook with the expectation that the published AWP is the actual Average Wholesale Price. Redbook does not verify the submitted AWP listing information for accuracy or compliance, as it merely publishes the AWP reported by the drug manufacturer, compounder, repackager, or relabeler. When the AWP submitted for publishing by the drug manufacturer, compounder, repackager, or relabeler is deemed to NOT be the actual Average Wholesale Price of the drug, the submission of a claim (based on this falsified information) for payment under a government funded medical benefit program may be considered a False Claim.

We urge the Committee to defer HB2164 as introduced — or adopt the three targeted improvements above. These changes will protect injured workers, restore cost predictability for employers, reduce administrative burdens, and finally curb the physician-dispensing practices that have plagued the system for over 20 years.

Mahalo for your consideration. I am available for questions and remain committed to working collaboratively toward solutions that benefit all stakeholders.

Respectfully submitted,

**Kris Kadzielawa**

Managing Director | Solera IMS | MediHawaii.com O: +1 808 531 2273 ext. 25 | kris.kadzielawa@solera.com

**Solera IMS** | 841 Bishop Street, Suite 2250 | Honolulu, Hawaii 96813

Aloha Billing Company
www.alohabillingcompany.com

To: Rep. Jackson D. Sayama, Chair
Rep. Mike Lee, Vice Chair
Members of the Committee LBT

Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Place: Conference Room 309

**Support for HB2164**

I strongly support HB2164, which defines "compounded prescription drug" by incorporating federal standards for pharmacy compounding under 21 U.S.C. section 353 (section 503A of the FD&C Act) and related federal guidance. By aligning state law with these federal definitions, the bill clarifies what counts as a compounded prescription drug in workers' compensation, supports safe and appropriate use of compounded medications, and confirms how such drugs should be reimbursed under DLIR's workers' compensation framework.

This bill is needed for the following reasons:

1. **State law background and gap**
   Hawaii's workers' compensation law was drafted when pharmacy compounding was understood mainly as traditional, patient-specific compounding in a pharmacy or physician's office under older federal language. Since then, federal law has clarified standards for compounded drugs under section 503A of the Federal Food, Drug, and Cosmetic Act, but Hawaii's workers' compensation statute has not yet been updated to fully align with those definitions.
2. **Newer compounded medications and reimbursement confusion**
   In the last decade, additional types of compounded medications have become available, some produced at larger scale and assigned their own National Drug Code (NDC) and Average Wholesale Price (AWP). These products differ from traditional 503A-type compounds that are custom-prepared for a specific patient and typically do not carry their own NDC and AWP, which has led to confusion among employers and payers about which NDC and AWP to use for reimbursement.
3. **DLIR practice and need for clarity**
   DLIR has determined that when a compounded medication has its own NDC and AWP, reimbursement in workers' compensation should be based on that specific NDC and AWP, consistent with how other drug products are treated under the medical fee schedule. Codifying this approach in statute will improve transparency and consistency for employers, insurers, pharmacies, and injured workers.

I would suggest, however, that these Committees amend this bill by adding the definition of "compounded prescription drug" in HRS 386-1 (and not HRS 386-21.7), which contains the definitions for Chapter 386. That is a more appropriate section to include this new definition.

More importantly, however, please do not allow opponents of this bill to add "poison pill" amendments that would dilute, undermine, or fundamentally alter the intent of this bill. This bill was crafted to address a clear policy need – the clarification of the statutory definition of a "compounded prescription drug" for workers' compensation purposes. Amendments designed not to improve the bill, but to quietly vitiate it, run counter to the main goal of the workers' compensation system, which is to help injured workers recover and return to work. In particular, opponents have proposed the following amendments:

1. **Limiting the dispensing of prescription drugs by physicians to thirty days following the industrial injury and requiring all prescription drugs to be obtained through the employer's pharmacy benefit manager (PBM) thereafter**
   This would be a fatal blow to physician dispensing and weaken a physician's ability to monitor a patient's compliance with medical advice and ultimately to treat the patient. In addition, you would simply enhance the profits of a PBM, which is the subject of a recent Hawaii Attorney General lawsuit against the three dominant PBMs, alleging price inflation, rebate manipulation, and anti-competitive practices in the prescription drug market. Under Hawaii law, the employer has a legal obligation to furnish to the employee all prescription drugs as the nature of the injury requires. The treating physician is far more qualified than a PBM to decide what prescription drugs are required to treat the patient. Further, this is certainly not the proper vehicle to address physician dispensing vs. PBMs.

2. **Requiring non-FDA-approved prescription drugs, such as compounds, to be identified as compounds when listed on the treatment plan and when billed, and be supported by a statement of medical necessity documenting the case of medical need for a compound drug over an FDA-approved over-the-counter or prescription drug of similar therapeutic effect**
   This is another ill-fated attempt to weaken a physician's authority to treat a patient, founded in an uninformed belief that a physician's medical opinion regarding a non-FDA-approved prescription drug should be second-guessed. Whenever a physician prescribes a medication, compound or not, they have made a diagnosis, and made the determination of medical necessity. We should not allow a PBM or claims adjuster to make that decision for the physician. Existing law permits a physician to prescribe a non-FDA-approved prescription drug without this added layer of scrutiny or bureaucracy. Adding this layer will only interfere with and potentially delay the injured worker's timely recovery and disincentivize physicians to treat injured workers.

3. **Changing the definition of "compound prescription drug" to be "a drug product that is compounded in a compounding facility in compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) or any other type of similar compounding facility approved by the Federal Drug Administration";**
   This revised definition of a "compound prescription drug" overly broadens the definition to include "any other type of similar compounding facility approved by the Federal Drug Administration," which would destroy the intent of the bill to align state law with federal law. This amendment would include drugs manufactured in a 503B Outsourcing Facility, which are manufactured under strict FDA oversight, have their own NDC, and (unlike 503A drugs) are assigned an AWP. This defeats the precise need for this bill – that unscrupulous bill review companies are exploiting an ambiguity in current law and treating dedicated physicians as outlaws and villains who are exploiting physician dispensing for profit rather than caring for their patient. In theory, the distinction between 503A and 503B drugs is clear under federal law. In practice, some bill reviewers routinely blur that line to delay or avoid proper payment—even after DLIR has definitively ruled against them in formal disputes. Please put an end to this ambiguity and bring needed clarity to state law.

Thank you for your consideration.

Cathy Wilson

WIMAH
Work Injury Medical Association of Hawaii
WIMAH808@Gmail.com

**Hearing Date:** Tuesday, February 17, 2026
**Time:** 9:00 a.m.
**Location:** Conference Room 309

## RE: Testimony in Support of HB2164

Dear Chair Sayama, Vice Chair Lee, and Members of the Committee,

My name is **Gary Okamura, MD**, and I submit this testimony in my capacity as **President of the Work Injury Medical Association of Hawai‘i (WIMAH)**, a nonprofit organization whose Board is composed entirely of practicing physicians across multiple specialties dedicated to improving workers' compensation education and care in our state. I also write as an orthopedic surgeon who has treated Hawai‘i's injured workers for several decades.

I am offering **strong support** for **HB2164**, which updates Hawai‘i's workers' compensation law by adopting the federal definition of a "compounded prescription drug" found in **21 U.S.C. §353 (Section 503A of the FD&C Act)**. This clarification is overdue and essential for ensuring consistency, safety, and fairness in the prescribing and reimbursement of compounded medications.

**Why HB2164 Is Necessary**

**1. Hawai‘i's statute has not kept pace with federal standards**

Our workers' compensation law was written at a time when compounding was understood almost exclusively as small-batch, patient-specific preparation. Since then, federal law has clearly distinguished **503A traditional compounding** from other types of drug production. Hawai‘i's statute has never been updated to reflect these distinctions, leaving room for misinterpretation.

**2. The emergence of newer compounded products has created reimbursement disputes**

Some compounded medications now carry their own **NDC** and **AWP**, while traditional 503A compounds do not. This difference has caused confusion among payers and bill reviewers, who sometimes apply the wrong pricing standard. These disputes delay care and burden both physicians and pharmacies who serve injured workers.

**3. DLIR already follows a clear reimbursement method—this bill simply codifies it**

DLIR has consistently held that when a compounded medication has its own NDC and AWP, reimbursement should be based on that specific code—just as with any other medication. HB2164 places this long-standing practice into statute, promoting uniformity and reducing unnecessary conflict.

WIMAH
Work Injury Medical Association of Hawaii
WIMAH808@Gmail.com

**Recommended Amendment**

For clarity and proper statutory placement, I respectfully recommend inserting the new definition of "compounded prescription drug" into **HRS §386-1**, the definitions section for the entire chapter, rather than HRS §386-21.7.

**Concerns About Proposed Opponent Amendments**

Several amendments being circulated by Solera/IMS would fundamentally alter the purpose of this bill and undermine the care of injured workers. I urge the Committee to reject the following proposals:

**1. Restricting physician dispensing to 30 days and forcing all prescriptions through PBMs**

This change would severely impair a treating physician's ability to monitor medication adherence and adjust treatment promptly. It would also shift control to PBMs—entities currently facing scrutiny, including litigation by Hawai'i's Attorney General for alleged anti-competitive practices.

Hawai'i law places the duty to furnish necessary medications on the employer, and the treating physician—not a PBM—is best positioned to determine what is medically required.

Shifting RX's to PBMs is not cost saving, it is simply shifting the revenue to the PBM.

**2. Requiring additional documentation and justification for compounded medications**

This proposal presumes that a physician's medical judgment regarding non-FDA-approved medications is suspect and must be second-guessed. In reality, every prescription—compound or otherwise—is already based on diagnosis and medical necessity. Adding new bureaucratic hurdles will delay treatment, discourage physicians from participating in workers' compensation, and ultimately harm injured workers.

**3. Broadening the definition of "compound prescription drug" to include 503B outsourcing facilities**

This amendment would erase the critical distinction between **503A** and **503B** products. 503B medications are manufactured under FDA oversight, have their own NDC, and are assigned an AWP. Including them in the definition of "compounded prescription drug" would directly contradict federal law and defeat the purpose of HB2164.
Unfortunately, some bill review companies already blur this line to deny or delay proper payment—even after DLIR rulings. HB2164 is designed to stop this practice, not enable it.

WIMAH
Work Injury Medical Association of Hawaii
WIMAH808@Gmail.com

**Conclusion**

HB2164 is a straightforward, necessary update that aligns Hawai‘i’s workers’ compensation law with federal standards, reduces disputes, and supports timely, appropriate care for injured workers. I respectfully urge the Committee to pass this measure without amendments that would weaken its intent.

Thank you for the opportunity to testify.

**Gary Okamura, MD**
President, Work Injury Medical Association of Hawai‘i (WIMAH)
Orthopedic Surgeon, Hawai‘i

**HB-2164**
Submitted on: 2/16/2026 1:30:17 PM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Gabe Merrill | Individual | Support | Written Testimony Only |

Comments:

## Testimony in Strong Support of HB2164

**Submitted by Gabriel Merrill**
**President, Hawaii Injured Workers Association (HIWA)**
**February 17, 2026**

To: Chair Sayama, Vice Chair Lee, and Members of the Committee,

Aloha Chair and Members,

My name is Gabriel Merrill, and I serve as President of the Hawaii Injured Workers Association (HIWA), a nonprofit organization dedicated to protecting the rights, access to care, and recovery of injured workers in our state.

On behalf of HIWA, I respectfully submit strong support for HB2164.

HB2164 is a technical but critically important update. It aligns Hawai‘i’s workers’ compensation statute with the federal distinction established in 2014 between:

- 503A traditional compounding pharmacies, and
- 503B FDA-regulated outsourcing facilities under 21 U.S.C. §353.

Hawai‘i law has never incorporated this federal clarification. That statutory gap has allowed certain bill review entities to misclassify medications and deny reimbursement—even when DLIR has ruled payment is appropriate.

From HIWA’s perspective, this is not an abstract legal issue.

When reimbursement is denied:

- Pharmacies hesitate to dispense.
- Physicians hesitate to prescribe.
- Injured workers experience treatment delay.
- Recovery is prolonged.

HB2164 does not expand prescribing authority.
It does not mandate new medications.
It simply codifies the reimbursement framework DLIR already applies when a medication has its own NDC and AWP.

---

# Concerns About Proposed Amendments

HIWA is particularly concerned about amendments that would:

• Limit physician dispensing to 30 days
• Require prescriptions to be routed through employer-selected PBMs
• Require prior approval for topical compounded medications
• Broaden the definition of compounded drugs to include 503B products

These amendments would:

- Disrupt continuity of care
- Introduce administrative delay
- Shift control from treating clinicians to pharmacy benefit managers
- Undermine the federal distinction this bill is intended to clarify

Workers' compensation already places the duty to furnish necessary medical treatment on the employer. That obligation should not be diluted by procedural barriers that delay access.

---

# HIWA's Position

HIWA supports:

- Clear statutory language
- Alignment with federal standards
- Reduction of administrative conflict
- Timely access to appropriate, often non-opioid treatment options

We respectfully urge the Committee to pass HB2164 as a clean bill and reject amendments that weaken its purpose.

Thank you for the opportunity to testify on behalf of Hawai‘i's injured workers.

Respectfully,

Gabriel Merrill
President
Hawaii Injured Workers Association (HIWA)

PREMIER MEDICAL GROUP HAWAII

**Scott Miscovich MD LLC**
46-001 Kamehameha Hwy Ste 109
Kaneohe, HI 96744
Phone: (808) 247-7596 Fax: (808) 824-3416

February 16, 2026

# Testimony in Opposition to HB2164 - Relating to Workers' Compensation

Dear Chair Jackson Sayama, Vice Chair Mike Lee, and the Committee on Labor:

My name is Dr. Scott J. Miscovich and I am a licensed physician actively engaged in the treatment of patients in our community. I respectfully submit testimony in opposition to HB2164.

As a treating physician, my foremost obligation is to provide safe, evidence-based, and individualized care to my patients. Medical decision-making is complex and must be guided by clinical training, peer-reviewed evidence, established standards of care, and federal regulatory frameworks that already govern the practice of medicine.

HB2164 raises serious concerns because it risks complicating existing federal regulations that are already carefully structured to ensure patient safety and professional accountability. When state law introduces requirements that overlap with, contradict, or add additional layers to federal regulations, it creates confusion — not only for physicians, but also for patients. This confusion can undermine trust, delay care, and increase administrative burdens that ultimately detract from time spent delivering direct patient care.

Patients rely on clarity. They expect that the medications, therapies, and standards guiding their treatment are consistent, medically sound, and not subject to shifting or conflicting legal interpretations. Any law that complicates federal regulations will only confuse the public and create uncertainty in clinical practice.

Further, medical standards should be developed and updated by medical experts — physicians, researchers, professional boards, and scientific bodies — who are trained to evaluate evolving evidence and clinical outcomes. Legislating specific medical standards outside of established professional and regulatory processes risks substituting policy decisions for medical judgment. This can inadvertently interfere with individualized patient care and may not reflect current best practices.

Our healthcare system functions best when:

- Federal and state regulations are aligned and clear;
- Clinical standards are set by medical and scientific experts; and
- Physicians are allowed to exercise professional judgment in partnership with their patients.

For these reasons, I respectfully urge the Committee to reconsider HB2164 and avoid enacting measures that could complicate federal regulations or undermine established medical standards.

Thank you for the opportunity to provide testimony.

Respectfully submitted,

***Scott J Miscovich MD***
***President and CEO***
***Premier Medical Group***
***Hawaii/USA/International***
46-001 Kamehameha Hwy
Kaneohe, HI 96744
Email: Scott.Miscovich@pmgusa.org

PREMIER
MEDICAL
GROUP
HAWAII

www.pmgusa.org

Hearing Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Location: Conference Room 309

Dear Chair Sayama, Vice Chair Lee, and Members of the Labor Committee,

**Testimony in Support of HB2164**

My name is Brandon Shirai, MD, and I am a physician at Hawaii Injury Recovery Center, a practice dedicated to caring for Hawai‘i’s injured workers. Our providers work within the workers’ compensation system every day, and we routinely encounter how outdated statutory language around compounded medications creates delays in treatment and disputes over reimbursement.

I write in strong support of HB2164 because it updates Hawai‘i’s workers’ compensation law to use the federal definition of “compounded prescription drug” found in 21 U.S.C. §353 (Section 503A). This clarification is necessary to bring our statute in line with current federal standards and modern prescribing and billing practices.

Why HB2164 Is Necessary:

Hawai‘i’s current statute predates the clear federal distinction between 503A traditional compounding pharmacies and 503B FDA-regulated outsourcing facilities. That gap has opened the door for some bill review entities to blur these categories, mislabel medications, deny correct payment, and generate avoidable disputes—even when DLIR has already ruled that the provider is entitled to reimbursement.

HB2164 addresses this problem by explicitly incorporating the federal definition into state law and by reinforcing the reimbursement method DLIR already applies when a compounded or 503B medication has its own NDC and AWP. This change promotes consistency, reduces administrative friction, and helps preserve access to appropriate, often non-opioid, therapies for injured workers.

Objections and Problematic Proposed Amendments:

Several proposed amendments from bill review and PBM-affiliated interests would undermine the bill’s intent and harm patient care:

1. Limiting physician dispensing to 30 days and forcing prescriptions into PBM control thereafter
   Capping physician dispensing in this way would interrupt continuity of care, delay necessary dose or therapy adjustments, and move control away from the treating physician, who is most familiar with the patient’s condition. It would also shift

dollars to PBMs without any clear evidence of improved outcomes or genuine cost savings for employers or the system.

2. Creating extra documentation hurdles only for compounded medications
   All prescriptions must already be justified by medical necessity. Singling out compounded medications for additional paperwork would slow down treatment, add administrative burden, and further discourage providers from participating in the workers' compensation system—ultimately to the detriment of injured workers.
3. Expanding "compounded prescription drug" to sweep in 503B products
   Including 503B outsourcing-facility medications within the definition of "compounded prescription drug" is inconsistent with federal law and would revive the very confusion HB2164 seeks to resolve. 503B products are manufactured under FDA oversight, carry their own NDC and AWP, and should be reimbursed as such under the medical fee schedule.

Preferred Placement in Statute:

For clarity and uniform application across the workers' compensation chapter, the definition of "compounded prescription drug" should be inserted into HRS §386-1, the general definitions section, rather than scattered elsewhere in the statute.

Closing:

HB2164 is a focused, sensible update that brings Hawai'i's workers' compensation law into alignment with federal standards, decreases unnecessary disputes, and supports timely access to appropriate care for injured workers. On behalf of Hawaii Injury Recovery Center, I respectfully urge the Committee to pass HB2164 without amendments that dilute or change its core purpose.

Thank you for the opportunity to testify.

Brandon Shirai, MD

**HB-2164**
Submitted on: 2/16/2026 3:39:41 PM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Kathleen Plack | Kathy Plack Medical Billing | Support | Written Testimony Only |

Comments:

Hearing Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Location: Conference Room 309
Testimony of Kathy Plack In Strong Support of HB 2164
Dear Chair Sayama, Vice Chair Lee, and Members of the Labor and Technology Committee,
My name is Kathy Plack, and I am a billing professional who manages workers' compensation pharmacy and medical billing
on behalf of multiple providers caring for Hawai'i's injured workers. I am submitting this testimony in strong support of HB
2164.
In the last 2 years, I have seen how outdated statutory language around compounded prescription drugs has been deliberately
misused by IMS/Solera to deny, delay and even greatly reduce payment on valid claims, particularly for 503B medications that are clearly defined and priced under federal law. These denials have forced my business into 100's of repeated disputes at DLIR and has created a bottleneck of unpaid bills and bills stuck in the overwhelmed DLIR dispute process, even in situations where DLIR has already ruled against IMS/Solera's arguments and ordered reimbursement. All of this has forced my provider to change how she could best treat the patient and get them back to work faster for two years now, while adding a ton of paperwork for both us and awaiting the DLIR to decide whether or not these medications which are topical, direct to the area injured without affecting the rest of the body and brain.
Why HB 2164 Is Critical From a Billing Perspective
HB 2164 updates Hawai'i's workers' compensation law by adopting the federal definition of "compounded prescription drug"
under 21 U.S.C. 353, Section 503A. This clarification is essential for those of us who actually process and submit claims,
because it:
• Clearly distinguishes 503A traditional compounds (no NDC/AWP, billed by ingredients) from 503B outsourcing-facility
products (with their own NDC and AWP, billed like other manufactured drugs).
• Aligns state law with DLIR's long-standing position that when a compounded or 503B medication has its own NDC
and AWP, reimbursement should be based on that code under the medical fee schedule.
• Removes the ambiguity that bill review companies currently exploit to deny payment as a business strategy rather

than a legitimate legal or clinical disagreement.
In my daily work, the pattern is consistent: claims for properly dispensed 503B medications are submitted with the
appropriate NDC and AWP, IMS/Solera denies or reduces them by wrongly treating them as 503A compounds, DLIR rules in
favor of the provider, and yet the same denials continue on future claims using the same rejected rationale. HB 2164 is
necessary to stop this cycle.
Impact of IMS/Solera's Practices on DLIR and Providers
Because IMS/Solera continues to blur the line between 503A and 503B despite clear federal standards and DLIR rulings, I
have been forced to file numerous disputes on behalf of multiple physicians and pharmacies just to secure payment that
should have been made in the first place. This has several consequences:
- DLIR is inundated with repetitive disputes on the same legal issue, tying up staff time and delaying resolution of other
matters.
- Providers experience significant cash-flow strain due to months or years of unpaid bills, even though the medications
were dispensed correctly and in good faith.
- Injured workers face delays and uncertainty around access to appropriate, often non-opioid, therapies when vendors
fight payment rather than follow established standards.

From a billing standpoint, this is not a documentation problem or a coding error; it is a deliberate use of outdated statutory
language to justify nonpayment on claims that fully comply with federal law and DLIR guidance.
Concerns With Opponent Amendments
As someone who sees the financial and operational effects on multiple practices, I am especially concerned about
amendments proposed by Solera/IMS and PBM-aligned entities, including:

- Limiting physician dispensing to 30 days and forcing prescriptions through PBMs thereafter, which shifts control and
revenue to PBMs and their vendors rather than improving efficiency or reducing true system costs.
- Misusing the definition of "compounded prescription drug" to sweep in 503B products, contradicting federal law and
reviving the very ambiguity that generates disputes today.
- Adding extra, compound-specific paperwork and justification requirements, which will only increase delays, denials,
and disputes without any benefit to patient care.

These amendments do not solve problems; they preserve and expand a business model in which revenue is generated by
denying legitimate claims and pushing prescriptions into PBM channels.
Recommended Placement in Statute

I support placing the updated definition of “compounded prescription drug” in HRS 386-1, the general definitions section, to
ensure consistent application across all workers’ compensation provisions and to give clear guidance to billers, payers, and
DLIR alike.
Request
On behalf of the many providers whose bills I manage, and the injured workers whose care those bills represent, I
respectfully urge the Committee to:
- Pass HB 2164 as a clean bill, aligning Hawai‘i law with federal 503A/503B standards and DLIR’s existing
reimbursement approach.
- Reject amendments from IMS/Solera or PBM-aligned interests that would limit physician dispensing, force
prescriptions into PBM control, or reintroduce ambiguity around 503A vs. 503B definitions.

Thank you for the opportunity to testify and for your efforts to protect both Hawai‘i’s injured workers and the providers who
care for them.
With aloha,
Kathleen "Kathy" Plack

**HB-2164**
Submitted on: 2/16/2026 4:53:09 PM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Scott Morioka | Hawaii Injury Recovery Center, Inc. | Support | Written Testimony Only |

Comments:

**Hearing Date:** Tuesday, February 17, 2026
**Time:** 9:00 a.m.
**Location:** Conference Room 309

**To:** Chair Sayama, Vice Chair Lee, and Members of the Committee on Labor and Technology

**Re: Support for HB2164**

Aloha Chair Sayama, Vice Chair Lee, and Members of the Committee. My name is **Scott Morioka, MD**, and on behalf of myself and the providers at **Hawaii Injury Recovery Center, we are in strong support of HB2164.**

Our teams care for injured workers across the state, and we see every day how outdated statutory language around compounded medications leads to unnecessary disputes, delayed treatment, and inconsistent reimbursement. HB2164 simply brings Hawai‘i’s law up to date with the federal definitions that distinguish 503A traditional compounding from 503B FDA-regulated outsourcing facilities.

This clarification aligns our statute with DLIR’s long-standing interpretation, reduces administrative conflict, and protects access to appropriate, often non-opioid, therapies.

I respectfully urge you to pass HB2164 as a clean bill and reject amendments that would limit physician dispensing, impose new documentation burdens, or blur the federal distinction between 503A and 503B products.

Mahalo for the opportunity to testify.

NUBRATORI RX

February 17, 2026
To: The Honorable Jackson D. Sayama, Chair,
The Honorable Mike Lee, Vice Chair, and
Members of the House Committee on Labor
Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Place: Conference Room 309, State Capitol
From: Robert P Nickell, CEO Nubratori INC.

**Re: H.B. 2164 RELATING TO WORKERS' COMPENSATION DEFINITION OF A COMPOUNDED DRUG**

Dear Chairs,

My name is Robert Nickell, and I am practicing pharmacist for over 40 years, I have been compounding medications for the same time frame, and I taught pharmacy compounding at USC school of pharmacy for ten years. I am currently the CEO of Nubratori RX, a FDA Registered Outsource Facility . Nubratori produces finished drug products, also referred to as manufactured compounds, which are sold all over the USA, including Hawaii, to hospitals, pharmacies and healthcare providers, as well as, VA Hospitals for administration or dispensing directly to the patient, whenever there is a clinical need as determined by the provider. These drugs go through high level rigorous testing to ensure they meet the requirements of the FDA to be on the market. They are produced in bulk just like any other pharmaceutical firm to ensure quality and standards are met.

There seems to be some confusion being introduced as to the difference between a 503A Traditional Compounding Pharmacy and a 503B FDA Registered Outsource Facility.

NUBRATORI RX

I think everyone understands the Traditional Compounding Pharmacy, the type my father operated in his corner drugstore. This was commonly a patient specific prescription, written by a doctor for a patient with an identified clinical need.

503B Registered Outsource Facilities came about as an Act of Congress because a compounding pharmacy in New England area was producing injections that were not sterile. The first 503B Outsource Facilities started up in late 2014, after the approval of HRS386-21.7, stating how a compounded drug is to be reimbursed under Hawaii Law.

It is extremely costly, and time consuming to build and open an Outsource Facility. The facility is inspected annually by the FDA. The facility must follow FDA Good Manufacturing Practice, commonly referred as GMP. These are the same standards that all pharmaceutical manufacturing entities are required to follow. Outsource Facility Drugs or OSF Drug Products are listed in Redbook as a manufacturer, they are assigned a labeler code by the FDA as a manufacturer, and OSF Drug Products are legally in the marketplace just like any other pharmaceutical company. OSF Drug Products are RX ONLY, and not OTC. Yes, OSF Drug Products are referred to as compounds, however, the difference is they are manufactured compounds as opposed to traditional compounds.

OSF Facilities are the only pharmaceutical companies allowed to step in and manufacturer other drug pharmaceutical products as copies when there is a drug shortage as determined by the FDA. OSF Facilities service hospitals, pharmacies and healthcare providers who determine there is a clinical need for their patient.

NUBRATORI RX

This bill was written to clarify what is a compounded drug in the Hawaii regulations for definitions.

*"A compounded drug is a drug compounded in a pharmacy or physician office for a specific patient. This captures the spirit of traditional compounding."*

The opponents of the bill are trying to bring in or exclude, all types of compounding whether known today or created in the future including 503B Outsource Facility Drug Products. This just does not make sense.

Manufactured compounded drugs or 503B FDA registered outsource drug products are found in Redbook and are not traditional compounded drugs.

A traditional compounded drug product will never be found in Redbook, which is why it was carved out specifically in HRS386-21.7(c).

Conversely, a manufactured compound is not formulated with underlying prescription drugs, as referenced in section (c.)

Finally, as to the discussion of "approved drugs" vs "unapproved drugs". This should not even be an issue. Any drug used off label is unapproved, grandfathered drugs are unapproved, home infusion bags in hospitals are unapproved, and finally OSF Drugs or manufactured compounds are EXEMPT from the approval process statutorily by the FDA.

I am against any amendment on this subject, however, if you wanted to amend, it should be "drugs prohibited by the FDA" should be disallowed, not "unapproved drugs by the FDA".

Respectfully submitted with Aloha

Robert P Nickell, Pharmacist

CEO Nubratori RX

**HB-2164**
Submitted on: 2/17/2026 8:42:31 AM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Marshall Orr, Jr. | Marshall H Orr Jr MS MPT LLC | Support | Written Testimony Only |

Comments:

Hearing Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Location: Conference Room 309

To: Chair Sayama, Vice Chair Lee, and Members of the Committee on Labor and Technology

Re: Support for HB2164

My name is Marshall H Orr Jr DPT, who has treated injured workers in Hawai‘i for many years. I am writing in strong support of HB2164.

HB2164 is a necessary update to Hawai‘i’s workers’compensation law. It aligns our statute with the federal definition of a “compounded prescription drug” under 21 U.S.C. §353 (Section 503A) and clarifies the difference between traditional 503A compounds and FDAregulated 503B products. This clarity is important because outdated language has been used by some bill review companies to deny or delay proper reimbursement—even when DLIR has already ruled that payment is required.

This bill does not change how medications are prescribed or dispensed. It simply codifies the reimbursement approach DLIR already follows when a compounded or 503B medication has its own NDC and AWP. Clear definitions will reduce unnecessary disputes and help ensure injured workers receive timely access to appropriate, often nonopioid, treatments.

I also urge the Committee to reject amendments that would limit physician dispensing, force prescriptions through PBMs, or broaden the definition of “compounded prescription drug” in ways that conflict with federal law. These proposals would undermine patient care, delay treatment, and shift control to entities whose business model profits from denials rather than recovery.

For these reasons, I respectfully ask you to pass HB2164 as a clean bill.

Thank you for the opportunity to testify.

**HB-2164**
Submitted on: 2/16/2026 11:06:41 AM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Matt Matsunaga | Individual | Support | In Person |

Comments:

February 16, 2026

To: Rep. Jackson D. Sayama, Chair

Rep. Mike Lee, Vice Chair

Members of the Committee on Labor

Date: Tuesday, February 17, 2026

Time: 9:00 a.m.

Place: Conference Room 309

Support for HB2164

I am an attorney and former State Senator who assisted then Sen. Hee and the late Rep. Nakashima in 2014 in crafting the existing law on prescription drug pricing for workers' compensation patients. That law now needs updating and clarification. I strongly support HB2164, which defines "compounded prescription drug" by incorporating federal standards for pharmacy compounding under 21 U.S.C. section 353 (section 503A of the FD&C Act) and related federal guidance. By aligning state law with these federal definitions, the bill clarifies what counts as a compounded prescription drug in workers' compensation, supports safe and appropriate use of compounded medications, and confirms how such drugs should be reimbursed under DLIR's workers' compensation framework.

This bill is needed for the following reasons:

1. State law background and gap

Hawaii's workers' compensation law was drafted when pharmacy compounding was understood mainly as traditional, patient-specific compounding in a pharmacy or physician's office under older federal language. Since then, federal law has clarified standards for compounded drugs under section 503A of the Federal Food, Drug, and Cosmetic Act, but Hawaii's workers' compensation statute has not yet been updated to fully align with those definitions.

2. Newer compounded medications and reimbursement confusion

In the last decade, additional types of compounded medications have become available, some produced at larger scale and assigned their own National Drug Code (NDC) and Average Wholesale Price (AWP). These products differ from traditional 503A type compounds that are custom prepared for a specific patient and typically do not carry their own NDC and AWP, which has led to confusion among employers and payers about which NDC and AWP to use for reimbursement.

3. DLIR practice and need for clarity

DLIR has determined that when a compounded medication has its own NDC and AWP, reimbursement in workers' compensation should be based on that specific NDC and AWP, consistent with how other drug products are treated under the medical fee schedule. Codifying this approach in statute will improve transparency and consistency for employers, insurers, pharmacies, and injured workers.

I would suggest, however, that these Committees amend this bill by adding the definition of "compounded prescription drug" in HRS 386-1 (and not HRS 386-21.7), which contains the definitions for Chapter 386. That is a more appropriate section to include this new definition.

More importantly, however, please do not allow opponents of this bill to add "poison pill" amendments that would dilute, undermine, or fundamentally alter the intent of this bill. This bill was crafted to address a clear policy need – the clarification of the statutory definition of a "compounded prescription drug" for workers' compensation purposes. Amendments designed not to improve the bill, but to quietly vitiate it, run counter to the main goal of the workers' compensation system, which is to help injured workers recover and return to work. In particular, opponents have proposed the following amendments:

1. Limiting the dispensing of prescription drugs by physicians to thirty days following the industrial injury and requiring all prescription drugs to be obtained through the employer's pharmacy benefit manager (PBM) thereafter

This would be a fatal blow to physician dispensing and weaken a physician's ability to monitor a patient's compliance with medical advice and ultimately to treat the patient. In addition, you would simply enhance the profits of a PBM, which is the subject of a recent Hawaii Attorney General lawsuit against the three dominant PBMs, alleging price inflation, rebate manipulation, and anti competitive practices in the prescription drug market. Under Hawaii law, the employer has a legal obligation to furnish to the employee all prescription drugs as the nature of the injury requires. The treating physician is far more qualified than a PBM to decide what prescription drugs are required to treat the patient. Further, this is certainly not the proper vehicle to address physician dispensing vs. PBMs.

2. Requiring non-FDA-approved prescription drugs, such as compounds, to be identified as compounds when listed on the treatment plan and when billed, and be supported by a statement of medical necessity documenting the case of medical need for a compound drug over an FDA-approved over-the-counter or prescription drug of similar therapeutic effect

This is another ill-fated attempt to weaken a physician's authority to treat a patient, founded in an uninformed belief that a physician's medical opinion regarding a non-FDA-approved prescription drug should be second-guessed. Whenever a physician prescribes a medication, compound or not, they have made a diagnosis, and made the determination of medical necessity. We should not allow a PBM or claims adjuster to make that decision for the physician. Existing law permits a physician to prescribe a non-FDA-approved prescription drug without this added layer of scrutiny or bureaucracy. Adding this layer will only interfere with and potentially delay the injured worker's timely recovery and disincentivize physicians to treat injured workers.

3. Changing the definition of "compound prescription drug" to be "a drug product that is compounded in a compounding facility in compliance with section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) or any other type of similar compounding facility approved by the Federal Drug Administration";

This revised definition of a "compound prescription drug" overly broadens the definition to include "any other type of similar compounding facility approved by the Federal Drug Administration," which would destroy the intent of the bill to align state law with federal law. This amendment would include drugs manufactured in a 503B Outsourcing Facility, which are manufactured under strict FDA oversight, have their own NDC, and (unlike 503A drugs) are assigned an AWP. This defeats the precise need for this bill – that unscrupulous bill review

companies are exploiting an ambiguity in current law and treating dedicated physicians as outlaws and villains who are exploiting physician dispensing for profit rather than caring for their patient. In theory, the distinction between 503A and 503B drugs is clear under federal law. In practice, some bill reviewers routinely blur that line to delay or avoid proper payment—even after DLIR has definitively ruled against them in formal disputes. Please put an end to this ambiguity and bring needed clarity to state law.

Sincerely,

Matthew M. Matsunaga

To whom it may concern,

As a physician treating injured workers, I am writing to express my strong support for HB2164 in its original form. This bill provides essential clarity by aligning Hawaii's definitions with federal standards, ensuring that reimbursement for compounded medications is transparent and consistent.

However, I am deeply concerned by the "poison pill" amendments introduced by Pharmacy Benefit Managers (PBMs). These amendments serve only to create confusion and obstruct direct patient care. I urge you to reject these changes for the following reasons:

- **Protecting the Physician-Patient Relationship:** Restricting physician dispensing to only 30 days and forcing patients into PBM-controlled networks interferes with my ability to monitor compliance and adjust treatment in real-time. A PBM is not a substitute for a treating physician. I have personally tried to use PBMs. The result has been 90 percent failure, with patients not being able to get their medications at all due to refusal of outside pharmacies to accept the workers' compensation insurance or pharmacies' inability to confirm the approval from the adjuster due to lack of response from the adjusters. Plus, it is a well-known fact that physician dispensing significantly increases patient compliance, and results in improved clinical outcomes.
- **Preventing Administrative Collapse:** We are already facing a shortage of providers willing to treat injured workers. Adding layers of "medical necessity" statements for compounds, which are already prescribed based on clinical judgment, imposes an undue administrative burden that delays recovery.
- **Avoiding "Penny Wise, Pound Foolish" Outcomes:** By allowing PBMs to delay or deny necessary medications, the system will see an increase in untreated patients and longer "lost time" from work. While carriers may seek to save pennies on drug costs, they will ultimately pay pounds in increased indemnity claims and permanent disability costs.
- **Restoring Federal Alignment:** The proposed changes to the definition of "compounded prescription drug" deliberately blur the line between 503A and 503B facilities. This ambiguity allows bill review companies to ignore DLIR rulings and delay proper payment, further disincentivizing physicians from participating in the workers' compensation system.

The goal of this system is to help injured workers recover and return to the workforce. These amendments do the opposite, they prioritize PBM profits over patient health.

Please pass HB2164 as originally intended and remove the negative amendments noted.

Thank you for your time and for supporting Hawaii's physicians and injured workers.

Sincerely,

Mankwan Wong MD

**HB-2164**
Submitted on: 2/17/2026 8:40:27 AM
Testimony for LAB on 2/17/2026 9:00:00 AM

| Submitted By | Organization | Testifier Position | Testify |
|---|---|---|---|
| Carol Ann Orr MD | Carol Ann Orr MD LLV | Support | Written Testimony Only |

Comments:

Hearing Date: Tuesday, February 17, 2026
Time: 9:00 a.m.
Location: Conference Room 309

To: Chair Sayama, Vice Chair Lee, and Members of the Committee on Labor and Technology

Re: Support for HB2164

My name is Carol Orr MD, who has treated injured workers in Hawai‘i for many years. I am writing in strong support of HB2164.

HB2164 is a necessary update to Hawai‘i’s workers’compensation law. It aligns our statute with the federal definition of a “compounded prescription drug” under 21 U.S.C. §353 (Section 503A) and clarifies the difference between traditional 503A compounds and FDAregulated 503B products. This clarity is important because outdated language has been used by some bill review companies to deny or delay proper reimbursement—even when DLIR has already ruled that payment is required.

This bill does not change how medications are prescribed or dispensed. It simply codifies the reimbursement approach DLIR already follows when a compounded or 503B medication has its own NDC and AWP. Clear definitions will reduce unnecessary disputes and help ensure injured workers receive timely access to appropriate, often nonopioid, treatments.

I also urge the Committee to reject amendments that would limit physician dispensing, force prescriptions through PBMs, or broaden the definition of “compounded prescription drug” in ways that conflict with federal law. These proposals would undermine patient care, delay treatment, and shift control to entities whose business model profits from denials rather than recovery.

For these reasons, I respectfully ask you to pass HB2164 as a clean bill.

Thank you for the opportunity to testify.