
A BILL FOR AN ACT

RELATING TO WORKERS' COMPENSATION.

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

1 SECTION 1. The legislature finds that workers'
2 compensation costs and transparency are critical to maintaining
3 fair and predictable benefits for injured workers while
4 controlling employer expenses. The legislature further finds
5 that compounded prescription drugs can provide essential
6 therapeutic options for injured workers when commercially
7 available Food and Drug Administration (FDA)-approved
8 medications are unsuitable due to allergies, dosage
9 requirements, or other clinical needs. However, inconsistent
10 definitions have led to confusion. Federal law under section
11 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 353a) establishes clear standards for pharmacy compounding,
13 including patient specific prescriptions, quality requirements
14 for bulk substances, and exclusions for simple reconstitution.
15 Aligning state law with these standards will promote patient
16 safety by ensuring compounded drugs meet recognized quality



1 benchmarks and enhance regulatory consistency between state and
2 federal oversight.

3 Accordingly, the purpose of this Act is to ensure that
4 injured workers in the State receive appropriate, individualized
5 medical care that is necessary and reasonable for the specific
6 injury by:

- 7 (1) Defining "compounded prescription drug" in the State's
8 Workers' Compensation Law that references section 503A
9 of the Federal Food, Drug, and Cosmetic Act;
- 10 (2) Limiting the dispensing of prescription drugs by
11 physicians to thirty days following the industrial
12 injury and requiring all prescription drugs to be
13 obtained through the employer's pharmacy benefit
14 manager thereafter; and
- 15 (3) Requiring prescription drugs not approved by the Food
16 and Drug Administration, such as compounds, to be
17 identified as compounds when listed on the treatment
18 plan and when billed, and be supported by a statement
19 of medical necessity documenting the case of medical
20 need for a compound drug over an over-the-counter or



1 prescription drug of similar therapeutic effect that
2 is approved by the Food and Drug Administration.

3 SECTION 2. Section 386-21.7, Hawaii Revised Statutes, is
4 amended to read as follows:

5 **"§386-21.7 Prescription drugs; pharmaceuticals. (a)**

6 Notwithstanding any other provision to the contrary, immediately
7 after a work injury is sustained by an employee and so long as
8 reasonably needed, the employer shall furnish to the employee
9 all prescription drugs as the nature of the injury requires;
10 provided that initial concurrent prescriptions for opioids and
11 benzodiazepines shall meet the requirements of section 386-29.
12 The liability for the prescription drugs shall be subject to the
13 deductible under section 386-100.

14 (b) Payment for all forms of prescription drugs including
15 repackaged and relabeled drugs shall be one hundred forty per
16 cent of the average wholesale price set by the original
17 manufacturer of the dispensed prescription drug as identified by
18 its National Drug Code and as published in the Red Book:
19 Pharmacy's Fundamental Reference as of the date of dispensing,
20 except where the employer or carrier, or any entity acting on



1 behalf of the employer or carrier, directly contracts with the
2 provider or the provider's assignee for a lower amount.

3 (c) Payment for compounded prescription drugs shall be the
4 sum of one hundred forty per cent of the average wholesale price
5 by gram weight of each underlying prescription drug contained in
6 the compounded prescription drug. For compounded prescription
7 drugs, the average wholesale price shall be that set by the
8 original manufacturer of the underlying prescription drug as
9 identified by its National Drug Code and as published in the Red
10 Book: Pharmacy's Fundamental Reference as of the date of
11 compounding, except where the employer or carrier, or any entity
12 acting on behalf of the employer or carrier, directly contracts
13 with the provider or provider's assignee for a lower amount.

14 (d) All pharmaceutical claims submitted for repackaged,
15 relabeled, or compounded prescription drugs shall include the
16 National Drug Code of the original manufacturer. If the
17 original manufacturer of the underlying drug product used in
18 repackaged, relabeled, or compounded prescription drugs is not
19 provided or is unknown, then reimbursement shall be one hundred
20 forty per cent of the average wholesale price for the original
21 manufacturer's National Drug Code number as listed in the Red



1 Book: Pharmacy's Fundamental Reference of the prescription drug
2 that is most closely related to the underlying drug product.

3 (e) Notwithstanding any other provision in this section to
4 the contrary, equivalent generic drug products shall be
5 substituted for brand name pharmaceuticals unless the
6 prescribing physician certifies that no substitution shall be
7 prescribed because the injured employee's condition does not
8 tolerate an equivalent generic drug product.

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

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



1 [~~f~~] (h) For purposes of this section [~~,"equivalent"]:~~

2 "Compounded prescription drug" means a drug product that is
3 compounded in a compounding facility in compliance with 503A of
4 the Food, Drug, and Cosmetic Act (21 U.S.C. 353a), or any other
5 type of similar compounding facility approved by the Food and
6 Drug Administration.

7 "Equivalent generic drug product" has the same meaning as
8 provided in section 328-91."

9 SECTION 3. This Act does not affect rights and duties that
10 matured, penalties that were incurred, and proceedings that were
11 begun before its effective date.

12 SECTION 4. Statutory material to be repealed is bracketed
13 and stricken. New statutory material is underscored.

14 SECTION 5. This Act shall take effect on January 1, 2077.

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Report Title:

Workers' Compensation; Benefits; Prescription Drugs; Compounded Prescription Drugs; Physician Dispensing Timeframe; Non-FDA-Approved Drugs; Identification; Statement of Medical Necessity

Description:

Defines compounded prescription drugs for the purposes of the State's Workers' Compensation Law. Limits dispensing of prescription drugs by physician to 30 days after the industrial injury and requires all prescription drugs to be obtained through the employer's pharmacy benefit manager thereafter. Requires prescription drugs not approved by the Food and Drug Administration (FDA), 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. Effective 1/1/2077. (SD1)

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