
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 FDA approved medications are unsuitable due to
8 allergies, dosage requirements, or other clinical needs.
9 However, inconsistent definitions have led to confusion.
10 Federal law under section 503A of the Federal Food, Drug, and
11 Cosmetic Act (21 U.S.C. 353a) establishes clear standards for
12 pharmacy compounding, including patient specific prescriptions,
13 quality requirements for bulk substances, and exclusions for
14 simple reconstitution. Aligning state law with these standards
15 will promote patient safety by ensuring compounded drugs meet
16 recognized quality benchmarks, enhance regulatory consistency
17 between state and federal oversight.



1 Accordingly, the purpose of this Act is to align state law
2 with federal standards for pharmacy compounding by codifying the
3 federal definition of a "compounded prescription drug", thereby
4 promoting regulatory consistency, supporting patient safety, and
5 ensuring access to individualized medications when an FDA
6 approved drug is not medically appropriate for a particular
7 patient. This Act incorporates by reference section 503A of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) and
9 clarifying federal guidance.

10 SECTION 2. Section 386-21.7, Hawaii Revised Statutes, is
11 amended by amending subsection (f) to read as follows:

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

13 "Compounded prescription drug" means a drug product that is
14 compounded by a licensed pharmacist in a state licensed pharmacy
15 for an identified individual patient based on the receipt of a
16 valid prescription order or a notation, approved by the
17 prescribing practitioner, on the prescription order that a
18 compounded product is necessary for the identified patient, and
19 otherwise meets the requirements of title 21 United States Code
20 section 353a.



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

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

6 SECTION 4. Statutory material to be repealed is bracketed
7 and stricken. New statutory material is underscored.

8 SECTION 5. This Act shall take effect on July 1, 3000.



Report Title:

Workers' Compensation; Benefits; Compounded Prescription Drugs

Description:

Defines compounded prescription drugs for the purposes of workers' compensation law. Effective 7/1/3000. (HD1)

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