
A BILL FOR AN ACT

RELATING TO THE UNIFORM CONTROLLED SUBSTANCES ACT.

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

1 SECTION 1. The legislature finds that recent updates to
2 the Federal Controlled Substances Act require state action in
3 order to be in conformance.

4 The legislature further finds that, on August 28, 2020, the
5 department of public safety received notice via publication in
6 the Federal Register of an interim final order that the
7 following substance was deleted from Schedule V of the federal
8 schedule of controlled substances, 21 C.F.R. § 1308.15, by the
9 United States Drug Enforcement Administration (DEA): "Drug
10 products in finished dosage formulations that have been approved
11 by FDA and that contain cannabidiol (CBD) derived from cannabis
12 and no more than 0.1 per cent (w/w) residual
13 tetrahydrocannabinols."

14 The legislature additionally finds that this federal
15 scheduling action removes the regulatory controls and the
16 administrative, civil, and criminal sanctions applicable to



1 federal schedule V controlled substances on persons who handle
2 or propose to handle the drug products listed above.

3 For clarity purposes, this Act specifically applies to the
4 FDA-approved prescription drug Epidiolex and any generic
5 versions of that drug that are FDA-approved and contain CBD
6 derived from cannabis and no more than 0.1 per cent (w/w)
7 residual tetrahydrocannabinols only.

8 The legislature also finds that Epidiolex was approved by
9 the FDA on June 25, 2018, for the treatment of seizures
10 associated with Lennox-Gastaux syndrome (LGS) and Dravet
11 syndrome, two rare and difficult-to-treat forms of childhood-
12 onset epilepsy, in patients two years of age or older.
13 Epidiolex's effectiveness was studied in three randomized,
14 double-blind, placebo-controlled clinical trials involving five
15 hundred sixteen patients with either LGS or Dravet. Epidiolex,
16 taken along with other medications, was shown to be effective in
17 reducing the frequency of seizures when compared with placebo.
18 On July 31, 2020, the FDA approved Epidiolex for a new
19 indication – the treatment of seizures associated with tuberous
20 sclerosis complex, a rare genetic disease, in patients one year



1 of age and older. Epidiolex is the only FDA-approved drug that
2 contains a purified drug substance derived from cannabis.

3 This Act should not be construed to change the legal status
4 of cannabis, marijuana, tetrahydrocannabinols, and other
5 marijuana related constituents, except for the narrow
6 application to the "approved cannabidiol drugs" listed in the
7 notice. Furthermore, unless further notice is given, the
8 controls under federal and state law pertaining to prescription
9 drugs continue to apply to Epidiolex and any generic versions of
10 that drug that are FDA approved and contain CBD derived from
11 cannabis and no more than 0.1 per cent residual
12 tetrahydrocannabinols.

13 The purpose of this Act is to update state statute to make
14 it consistent with amendments in the federal controlled
15 substances law as required under section 329-11, Hawaii Revised
16 Statutes.

17 SECTION 2. Section 329-22, Hawaii Revised Statutes, is
18 amended to read as follows:

19 "§329-22 Schedule V. (a) The controlled substances
20 listed in this section are included in schedule V.



1 (b) Narcotic drugs containing nonnarcotic active medicinal
2 ingredients. Any compound, mixture, or preparation containing
3 limited quantities of any of the following narcotic drugs, which
4 also contains one or more nonnarcotic active medicinal ingredients
5 in sufficient proportion to confer upon the compound, mixture, or
6 preparation, valuable medicinal qualities other than those
7 possessed by the narcotic drug alone:

8 (1) Not more than 200 milligrams of codeine, or any of its
9 salts, per 100 milliliters or per 100 grams;

10 (2) Not more than 100 milligrams of dihydrocodeine, or any
11 of its salts, per 100 milliliters or per 100 grams;

12 (3) Not more than 100 milligrams of ethylmorphine, or any of
13 its salts, per 100 milliliters or per 100 grams;

14 (4) Not more than 2.5 milligrams of diphenoxylate and not
15 less than 25 micrograms of atropine sulfate per dosage
16 unit;

17 (5) Not more than 100 milligrams of opium per 100
18 milliliters or per 100 grams; and

19 (6) Not more than 0.5 milligram of difenoxin and not less
20 than 25 micrograms of atropine sulfate per dosage unit.



1 (c) Stimulants. Unless specifically exempted or excluded
2 or unless listed in another schedule, any material, compound,
3 mixture, or preparation that contains any quantity of the
4 following substances having a stimulant effect on the central
5 nervous system, including its salts, isomers, and salts of
6 isomers.

7 (d) Depressants. Unless specifically exempted or excluded
8 or unless listed in another schedule, any material, compound,
9 mixture, or preparation that contains any quantity of the
10 following substances having a depressant effect on the central
11 nervous system, including its salts, isomers, and salts of
12 isomers:

13 (1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-
14 propionamide], (Vimpat);

15 (2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic
16 acid]; and

17 (3) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-
18 yl]butanamide) (Other names: BRV; UCB-34714; Briviact)
19 and its salts.

20 ~~[(e) Approved cannabidiol drugs. A drug product in~~
21 ~~finished dosage formulation that has been approved by the United~~



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1 ~~States Food and Drug Administration that contains cannabidiol~~
2 ~~(2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-~~
3 ~~pentyl-1,3-benzenediol) derived from cannabis and no more than~~
4 ~~0.1 per cent (w/w) residual tetrahydrocannabinols.] "~~

5 SECTION 3. Statutory material to be repealed is bracketed
6 and stricken. New statutory material is underscored.

7 SECTION 4. This Act shall take effect upon its approval.

8

INTRODUCED BY:

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JAN 22 2021



H.B. NO. 542

Report Title:

Uniform Controlled Substances Act; Schedule V

Description:

Removes cannabidiol drugs that have been approved by the United States Food and Drug Administration from the list of Schedule V substances for consistency with federal laws.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

