SB190

Measure Title: RELATING TO THE CONTROLLED SUBSTANCES ACT.

Report Title: Controlled Substances Act; Prescriptions; Detoxification Treatment;

Maintenance Treatment

Amends Hawaii's controlled substances act to mirror federal regulations, which permit qualified practitioners to administer, dispense, and prescribe any schedule III, IV, or V narcotic drug

Description: approved by the Food and Drug Administration for use as a

detoxification treatment or maintenance treatment; provided the

practitioner complies with specific federal requirements.

Companion:

Package: None

Current Referral: CPH/PSM, JDL

Introducer(s): GREEN, BAKER, KEITH-AGARAN



STATE OF HAWAII DEPARTMENT OF PUBLIC SAFETY

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TESTIMONY ON SENATE BILL 190 RELATING TO THE CONTROLLED SUBSTANCES ACT

by
Nolan P. Espinda, Director
Department of Public Safety

Senate Committee on Commerce, Consumer Protection, and Health Senator Rosalyn H. Baker, Chair Senator Clarence K. Nishihara, Vice Chair

Senate Committee on Public Safety, Intergovernmental, and Military Affairs Senator Clarence K. Nishihara, Chair Senator Glenn Wakai, Vice Chair

Thursday, February 9, 2017; 1:15 p.m. State Capitol, Conference Room 229

Chairs Nishihara and Baker, Vice Chair Wakai, and Members of the Committees:

The Department of Public Safety (PSD) **supports** Senate Bill (SB) 190, which proposes to amend Hawaii's controlled substances act to clarify the state law and mirror federal regulations which permit qualified practitioners to administer, dispense, and prescribe controlled substances for use as detoxification treatment or maintenance treatment, provided the practitioner complies with specific federal requirements. PSD, however, offers the following comments.

First, PSD respectfully refers the Committees to SB 998 which further clarifies that a prescription may not be issued for detoxification treatment or maintenance treatment unless the practitioner complies with Title 21 of the Code of Federal Regulations section 1301.28, the registration and any requirements of section 329-32(e) of this chapter, and "any other federal or state regulatory standards relating to

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the treatment qualification, security, records, and unsupervised use of drugs." PSD would suggest adopting the wording on page 5, line 1 - 12 of SB 998.

Second, PSD again refers the Committees to SB 998 which would clarify two additional situations. The first allows a physician to treat a person to relieve acute withdrawal symptoms for not more than three days, without renewal or extension. The second clarifies the situation wherein a doctor or authorized hospital staff may administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment in limited situations. Both of these situations are referenced in title 21 Code of Federal Regulations section 1306.07, and included on page 6, lines 3 – 22 of SB 998.

Lastly, again referring to SB 998, we would suggest incorporating the exclusion wording on page 1, lines 10 - 14 for clarification.

Thank you for the opportunity to present this testimony.



ON THE FOLLOWING MEASURE:

S.B. NO. 190, RELATING TO THE CONTROLLED SUBSTANCES ACT.

BEFORE THE:

SENATE COMMITTEES ON COMMERCE, CONSUMER PROTECTION, AND HEALTH AND ON PUBLIC SAFETY, INTERGOVERNMENTAL AND MILITARY AFFAIRS

DATE: Thursday, February 9, 2017 **TIME:** 1:15 p.m.

LOCATION: State Capitol, Room 229

TESTIFIER(S): Douglas S. Chin, Attorney General, or

Laura Maeshiro, Deputy Attorney General

Chairs Baker and Nishihara and Members of the Committees:

The Department of the Attorney General ("Department") appreciates the intent of this measure and offers comments.

This measure serves to clarify that medical practitioners are allowed to prescribe medications such as Suboxone for the treatment of drug addiction by amending chapter 329, Hawaii Revised Statutes (HRS). The resulting amendments make clear that practitioners may prescribe any Schedule III, IV, or V narcotic drug for the purpose of drug addiction maintenance or detoxification treatment. This wording is taken directly from the Code of Federal Regulations at 21 C.F.R. section 1306.07

Buprenorphine is classified as a Schedule III drug pursuant to section 329-18(7), HRS, and is an ingredient of Suboxone.

Another ingredient of Suboxone is naloxone, which is an opioid antagonist that aids to block the effects of opioid medication. Federal laws have expressly excluded naloxone and its derivatives from its Schedule II, even though it is not a controlled substance. See 21 C.F.R. section 1308.12.

For consistency and clarity, in this highly regulated area of prescription medication, we suggest that the exclusion of naloxone and other substances also be provided for, as in the federal counterpart to chapter 329, by adding the following underlined wording to section 329-16(b)(1):

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- (b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:
- (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, <u>excluding apomorphine</u>, <u>thebaine-derived butorphanol, dextrorphan, nalbuphine</u>, <u>nalmefene</u>, <u>naloxegol</u>, <u>naloxone</u>, <u>and naltrexone</u>, <u>and their respective salts</u>, <u>but including the following:</u>

[set forth the rest of subsection (b)]

The Governor has proposed amendments similar to the instant measure, as a part of his administration package in S.B. No. 998. The Governor's proposal includes this naloxone exclusion. S.B. No. 998 also includes other edits for clarity and consistency with the federal law and we respectfully suggest those edits also be adopted by either including them in this measure or passing S.B. No. 998.



SB 190 Administer Detox Medication: Amends Hawaii's controlled substances act to mirror federal regulations, which permit qualified practitioners to administer, dispense, and prescribe any schedule III, IV, or V narcotic drug approved by the Food and Drug Administration for use as a detoxification treatment or maintenance treatment; provided the practitioner complies with specific federal requirements.

SENATE COMMITTEE ON COMMERCE, CONSUMER PROTECTION AND HEALTH

- Senator Rosalyn Baker, Chair; Senator Clarence Nishihara Vice Chair SENATE COMMITTEE ON PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY AFFAIRS:
 - Senator Clarence Nishihara, Chair; Senator Glenn Wakai, Vice Chair
 - Thursday, Feb. 9, 2017: 1:15 p.m.
 - Conference Room 229

HAWAII SUBSTANCE ABUSE COALITION (HSAC) Supports SB190 subject to Recommendations:

GOOD MORNING CHAIRS BAKER, NISHIHARA, VICE CHAIRS NISHIHARA, WAKAI AND DISTINGUISHED COMMITTEE MEMBERS. My name is Alan Johnson. I am the current chair of the Hawaii Substance Abuse Coalition (HSAC), a statewide hui of over 30 non-profit alcohol and drug treatment and prevention agencies.

HSAC supports the American Society of Addiction Medicine (ASAM) that recommends clarifying language to avoid unintended consequences.

- 1. There is no reason to exclude Schedule II medications, given that the modifying wording explicitly qualifies only such medications within those categories (II-V) that have been approved for detoxification. This will cause problems if a misguided enforcer then applies it to methadone, despite methadone prescribing operating under other statutes.
 - Also, the FDA often takes the approach to approve new, effective medications by first classifying it provisionally or even permanently for a time as Schedule II. Including Schedule II, given the existing protective language that it must be FDA approved detoxification medication, makes sense for current and future practices.
- 2. While the word "detoxification" works, the more appropriate and accurate medical term is "medically-managed withdrawal." Detoxification has become widespread in its use to encompass other definitions such as diet powders, herbal remedies, etc.
- 3. Recommended language:

- (3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for the purpose of "medically-managed withdrawal aka detoxification treatment" or "maintenance treatment" except as follows:
 - (C) An individual practitioner may administer or dispense (including prescribe) any schedule II, III, IV, or V narcotic drug approved by the United States Food and Drug Administration specifically for use as a "medically-managed withdrawal aka detoxification treatment" or "maintenance treatment" to a narcotic drugdependent person; provided that the practitioner complies with the requirements of title 21 United States Code section 823(g) and title 21 Code of Federal Regulations section 1301.28;

We appreciate the opportunity to provide testimony and are available for questions.

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DATE: February 8, 2017

TO: Senator Rosalyn Baker

Chair, Committee on Commerce, Consumer Protection, and Health

Senator Clarence Nishihara

Chair, Public Safety, Intergovernmental, and Military Affairs

Submitted Via Capitol Website

RE: S.B. 190 - Relating to The Controlled Substances Act

Hearing Date: Thursday, February 9, 2017 at 1:15 p.m.

Conference Room: 229

Dear Chairs Baker and Nishihara and Members of the Joint Committees:

We submit these comments on behalf of Walgreen Co. ("Walgreens"). Walgreens operates stores at more than 8,200 locations in all 50 states, the District of Columbia and Puerto Rico. In Hawaii, Walgreens now has 20 stores on the islands of Oahu, Maui, and Hawaii.

Walgreens **supports** S.B. 190, which amends Hawaii's controlled substances act to mirror federal regulations, which permit qualified practitioners to administer, dispense, and prescribe any schedule III, IV, or V narcotic drug approved by the Food and Drug Administration for use as a detoxification treatment or maintenance treatment.

Walgreens is committed to comprehensive efforts to combat drug abuse. Last year, Walgreens supported Act 68, Session Laws Hawaii 2016, which created immunity for practitioners, including pharmacists, to prescribe, dispense, distribute or administer opioid antagonists. S.B. 190 furthers that concept and adopts federal law which allows the prescribing or dispensing of other qualified detoxification treatments to be used in the event of an overdose or as a maintenance treatment.

Allowing pharmacists to dispense these detoxification treatments adds an important mechanism to saving lives and help combat drug overdoses in the community.

For the above reasons, Walgreens supports this measure and respectfully requests that it be passed out of Committee for further consideration. Thank you for the opportunity to testify in support of this measure.