
SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair

2017 - 2018 Regular

Bill No: AB 2783 **Hearing Date:** June 12, 2018
Author: O'Donnell
Version: April 11, 2018
Urgency: No **Fiscal:** Yes
Consultant: SJ

Subject: *Controlled Substances: Hydrocodone Combination Products: Schedules*

HISTORY

Source: California Board of Pharmacy

Prior Legislation: SB 482 (Lara), Ch. 708, Stats. 2016
SB 809 (DeSaulnier), Ch. 400, Stats. 2013
SB 360 (DeSaulnier), Ch. 418, Stats. 2011
AB 3042 (Takasugi), Ch. 738, Stats. 1996

Support: Unknown

Opposition: California Attorneys for Criminal Justice

Assembly Floor Vote: 73 - 0

PURPOSE

The purpose of this bill is to reschedule specified hydrocodone combination products from Schedule III to Schedule II controlled substances.

Existing law classifies controlled substances in five schedules according to their danger and potential for abuse. Schedule I includes the most serious and heavily controlled substances; Schedule V includes the most lightly controlled substances. (Health & Saf. Code, §§ 11054-11058.)

Existing law provides that, except as specified, the term “controlled substance analog” means either of the following:

- A substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance classified in Section 11054 or 11055 or a synthetic cannabinoid compound defined in Section 11357.5.
- A substance that has, is represented as having, or is intended to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to, or greater than, the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance classified in Section 11054 or 11055 or a synthetic cannabinoid compound defined in Section 11357.5. (Health & Saf. Code, § 11401, subd. (b).)

Existing law establishes the Controlled Substances Utilization Review and Evaluation System (CURES) within the Department of Justice (DOJ) for electronic monitoring of Schedule II, III and IV controlled substance prescriptions. (Health & Saf. Code, § 11165, subd. (a).)

Existing law requires a pharmacy or clinic, in filling a controlled substance prescription, to provide specified information to the DOJ. (Health & Saf. Code, § 11165, subd. (d).)

Existing law requires health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient, with specified exemptions. (Health & Saf. Code, § 11165.4.)

Existing law requires health practitioners who prescribe or administer a controlled substance classified in Schedule II to make a record containing the name and address of the patient, date, and the character, name, strength, and quantity of the controlled substance prescribed, as well as the pathology and purpose for which the controlled substance was administered or prescribed. (Health & Saf. Code, § 11190, subds. (a) & (b).)

Existing law requires authorized prescribers who dispense Schedule II, III or IV controlled substance in their office or place of practice to record and maintain information for three years for each such prescription that includes the patient's name, address, gender, and date of birth, prescriber's license and license number, federal controlled substance registration number, state medical license number, National Drug Code number of the controlled substance dispensed, quantity dispensed, diagnosis code and original date of dispensing. Requires this information to be provided to the DOJ on a monthly basis. (Health & Saf. Code, §§ 11190, subd. (c) and 11191.)

Existing law provides that no prescription for a Schedule II substance may be refilled. (Health & Saf. Code, § 11200, subd. (c).)

Existing law provides that no prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply. (Health & Saf. Code, § 11200, subd. (c).)

Existing law provides that a prescription for a controlled substance, except those appearing in Schedule II, may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might present an immediate hazard to the patient's health and welfare or might result in intense suffering. (Health & Saf. Code, § 11201.)

This bill reschedules hydrocodone combination products (HCPs) from a Schedule III controlled substance to a Schedule II controlled substance.

COMMENTS

1. Need for This Bill

According to the author:

The California Uniform Controlled Substances Act (Health and Safety Code (HSC) Sec. 11000 et seq.) is the state drug policy on acquiring, maintaining, storing, using and disposing of controlled substances. The law (HSC Sec. 11054-11058) classifies controlled substances into five distinct schedules according to their danger and potential for abuse. . . . The Controlled Substances Act (CSA) (Title 21 United States Code (USC) Sec. 801 et seq.) is the federal drug policy that regulates the manufacture and distribution of drugs, substances, and certain chemicals used to make drugs. The CSA also places all substances into one of five schedules (USC Sec. 812), based upon the substance's medical use, potential for abuse, and safety or dependence liability. . . .

Existing state law (HSC Sec. 11165 et seq.) also includes the Controlled Substance Utilization Review and Evaluation System (CURES), which is California's prescription drug monitoring program operated under the California Department of Justice. CURES provides for electronic transmission of Schedule II, III, and IV prescription data to the DOJ at the time the prescriptions are dispensed. . . . Licensed prescribers (physicians, dentists, optometrists, registered nurses, etc.) possessing a federal Drug Enforcement Administration Controlled Substance Registration Certificate and licensed pharmacists are both required to register for CURES.

Although the federal and state controlled substance schedules are generally consistent, discrepancies have arisen over the last several years. For example, hydrocodone combination products (HCPs), which are drugs that combine hydrocodone with non-narcotic ingredients including acetaminophen or ibuprofen, were previously Schedule III in both the federal and California schedules. Effective October 6, 2014, HCPs were rescheduled at the federal level from Schedule III to Schedule II in recognition of the drug's abuse potential. However, no change was made in California and these drugs remain on Schedule III at the state level. This discrepancy can be confusing for prescribers and pharmacists who don't know which schedule to refer to or what prescribing and/or dispensing responsibilities they are required to meet by law. It is also especially problematic for HCPs, which are a category of opioids prescribed more frequently than all other medicinal opioids combined.

AB 2783 aligns federal and state policy by rescheduling HCPs from a Schedule III drug to a Schedule II drug. This will clarify applicable law for prescribers, dispensers, health practitioners, and others who rely on these schedules for compliance.

2. Controlled Substance Schedules

Through the Controlled Substances Act of 1970, the federal government regulates the manufacture, distribution, and dispensing of controlled substances. The Act groups drugs into

five schedules with decreasing potential for physical or psychological harm, based on three considerations: (a) their potential for abuse; (b) their accepted medical use; and, (c) their accepted safety under medical supervision. Federal law includes relatively detailed explanations of the factors and standards for placement of drugs in the various schedules.

- Schedule I controlled substances, such as heroin, ecstasy, and LSD, have a high potential for abuse and no generally accepted medical use.
- Schedule II controlled substances have a currently accepted medical use in treatment, or a currently accepted medical use with severe restrictions, and have a high potential for abuse and psychological or physical dependence. Schedule II drugs can be narcotics or non-narcotic. Examples of Schedule II controlled substances include morphine, methadone, Ritalin, Demerol, Dilaudid, Percocet, Percodan, and Oxycontin.
- Schedule III and IV controlled substances have a currently accepted medical use in treatment, less potential for abuse but are known to be mixed in specific ways to achieve a narcotic-like effect. Examples include drugs include Vicodin, Xanax, Ambien and other anti-anxiety drugs.
- Schedule V controlled substances have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

3. Scheduling of Controlled Substances

California's controlled substances schedules closely mirror the federal schedules, categorizing controlled substances into five schedules based on medical utility and potential for abuse. (Health & Saf. Code §§ 11054-11058.) Schedule I controlled substances have the greatest restrictions and penalties, including prohibiting the prescribing of a Schedule I controlled substance. California does not have a formal controlled substance classification procedure, and instead relies on the federal controlled substance schedule to determine the appropriateness of scheduling a particular substance.

21 United States Codes Section 811 authorizes the U.S. Attorney General to add a controlled substance to the schedule or transfer a controlled substance between the schedules according to specific criteria. Before initiating proceedings to control a drug or other substance or to remove a drug or other substance from the schedules, and after gathering the necessary data, the Attorney General requests from the Secretary of Health and Human Services a scientific and medical evaluation, and his or her recommendations, as to whether such substance should be controlled or removed. The recommendations must include a recommendation with respect to the appropriate schedule of the substance. If the Attorney General determines based on these facts and all other relevant data that control or removal of a substance is warranted, then proceedings for control or removal will be initiated.

The Attorney General is required to consider the following with respect to each drug or substance proposed to be controlled or removed from the schedules:

- Its actual or relative potential for abuse;
- Scientific evidence of its pharmacological effect, if known;
- The state of current scientific knowledge regarding the drug or other substance;
- Its history and current pattern of abuse;
- The scope, duration, and significance of abuse;

- What, if any, risk there is to the public health;
- Its psychic or physiological dependence liability; and,
- Whether the substance is an immediate precursor of a substance already controlled under this subchapter. (21 U.S.C. § 811(c).)

4. HCPs Were Placed on Federal Schedule II in 2014

Although the federal and state controlled substance schedules are generally consistent, there are discrepancies. HCPs are drugs that combine hydrocodone with non-narcotic ingredients, including acetaminophen or ibuprofen. Vicodin and Norco are examples of commonly prescribed HCPs. (<https://medlineplus.gov/druginfo/meds/a601006.html>.) HCPs are classified as Schedule III controlled substances in the California schedule. (Health & Saf. §11056.) HCPs were previously Schedule III substances in the federal schedule, but were rescheduled from Schedule III to Schedule II effective October 6, 2014, in part because of the high potential for abuse. (79 Fed.Reg. 11037 (Feb. 27, 2014).) This bill would reschedule HCPs from Schedule III to Schedule II. This change would not affect criminal penalties for drug offenses such as possession, possession for sale, or transport.

5. Argument in Support

According to the California State Board of Pharmacy, the bill's sponsor:

AB 2783...is an important step forward in California's efforts to address the opioid crisis. . . .

The recent amendments to AB 2783 would reclassify hydrocodone combination products which are currently classified in California's Controlled Substances Schedules from Schedule III drugs to Schedule II drugs. Currently these medications are classified in federal Schedule II. The reclassification of these drugs in California will aid practitioners in being compliant with the conditions for prescribing and refilling Schedule II medications, which are the most highly regulated tier of prescription medication.

6. Argument in Opposition

According to California Attorneys for Criminal Justice:

[S]uch a change, in isolation from the overall scope of the schedules and the policies they reflect would be a mistake. Our experience strongly suggests that piecemeal changes to a comprehensive scheme like the schedules will produce unintended negative consequences.

We are also mindful of the fact that by statute and initiative over the last decade there has been a shift away from severe criminal penalties for drug use and possession. This proposal in AB 2783 to increase the scheduling and penalties for prescription compounds which contain hydrocodone with non-narcotic medications is the wrong direction for drug policy.