



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

RE: Agenda Item VIII Discussion and Consideration of Possible Statutory Proposal to Reconcile Federal and State Controlled Substances Schedules

Background

At the November Board Meeting, the board discussed the possibility of finding a means to address differences in federal and state controlled substances schedules so that the more restrictive provision would prevail. Staff was directed to work on this concept and bring proposed legislation back to board for review and discussion. Below is this proposal.

During this meeting, the board is asked to consider the following :

Concept Draft for Reconciling Federal and California Controlled Substance Schedules

Although the federal and state controlled substances schedules are generally consistent, over the last several years discrepancies have arisen between the federal controlled substance schedules (21 C.F.R. §§ 1308.11, 1308.12, 1308.13, 1308.14, 1308.15) and the California controlled substance schedules (Health & Saf. Code, §§ 11054, 11055, 11056, 11057, 11058), both in terms of whether certain drugs are listed on those schedules at all, and in terms of the location of certain drugs on Schedule I, II, III, IV, or V.

For instance:

- hydrocodone combination products (HCPs), those 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 moved at the federal level from Schedule III (21 C.F.R. § 1308.13(e)(1)(iii) and (iv)) to Schedule II (21 C.F.R. § 1308.12(b)(1)). No change was made in California, where these drugs remain Schedule III. (Health & Saf. Code, § 11056(e)(4).)
- Similarly, whereas tramadol was added to the federal version of Schedule IV effective August 18, 2014 (21 C.F.R. § 1308.14(b)(3)), it remains an unscheduled drug under California law. Likewise, carisoprodol (Soma) was added to Schedule IV under federal law effective January 11, 2012 (21 C.F.R. § 1308.14(c)(6)) but California has not yet taken action to add carisoprodol to its schedules.

The discrepancies have become noticeable enough that since 2012, pursuant to language added by SB 360 (DeSaulnier), the California Controlled Substance Utilization Review and Evaluation System (CURES), the state database of controlled substances dispensed pursuant



to prescription, has specified that what constitutes a Schedule II, III, or IV controlled substance for purposes of reporting shall be determined according to the *federal* rather than the California schedules. (Health & Saf. Code, § 11165(d).)

These discrepancies can also lead to confusion about prescriber and dispenser responsibilities regarding the various controlled substances, and their obligations as to prescribing, handling, dispensing, and/or record-keeping, particularly as to certain duties under California law. For instance, Health and Safety Code section 11200 says that prescriptions for Schedule III and IV controlled substances may only be refilled five (5) times and only up to a one hundred twenty (120)-day supply, while it prevents Schedule II prescriptions from being refilled at all. Where HCPs are Schedule III under California law, this would seem to permit refills of prescriptions for this substance. However, federal law would prohibit refilling a prescription for what is a Schedule II controlled substance under federal law. (21 C.F.R. § 1306.12(a).)

To resolve these discrepancies and the resulting confusion, there would appear to be three options:

- (1) reconciling the California controlled substance schedules with the federal schedules;
- (2) eliminating the California controlled substance schedules entirely, and depending solely on the federal schedules; or
- (3) taking an approach similar to that taken by the CURES statute, and incorporating the federal controlled substance schedules into the application of California law.

Of these three, (3) seems the most possible. However, California has scheduled drugs that do not appear on the federal controlled substance schedule, or perhaps in the future recognized a higher abuse potential in a drug than has been recognized at the federal level (and thus placed the drug on a lower-numbered schedule), instead of simply incorporating the federal schedules we will require compliance with whichever of the schedules lists a drug, and lists it on a lower-numbered schedule to indicate higher abuse potential.

The following concept draft attempts to achieve this objective.

Business and Professions Code section 4021. “Controlled substance” defined

“Controlled substance” means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code and any substance listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any substance listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.

Health and Safety Code section 11007. Controlled substance

“Controlled substance,” unless otherwise specified, means a drug, substance, or immediate precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058 and any drug, substance, or immediate precursor which is listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any drug, substance, or immediate precursor listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.