

Rescheduling Hydrocodone

The DEA has announced that it is rescheduling all hydrocodone combination products (HCPs) from federal Schedule III to federal Schedule II effective October 6.

This change will impact how hydrocodone combination products are prescribed and dispensed in California. Federal requirements for prescribing and dispensing Schedule II controlled substances will apply to all hydrocodone combination products. This means, among other things, a very limited ability to orally prescribe HCPs (see below) and ability to authorize refills.

This “up scheduling” is a major change for California. According to CURES, over 1 billion dosage units of HCPs were dispensed last fiscal year in California.

This guidance document provides information on some of the questions that will likely arise regarding the transition of hydrocodone combination products to federal Schedule II.

From the federal announcement:

On Friday, August 22, 2014, the DEA published in the Federal Register the final rule to transfer HCPs from federal Schedule III to federal Schedule II. HCPs have been controlled in schedule III since enactment of the Controlled Substances Act (CSA) in 1971. HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.

- Effective October 6, 2014, HCPs will be controlled as Schedule II substances under the Controlled Substances Act (CSA).
- DEA is also permitting legitimate HCP prescriptions issued before October 6, 2014 to be refilled until April 8, 2015, if the prescription authorizes refills.
- The Notice of Proposed Rulemaking (NPRM), Final Rule, and its supporting documents (i.e., medical and scientific evaluations, and economic impact analysis) may be viewed online at www.regulations.gov<<http://www.regulations.gov>>, Docket No. DEA-389.
- Alternatively, the documents can be obtained on the DEA website at www.deadiversion.usdoj.gov<<http://www.deadiversion.usdoj.gov>>.

Questions and Answers;

1. Starting October 6, 2014, all HCPs will be reclassified at the federal level as Schedule II controlled substances, does this mean California law has also reclassified all hydrocodone combination products as Schedule II controlled substances?

A: Technically, no; there has been no equivalent change to California law, or to the controlled substance schedules in California. But for many intents and purposes, the practical effect will be the same: that all prescribers and practitioners in California will be required to treat HCPs as Schedule II controlled substances.

2. Prescriptions written for HCPs **before** October 6, 2014 that are presented to the pharmacy for dispensing on October 6, 2014: are these dispensed as a Schedule II or Schedule III controlled substance?

A: On and after October 6, 2014, under federal law, all HCPs must be prescribed according to federal Schedule II requirements. This means no HCP prescription issued on or after this date may authorize any refills. Also, for example, as of October 6, 2014, oral, telephone or fax-transmitted prescriptions for HCPs are no longer possible. The DEA has stated, however, that it will allow refills on HCPs written and initially filled before October 6 (under Schedule III requirements and limitations), to be dispensed up to six months from October 6, 2014 (until April 8, 2015). This extends the Schedule III treatment of prescriptions for HCPs written and initially dispensed prior to October 6, 2014 to the maximum allowable period for Schedule III refills.

3. Prescriptions written for hydrocodone combination products dispensed before October 6, 2014 as a Schedule III, but with refills remaining, can the remaining refills be dispensed?

A: According to guidance from the DEA, yes.

4. If a patient presents a prescription for a hydrocodone combination product on or after October 6, 2014 that is written on October 6, 2014 with refills, can the refills be honored?

A: No, the DEA stated the prescription needed to be presented before October 6 to use the refills.

5. When transmitting to CURES, should I change my computer software to report all HCPs dispensed as Schedule II controlled substances or keep HCPs as Schedule III controlled substances until California law (also) reschedules all HCPs to a Schedule II controlled substance?

A: Health and Safety Code section 11165, subdivision (d) references and incorporates the federal controlled substance schedules for the purpose of defining the reporting requirements under CURES. As a result, dispensers in California are responsible for reporting to CURES controlled substances dispensed according to the federal schedules. Thus, a software change will be required.