

Frequently Asked Questions Regarding the DEA Rescheduling of Hydrocodone Combination Products (HCPs)

Background

On Friday, August 22nd, the U. S. Drug Enforcement Administration (DEA) published a Final Rule moving HCPs from Schedule III to the more-restrictive Schedule II. This Final Rule imposes the regulatory controls and sanctions applicable to Schedule II substances on those who handle or propose to handle HCPs. The rule goes into effect 45 days from its publish date.

What is the effective date of the new rescheduling?

The final rule that changes hydrocodone combination products to Schedule II takes effect on October 6, 2014.

This is a change in Federal law. What does that mean in Florida?

Florida law requires all Florida-licensed pharmacists to comply with all relevant state and federal laws. As of October 6, 2014 HCPs will be legally assigned to Schedule II.

Hydrocodone combination products are currently listed as Schedule III in chapter 893.03 of Florida Statutes. Will that change now that the federal government gave these medications a Schedule II classification?

Scheduling of controlled substances is done by the Florida Legislature. In order to reschedule HCPs, the Legislature would have to revise F.S. 893.03 - either during a special session or during its regular session (set to next convene in March of 2015).

What happens to prescriptions written for HCPs and issued prior to October 6, 2014?

The final rule states:

“All prescriptions for HCPs must comply with 21 U.S.C. 829(a) and must be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of October 6, 2014. No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22–1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015.”

This means the DEA is allowing prescriptions for HCPs that are dated prior to October 6, 2014 to be filled up to 5 times prior to April 8, 2014. These prescriptions can also be transferred between pharmacies similar to how other schedule III prescriptions are currently transferred.

Won't some pharmacy systems have difficulty dispensing refills on Schedule II drugs?

The Board of Pharmacy understands that some pharmacy management systems require a prescription in order for Schedule II drugs to be dispensed. In such cases the Board urges pharmacists to work with the physicians in the communities before October 6 to inform them of this difficulty, and the potential need for new prescriptions.