

DEA Rescheduling of Hydrocodone Combination Products Impact on Kentucky Prescribers

Effective October 6, 2014 hydrocodone combination products (HCPs) are Schedule II controlled substances. KRS 218A.020 (3) reproduced below, indicates that prescribing rules and regulations in effect for Kentucky prescribers on March 19, 2013 will remain in effect for the rescheduled hydrocodone products. The impact on Kentucky prescribers is described below. Restrictions on prescribing existing Schedule II pure hydrocodone products remain under current Kentucky statutes and regulations because these products were not **rescheduled** to Schedule II.

KRS 218A.020 (3) If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under this chapter by regulation. If hydrocodone or any drug containing hydrocodone is rescheduled to Schedule II in this manner, the prescriptive authority existing on March 19, 2013, of any practitioner licensed under the laws of the Commonwealth to prescribe, dispense, or administer hydrocodone or drugs containing hydrocodone shall remain inviolate and shall continue to exist to the same extent as if those drugs had remained classified as Schedule III controlled substances.

Advanced Practice Registered Nurses

KRS 314.011 Section 8 (a) limits APRN prescribing of Schedule II controlled substances to a 72 hour supply with no refills, except psychiatric-mental health nurses are permitted to prescribe up to a 30 day supply of a Schedule II psychostimulant with no refills. KRS 314.011 Section 8 (b) limits APRN prescribing of Schedule III controlled substances to a 30 day supply with no refills. Because KRS 314.011 Section 8 (b) was in effect March 19, 2013 all APRNs will continue to be permitted to prescribe a 30 day supply of Schedule II hydrocodone combination products if allowed under their DEA license.

Dentists

The rescheduling will have no effect on the ability of Kentucky dentists to prescribe Schedule II hydrocodone combinations if allowed under their DEA license.

Optometrists

201 KAR 5:130 allows optometrists to prescribe Schedule III, IV or V controlled substances. KRS 320.240 Section 13 limits optometrist prescribing of Schedule III controlled substances to a 72 hour supply. Because 201 KAR 5:130 and KRS 320.240 were in effect March 19, 2013, optometrists will be allowed to prescribe up to a 72 hour supply of Schedule II hydrocodone combination products if allowed under their DEA license.

Physicians

The rescheduling will have no effect on the ability of Kentucky physicians to prescribe Schedule II hydrocodone combinations if allowed under their DEA license.

Podiatrists

The rescheduling will have no effect on the ability of Kentucky podiatrists to prescribe Schedule II hydrocodone combinations if allowed under their DEA license.

Clarification of Requirements of Hydrocodone Combination Products on or after October 6, 2014

Pharmacists

The Final Rule states all Schedule II requirements will now apply to any hydrocodone combination products (HCPs). Such requirements may include: any necessary changes in DEA registration, ordering, inventory, labeling, packaging, record keeping, reporting, security, and operational policies. As pharmacists, it will be increasingly important to pay close attention when filling prescriptions for HCPs to ensure all requirements are met.

DEA guidance concerning authorized refills for existing HCP prescriptions and HCP prescriptions written before October 6, 2014 is a bit confusing. It appears the DEA is trying to accommodate the transition by permitting refills authorized before October 6 to be dispensed after October 6, the effective date of the Final Rule. In the Final Rule the following regulation is stated as follows:

- 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 are authorized for refilling, may be dispensed (in accordance with 21 CFR 1306.22-1306.23 (refills and partial fills), 1306.25 (transfers), and 1306.27 (central fill)) if such dispensing occurs prior to April 8, 2015.

For example, if a physician writes a prescription for a HCP on October 4, 2014, with two refills, and the prescription is brought to the pharmacy on October 12, 2014, the prescription will still be considered a Schedule III and the refills are all still valid, due to the date of issuance, provided the refills are dispensed prior to April 8, 2015.

Please be advised, under Title 21 US Code 829(a) of the Controlled Substance Act, refills are not permitted on a Schedule II prescription. As such, most pharmacy computer systems do not permit a Schedule II prescription to be refilled. That said, DEA has advised the following for HCPs:

- Or: Refilling a prescription for an HCP prior to April 8, 2015 is allowed under the Final Rule and existing Kentucky Revised Statutes provided the original prescription was written before October 6, 2014 and the prescription meets other requirements set forth in applicable state and federal laws, rules, and regulations. This does not negate pharmacists' duties in fulfilling their corresponding responsibilities.
- If your pharmacy software allows you to refill a Schedule II prescription, you may refill a HCP prescription after October 6 up to six months after the date of issuance, until all authorized refills are used or prior to April 8, 2015, whichever occurs first.
- If your pharmacy software does not allow you to refill a Schedule II prescription, the patient must obtain a new written prescription from their provider for any HCP refills authorized prior to October 6, 2014 or the prescription refill can be transferred to another pharmacy whose system allows refills. A pharmacist may **NOT** rewrite the HCP as a new prescription and indicate this is a refill assigned back to the original prescription number under current state and federal laws, rules, and regulations.

Storage

- Pharmacies are not required by the CSA or DEA regulations to place schedule II controlled substances in a vault or safe, in accordance with 21 CFR 1301.75(b)
- Pharmacies may disperse schedule II controlled substances throughout their stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

For example, if most of the pharmacy's inventory of Schedule II products are stored in a locked safe and you have overflow of a product, that product may be dispersed among the non-controlled substances, while the other Schedule II product may remain in the safe.

Inventory When a drug not previously listed as a controlled substance is scheduled or a drug is **rescheduled**, the drug must be inventoried as of the effective date of scheduling or change in scheduling. The inventory shall either be done at the end of the business day on October 5, 2014 or the start of the business day on October 6, 2014.

Last, but not least, remember any HCP prescription issued on or after October 6, 2014 must satisfy all requirements of any Schedule II prescription.