DEA Final Rule Rescheduling Hydrocodone Combination Products

Recently, the Drug Enforcement Administration (DEA) issued a final rule **rescheduling hydrocodone combination products (HCPs) into Controlled Substance Schedule II**, effective October 6, 2014.

The DEA clarified key points impacting implementation that are of interest to health care providers and patients:

- Prescriptions for HCPs that are issued **on or after October 6, 2014**, must comply with requirements for Schedule II prescriptions; refills of these prescriptions will be prohibited.
- Prescriptions for HCPs that are issued **before October 6, 2014**, that have authorized refills may be dispensed in accordance with DEA rules for refilling, partial filling, transferring, and central filling Schedule III-V controlled substances until April 8, 2015. However, state law, insurance limitations, and some pharmacy quality and safety operations and processes may not allow for these prescriptions to be refilled.
- **On or after October 6, 2014**, pharmacies with HCPs in commercial containers labeled as Schedule III controlled substances are authorized to continue dispensing these products, but the DEA requires all other commercial containers of HCP to be labeled as Schedule II controlled substances.

Impact of State Law:

- State law, if more stringent, will govern how HCPs are handled with respect to refills. Several states have published notices that they intend to treat HCP refills for prescriptions written prior to October 6, 2014 like the federal rule. **However, most states have not provided clarity. Thus, prescribers should be prepared to provide new hard copy or electronic prescriptions for patients beginning on October 6, 2014 rather than have patients use what would have been existing refills.**

Impact on Prescribers Starting on October 6, 2014:

- Prescriptions for HCPs must be written on a hard copy, original prescription or electronically transmitted where e-prescribing of C-IIs is allowed by state law, the prescriber is certified to e-prescribe C-IIs, and the pharmacy is certified to accept electronically prescribed controlled substances. Fax transmission is not allowed.
- Prescriptions for HCPs cannot be called into a pharmacy.[i]
- Prescriptions for HCPs cannot be refilled (unless the prescription was issued before October 6, 2014). Note that many health insurers will not honor these refills and that many pharmacies will not be able to refill prescriptions issued prior to October 6, 2014 due to state law limitations and some pharmacy safety and quality systems and processes.

Impact on Pharmacists Starting on October 6, 2014:

- Pharmacies cannot accept prescriptions for HCPs by telephone.[i]
- Prescriptions for HCPs cannot be refilled.
- Prescriptions for HCPs may be written on a hard copy, original prescription, or received by electronic transmission, where allowed. Receipt by fax will not be allowed. HCPs as Schedule II will require additional recordkeeping and security requirements.
- The changeover from Schedule III to Schedule II may bring short term inventory challenges.

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Impact on Patients Starting on October 6, 2014:

- In many cases, prescriptions for HCPs issued prior to October 6, 2014 will not be refillable due to state law restrictions or feasibility pursuant to some pharmacy's safety and quality systems and processes. Please check with your pharmacy. Also note that your health plan may not honor such refills; patients should check with their health insurer.
- New prescriptions for HCPs will not have refills.

How Prescribers Should Prepare for October 6, 2014:

- Be prepared to issue new written or electronic prescriptions for patients beginning on October 6. Some prescriptions may be refillable, but many will not.
- Notify patients with HCP prescriptions of the new steps required to obtain prescriptions issued after October 6, 2014.
- Ascertain possible state-based restrictions applicable to allied health professionals with prescriptive authority and determine whether modifications to collaborative practice agreements between physicians and allied health professionals with prescriptive authority are needed.
- Determine, based on sound medical judgment and consistent with established medical standards and federal **and state laws**, the appropriateness of issuing multiple prescriptions. The DEA permits multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of HCP where a prescriber has determined it is appropriate to see the patient only once every 90 days. Each prescription must "be dated as of, and signed on, the day issued" and include written instructions on each prescription indicating the earliest date on which that prescription may be filled.

How Pharmacists Should Prepare for October 6, 2014:

- Educate local prescribers about the new rule by sharing this document.
- Educate patients suffering chronic pain about the new rule.
- Advise patients and prescribers whether refills for prescriptions issued prior to October 6, 2014 will be refillable after October 6, 2014.
- Contact your wholesale distributor to make sure the distributor will have enough of the correctly labeled products to meet demand. Manufacturers and wholesalers will need some time to make necessary changes from Schedule III to Schedule II product.

[i] Except for limited quantities in emergency situations. In emergency situations, a pharmacist may dispense a Schedule II controlled substance upon oral authorization of a prescribing individual practitioner, provided that the quantity is limited to the amount needed to treat the patient during the emergency period, the prescription is immediately reduced to writing and delivered to the pharmacy within seven days, and the pharmacist makes a reasonable effort to determine that the oral authorization came from a registered individual practitioner. If the hard copy prescription is not received by the pharmacy in seven days, the pharmacist should notify the DEA.