

## The Drug Enforcement Administration

### **ADA FAQ ON NEW HYDROCODONE COMBINATION PRODUCTS (HCP) REGULATIONS**

#### **What's the difference between a Schedule II and a Schedule III classification?**

Substances with recognized medical uses are categorized into one of five schedules according to their potential for harm and abuse. Schedule I drugs are highly addictive and have no currently accepted medical use. Those with the highest addiction potential with an accepted medical use fall under Schedule II and those with progressively less potential for harm and abuse fall into Schedules III through V. Hydrocodone itself has been classified as a Schedule II drug since 1971 and now all products containing hydrocodone, most of which are a mix of hydrocodone and other substances, (such as acetaminophen or aspirin) will also fall under Schedule II.

#### **When did this change take place?**

The reclassification took effect Oct. 6, 2014. The DEA allowed prescriptions for hydrocodone combination products written before Oct. 6, 2014 to be refilled until April 8, 2015, providing refills are properly authorized.

#### **Will I be able phone in prescriptions to a pharmacy for a Schedule II HCP?**

Prescribers cannot call or fax initial prescriptions or any refills into a pharmacy unless it's an emergency, in which case a prescription for medication covering up to 72 hours may be phoned to a pharmacy.

#### **Are there other restrictions associated with writing prescriptions for Schedule II drugs?**

- Restrictions on Schedule II drugs limit patients to a single supply of medication and require the patient to visit a health care professional to get a written prescription for all refills.
- New prescription forms are not required, unless mandated by your state. Prescribers may continue to use the same tamper-resistant prescription forms that had been used for other prescriptions. Some states require prescribers to use tamper-resistant prescription forms from approved printers and generally offer a listing of approved printers online.
- **E-prescribing is allowed IF** the software used meets DEA requirements, which can be found [here](#). Check with your state agency that regulates pharmacies to confirm that e-prescriptions are allowed and to determine whether any additional local regulations apply.

#### **I am registered with the DEA to prescribe Schedule III-V drugs. What must I do to change my registration status with the DEA?**

Dentists who are not registered for Schedule II will have to reregister with the DEA for Schedule II authority to continue prescribing/refilling HCPs for their patients. Visit [the DEA's website](#). You can also call the DEA Registration Service Center at **1-800-882-9539 from 8:30 a.m. – 6:00 p.m. EST or send an email to [DEA.Registration.Help@usdoj.gov](mailto:DEA.Registration.Help@usdoj.gov)**. Be sure to include your DEA Registration number in your email.

#### **How can I locate a DEA field office near me?**

Visit [the DEA website](#) for a complete list of mailing addresses and phone numbers for DEA Field Offices in each state. Registration assistants are available during normal business hours and can provide information about new applications, renewal applications, order forms, or changing your DEA registration status.

#### **How does the reclassification impact my patients?**

Patients may experience increased out of pocket costs associated with additional office visits to obtain a written prescription if a refill for the medication is needed.

#### **What if there's an emergency?**

Prescribers with the proper DEA registration may phone in a prescription to a pharmacy to provide a patient with enough medication to last up to 72 hours. Patients needing additional medication will need to obtain a written prescription. Emergencies are defined as situations that require the immediate administration of the controlled substance; the lack of appropriate alternative treatments; and those

situations where it is not “reasonably possible” for you to provide the patient with a written prescription. Specific details for assessing whether a situation is an emergency are available [online](#).

**What do I tell my patients if they complain about having to come to the office to get a prescription for a refill?**

- Let them know you empathize with their frustrations and the inconvenience caused by this change.
- Remind them that these drugs can be addictive and using them other than prescribed is illegal, dangerous, and can even be fatal.
- Urge them to visit [MouthHealthy.org/rxabuse](http://MouthHealthy.org/rxabuse) to learn how to keep prescription drugs from becoming a source of harm.

**Does the reclassification impact anyone besides prescribers and patients?**

Yes. Manufacturers will be subject to production quotas and pharmacies will need to follow additional recordkeeping procedures and implement additional measures to ensure the secure storage of Schedule II substances. Manufacturer production quotas should have no impact on the production requirements or the availability of Schedule II substances in the marketplace.

**Where can I learn more about prescribing opioids?**

Information on prescription drug abuse and opioids can be found on the ADA website [in our health and wellness section](#) or [in our advocacy section on prescription drug abuse](#).

Dentists are urged to take advantage of ADA’s free continuing education webinars—available through the Prescribers' Clinical Support System for Opioid Therapies (PCSS-O)—to refresh their knowledge about opioid prescribing in the context of modern day drug-seeking behavior. Learn more at [pcss-o.org](http://pcss-o.org).

**A final reminder:**

Keep in mind that your state may have additional regulations or restrictions regarding Schedule II substances, so check with your state dental association or licensing authority. Examples of additional state regulations include requiring triplicate prescription forms or imposing specific limits on prescribing schedules.