

## The Drug Enforcement Administration

### **ADA FAQ ON NEW HYDROCODONE COMBINATION PRODUCTS (HCP) REGULATIONS, PART 2**

Here is a second installment of questions and answers about the new regulations for hydrocodone combination products.

#### **What happens when a patient needs an emergency prescription?**

Emergency prescriptions can be phoned into a pharmacy in emergency situations. However, the prescribing dentist **must** give the pharmacist a written and signed prescription form confirming the prescription within seven days. It's important to know that the pharmacy is required to notify the DEA if they do not receive a written prescription.

If you determine that a patient needs more medication than the amount initially prescribed via telephone in response to the emergency situation, it's best to write one prescription for the initial emergency dosage and another for the follow-up prescription. If a pharmacist calls with questions about a prescription for HCPs, understand that they have a corresponding responsibility for confirming the accuracy of the prescription and assist them however you can. Generally speaking, pharmacists are not likely to deny emergency prescriptions for HCPs that are called in by a dentist who has proper DEA credentials.

#### **Has anything else changed in terms of how I write patient prescriptions for HCPs?**

Prescriptions for any Schedule II substances must be in a written format, require the practitioner's signature and cannot be automatically refilled. While prescriptions for Schedule II substances can be faxed to a pharmacy for fulfillment, the original, signed prescription must be given to the pharmacist before the medication can be dispensed. Also, since some states have additional regulations or restrictions regarding Schedule II substances, such as requiring triplicate prescription forms or imposing specific limits on prescribing schedules, you should check with your state dental association or licensing authority to determine whether any additional regulations apply.

#### **Does the DEA have recommendations about protecting prescription pads?**

Your practice likely has security measures already in place to safeguard against the theft of blank prescription pads. Recommendations outlined in the DEA [Practitioner's Manual](#) include not signing blank prescription forms before they're needed; using the pads for prescriptions only, not for taking notes; keeping unused pads in a secure place and minimizing the number of pads in use; writing out, in both digits and words, the actual number of pills prescribed; and using tamper-resistant pads. Notify your local DEA field office with questions or to report suspicious prescription activities.

#### **Is a single DEA registration sufficient even though I practice in multiple locations?**

Possibly. One DEA registration is sufficient if you only prescribe medications and don't order, dispense or administer any Schedule II substances. However, a dentist who orders, dispenses and/or administers Schedule II substances in more than one location is required to have separate DEA registration authority for each location where those activities take place.

#### **Does every dentist in a group practice need to register with the DEA?**

Not necessarily. A dentist who is an agent or employee of another practitioner who is registered to dispense controlled substances may be allowed to dispense or administer a controlled substance in the normal course of business under the registration of the employer or principal practitioner if and to the extent that doing so is authorized or permitted by the jurisdiction in which the individual practices.

#### **I maintain a very small inventory of HCPs in my practice to dispense to patients. Are there any specific storage, recordkeeping, disposal and/or staff access requirements for Schedule II substances?**

Yes. The DEA's [Practitioner's Manual: An Informational Outline of the Controlled Substances Act](#) provides details regarding requirements for recordkeeping, disposal, on-site storage, and employee access to Schedule II substances. Some key highlights of those provisions are:

□ **Recordkeeping:** You are required to develop a detailed, ongoing inventory of all Schedule II substances. The DEA’s regulations on [inventory requirements](#) for Schedule II substances contains a specific section for dispensers. Generally speaking, the inventory can be typed, written or printed. It should specify the date the inventory was conducted, whether it was taken at the beginning or at the close of the day, include the signature of the person who conducted or confirmed the inventory, and must be kept for at least two years. While the DEA mandates that all records should be kept for two years, some states may require a longer record retention period, so check with your local dental association or licensing agency. Your inventory should include the following information about all controlled substances in the practice:

- The name of each substance and its finished form (such as “tablet” with an indication of the number of milligrams)
- The number of dosage units of each finished form in the commercial container (such as the number of tablets per bottle)
- The number of commercial containers for each finished form (i.e. the number of bottles for each type of tablet)
- How the substances were dispensed and/or disposed

Keep all receiving, dispensing and disposal records with your inventory and notify the DEA immediately of any theft or significant loss of any controlled substance by submitting a completed [DEA Form 106](#) to document what has occurred. Always confirm that the physical contents of any shipments of Schedule II narcotics match the details on the forms sent by the shipper and note any discrepancies on the forms and in your inventory log. It’s also a good idea to notify the shipper of any discrepancies. Your inventory records must be accurate and up-to-date at all times: if an inspection were to take place, DEA Duty Investigators can assess fines of up to \$10,000 for each recordkeeping deficiency.

□ **Dispensing:** Adjust your inventory anytime any Schedule II substances are dispensed or administered to patients. The easiest way to do this is to maintain a daily log that details the date a drug was dispensed or administered; the name of the drug used and the amount given; the name of the patient receiving the medication; and the initials of the individual who administered or dispensed the medication. Of course, the inventory will also need to indicate when narcotics have been disposed of or transferred to a “reverse distributor” for disposal.

□ **Storage:** Controlled substances that fall into Schedules II through V must be kept in a securely-locked, substantially constructed cabinet or another secure storage place, such as a safe or vault, to guard against theft or diversion. Limit the number of employees who have access to the key or the combination to open the lock and make certain that anyone with access does not have any felony or misdemeanor convictions, any pending charges relating to criminal offenses, and has not knowingly used narcotics other than those prescribed by a physician. It’s also a good idea to conduct background checks on any employee with access to controlled substances. And under no circumstances should an employee whose DEA registration has been revoked or denied be able to access any controlled substances.

The DEA’s Controlled Substances Security Manual contains a number of [General Security Requirements](#) to assist practices that maintain inventories of any controlled substances on-site. Its Security Manual’s [Security Requirements for Practitioners](#) can help you determine whether your practice’s controlled substance security measures are sufficient. Keep in mind that multiple variables—local crime rates, the number of people able to access the controlled substances, the use of an effective alarm system, etc.—are taken into account when determining whether security measures are adequate. While federal regulations do not explicitly state minimum requirements for the placement or construction of the space used to store controlled substances, the intent of the law requires that they be “adequately safeguarded.”

□ **Disposal:** Controlled substances that have expired, been damaged, are unusable or no longer needed must be disposed of in accordance with DEA regulations. One option, generally used by those with a large supply of Schedule II substances, is to transfer the controlled substances to a “reverse distributor” who is specially authorized to receive and dispose of them. Your local DEA field office can provide you with a list of authorized reverse distributors in your area. Be aware that the reverse distributor will bill you

for taking control of the inventory and that you will need to complete [DEA Form 222](#) to facilitate that transfer. Keep a copy of the form with your inventory records for at least two years.

In the event that your practice wants to destroy a small quantity of Schedule II substances, fax a completed [DEA Form 41](#) to your local DEA office and they will advise whether you can destroy that inventory by removing the medications from their containers, mixing them with coffee grounds or kitty litter and then sealing them in a bag or disposable container before placing in the trash. If that type of disposal is approved by the DEA, two DEA-licensed individuals should witness the process and sign the form confirming that the disposal took place as directed. Update your inventory and keep the form on file with your inventory records for at least two years. More information is available in the DEA's [final rule on the disposal of controlled substances](#).

□ **Staff:** Practitioners with controlled substances on-site are prohibited from employing anyone who may have access to controlled substances if that individual has been denied a DEA registration or has had a DEA registration revoked. The DEA suggests that any comprehensive [employee screening](#) program include questions regarding criminal records and the use of controlled substances not prescribed by a healthcare provider. The agency assumes that the comprehensive employee screening program of any business storing controlled substances will include questions on felony and misdemeanor convictions, any pending charges relating to criminal offenses, and whether the employee has ever knowingly used narcotics other than those prescribed by a physician. It also recommends that employees with access to controlled substances give written consent for the employer to conduct a background check. The specific recommendations are available in the agency's Controlled Substances Security Manual's section on [Employee Screening](#).

While many of the DEA's [Additional Security Measures](#) are not specifically required, they do outline some safeguards—such as regularly testing alarm systems and changing lock or safe combinations annually or whenever a staff member ceases employment—that are easy to implement and provide added security.