

HYDROCODONE COMBINATION PRODUCTS: FACT SHEET

On August 22, 2014, the DEA published a final rule rescheduling hydrocodone combination products (HCPs) to schedule II of the Controlled Substances Act. The final rule is available on www.regulations.gov, and on our website, www.DEAdiversion.usdoj.gov. This Fact Sheet contains a general summary of the effects of the rescheduling on the general public. For further information, please visit our website or contact your local DEA office.

1. What are HCPs?

HCPs are pharmaceutical drugs containing hydrocodone in certain combinations with other drugs. Common names include: Vicodin, Lortab, Hycodan, Tussionex, and several generics.

2. What does this final rule do?

HCPs will be controlled as schedule II substances effective October 6, 2014. DEA registrants (e.g., distributors, physicians, and pharmacies) will be required to adhere to more stringent security and recordkeeping requirements with respect to HCPs.

3. I have a current prescription for HCPs that authorizes refills. Can I still have it refilled?

Yes. Any legitimate prescriptions for HCPs that are issued before October 6, 2014 that authorize refills may be dispensed by a pharmacy if such dispensing occurs before April 8, 2015.

4. Can my practitioner issue me a prescription for an HCP with refills after October 6, 2014?

No; a prescription for a schedule II controlled substance may not be refilled. However your practitioner may issue multiple prescriptions authorizing you to receive a total of up to a 90-day supply, provided certain regulatory requirements are met.

5. Will I now have to see my practitioner every month?

Not necessarily--the DEA does not regulate the practice of medicine. Your practitioner must determine on his/her own, based on sound medical judgment, and in accordance with established medical standards, how often to see you.

6. Will I have to show my ID at the pharmacy when I pick up my prescription?

There is no federal requirement for you to show ID; however, you may be required to do so by your pharmacy or applicable state law.

HYDROCODONE COMBINATION PRODUCTS: BACKGROUND

- **What are hydrocodone combination products (HCPs)?**
 - HCPs are pharmaceutical drugs containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for marketing for the treatment of pain and cough suppression.
 - All pharmaceutical drug products containing hydrocodone approved for marketing in the United States by the U.S. Food and Drug Administration are HCPs, except Zohydro™ ER which is a single-entity hydrocodone product and as such is already a schedule II controlled substance.
 - There are several hundred brand name and generic hydrocodone products marketed with the most frequently prescribed combination being hydrocodone and acetaminophen (e.g., Vicodin®, Lortab®). Currently marketed cough suppressants containing HCPs include Hycodan®, Mycodone®, Tussionex®, Pennkinetic®, Tussigon®, and several generics.
 - HCPs have been controlled in schedule III since enactment of the CSA in 1971.
 - HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.
- **What is the purpose of this rescheduling action?**
 - Effective October 6, 2014, HCPs will be controlled as schedule II substances under the Controlled Substances Act (CSA). *For details on the applicable regulatory requirements and various compliance dates, see attached handling requirements.*
 - For prescribers, the change primarily means that they may not authorize refills for any HCP prescriptions. However they may issue multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of HCPs, in accordance with 21 CFR 1306.12.
 - DEA is allowing legitimate HCP prescriptions issued before October 6, 2014 that authorize refills to be refilled until April 8, 2015.
 - For pharmacies, the primary changes are that they must utilize a DEA Form 222 in order to obtain HCPs from a distributor, and they must keep HCP records separate or readily retrievable.
 - For distributors, the primary change is that they must physically store HCPs in a vault that meets specific requirements.
 - Manufacturers are relatively unaffected by the rescheduling action, except manufacturers that repackage or relabel HCPs will be required to obtain a quota in order to repackage or relabel HCPs.
 - DEA is allowing HCPs to be repackaged and relabeled without the requirement of a quota until December 8, 2014.
- **Why did the DEA reschedule HCPs into schedule II of the CSA?**
 - A detailed analysis of the data and evidence supporting the DEA's action is available in the NPRM, the final rule, and the supporting and related materials.

HYDROCODONE COMBINATION PRODUCTS: TALKING POINTS

- The final rule controlling HCPs as schedule II substances is on public display beginning at 8:45 am on Thursday, August 21, 2014, at: <https://www.federalregister.gov/public-inspection>.
- The final rule will be published in the Federal Register on Friday, August 22, 2014, and will be available on the DEA website, <http://www.DEAdiversion.usdoj.gov>, and at <http://www.regulations.gov>.
- HCPs will be controlled as schedule II substances beginning October 6, 2014.
- The DEA has attempted to alleviate any burdens upon registrants caused by a 45-day effective date.
 - For example, DEA modified quota requirements to allow repackaging/relabeling of HCPs without a quota until December 8, 2014.
 - DEA is also permitting legitimate HCP prescriptions issued before October 6, 2014 to be refilled until April 8, 2015, if the prescription authorizes refills.
- HCPs have been controlled in schedule III since enactment of the Controlled Substances Act in 1971. Hydrocodone products that are not HCPs (i.e., Zohydro ER) are already schedule II substances.
- HCPs are the most frequently prescribed opioid in the United States: nearly 137 million prescriptions for HCPs were dispensed in 2013.
- HCPs are also among the most widely diverted and abused pharmaceuticals in the country.
- The rescheduling process began in 1999 when DEA received a petition to reschedule HCPs from schedule III to schedule II. Since 1999, the DEA has corresponded with HHS regarding the rescheduling action.
- In January 2013, the FDA held an Advisory Committee meeting and voted to reschedule HCPs. The DEA presented at this meeting. Information on the FACA meeting and the DEA presentation is available on the following link:
<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm332858.htm>.
- In December 2013, HHS formally recommended to the DEA that HCPs be controlled in schedule II.
- On February 27, 2014, the DEA published a NPRM, soliciting public comment (for 60 days) and hearing requests (30 days) from interested persons regarding the rescheduling action.
- The DEA received nearly 600 comments from the public. DEA's summarized responses to the comments are contained in the August 22, 2014, final rule.

- Schedule II controlled substances are substances that have a currently accepted medical use in the United States, but also have a high potential for abuse, and the abuse of which may lead to severe psychological or physical dependence. After considering the analysis and rescheduling recommendation of HHS and reviewing available data, the DEA found that HCPs meet the statutory definition of a schedule II controlled substance.
- Various drug abuse indicators for HCPs indicate that HCPs are widely diverted and abused at rates largely similar to that of oxycodone products (schedule II). The data indicate that HCPs have an abuse potential similar to schedule II opioid analgesics such as oxycodone and their abuse is associated with severe psychological or physical dependence.
- Abuse of HCPs is also associated with large numbers of individuals being admitted to addiction treatment centers. Individuals are taking these drugs in sufficient quantities to create a hazard to their health, and abuse of HCPs is associated with large numbers of deaths.
- **Did the public have the opportunity to provide comments to DEA on this rescheduling?**
 - Yes. The NPRM invited members of the public to comment on the proposal. The DEA considered the 573 comments received as summarized in the final rule published on August 22, 2014.
 - *See attached summary of comments for detailed statistical analysis of the types of comments received, and from whom.*
 - The NPRM also provided an opportunity for interested persons to file a request for hearing. No requests for such a hearing were received.
- **Summarized timeline**
 - DEA received the petition in 1999.
 - On July 28, 2004, DEA forwarded the petition and related materials to HHS for a scientific and medical evaluation and scheduling recommendation.
 - On March 6, 2008, HHS forwarded to the DEA a scientific and medical evaluation and recommended that HCPs continue to be subject to control under schedule III of the CSA.
 - On February 13, 2009, the DEA submitted the reanalyzed data to HHS and requested a reevaluation and scheduling recommendation.
 - As mandated by the Food and Drug Administration Safety and Renovation Act of 2012, on January 24-25, 2013, the FDA held an Advisory Committee meeting. The Committee voted in favor of rescheduling HCPs from schedule III to schedule II.
 - On December 16, 2013, HHS forwarded to the DEA its scientific and medical evaluation and recommendation that HCPs be controlled in schedule II.
 - On February 27, 2014, DEA published the NPRM, Economic Impact Analysis, and the DEA and HHS 8-factor analyses.
 - On August 22, 2014, DEA published the final rule.