

DEA Publishes Proposal to Reschedule Hydrocodone

Today the U. S. Drug Enforcement Administration (DEA) published in the Federal Register a Notice of Proposed Rulemaking (NPRM) to move hydrocodone combination products (HCPs) from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) and as supported by the DEA's own evaluation of relevant data. This NPRM proposes to impose the regulatory controls and sanctions applicable to Schedule II substances on those who handle or propose to handle HCPs. The public is invited to review the proposed rule, which is posted on the DEA's website at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0227.htm

The Controlled Substances Act (CSA) places substances with accepted medical uses into one of four schedules, with the most potentially harmful and abusable medications being placed in Schedule II, and medications with progressively less potential for harm and abuse being placed in Schedules III through V. (Schedule I is reserved for those controlled substances with no currently accepted medical use and lack of accepted safety for use.) HCPs are drugs that contain both hydrocodone, which by itself is a Schedule II drug, and specified amounts of other substances, such as acetaminophen or aspirin.

When Congress passed the CSA in 1970, it placed HCPs in Schedule III even though it had placed hydrocodone itself in Schedule II. The analysis by HHS and the DEA shows HCPs have a high potential for abuse and abuse may lead to severe psychological or physical dependence. The many findings by the DEA and HHS and the data that support these findings are presented in detail in the NPRM and supporting materials on the website. Data and surveys from multiple federal and non-federal agencies show the extent of abuse of HCPs. For example, Monitoring the Future surveys of 8th, 10th, and 12th graders from 2002 to 2011 found that twice as many high school seniors used Vicodin®, an HCP, nonmedically as used OxyContin®, a Schedule II substance, which is more tightly controlled.

All substances placed under the control of the CSA since it was passed by Congress in 1970 are scheduled or rescheduled by the DEA, as required by the CSA and its implementing regulations, found in Title 21 of the Code of Federal Regulations. Scheduling or rescheduling of a substance can be initiated by the DEA, by the HHS Assistant Secretary of Health, or on the petition of any interested party. (Detailed information on the scheduling and rescheduling process can be found in the first chapter of Drugs of Abuse [\[link\]](#) on the DEA's website.)

The rescheduling of HCPs was initiated by a petition from a physician in 1999. The DEA submitted a request to HHS for a scientific and medical evaluation of HCPs and a scheduling recommendation. In 2013, the U. S. Food and Drug Administration held a public Advisory Committee meeting on the matter, and the committee voted to recommend rescheduling HCPs from Schedule III to Schedule II by a vote of 19 to 10. Consistent with the outcome of that vote, in December of 2013 HHS sent such a recommendation to the DEA. With the receipt of that recommendation, the DEA initiates the formal rulemaking process by publishing a notice and soliciting public comments, as we are doing today.

After reviewing today's NPRM, members of the public are invited to submit comments or request a hearing through www.regulations.gov (follow the instructions at that site). Electronic comments must be submitted, or written comments postmarked, by 11:59 p.m. Eastern Time on April 27. Requests for hearings must be submitted by March 31. Additional instructions about this may be found in the NPRM.

Once the public comment period has closed and the DEA has considered all comments, the DEA will publish a Final Rule in the Federal Register.