Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II

A Rule by the Drug Enforcement Administration on 08/22/2014

See https://www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule#h-64

PLEASE NOTE PRESCRIPTION INFORMATION BELOW

With the issuance of this final rule, the Administrator of the Drug Enforcement Administration reschedules hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with, or possess) or propose to handle hydrocodone combination products.

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of HCPs. As such, the DEA is rescheduling HCPs (hydrocodone products) as a schedule II controlled substance under the CSA.

Records and Reports. Every DEA registrant must maintain records and submit reports with respect to HCPs pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312 as of October 6, 2014. Each pharmacy with a modified registration under 21 U.S.C. 823(f) that authorizes the dispensing of controlled substances by means of the Internet must submit reports to the DEA regarding HCPs pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.55 as of October 6, 2014.

Orders for HCPs. Every DEA registrant who distributes HCPs must comply with order form requirements, pursuant to 21 U.S.C. 821, 828, 871 and in accordance with 21 CFR parts 1305 and 1307 as of October 6, 2014.

Prescriptions. All prescriptions for HCPs must comply with 21 U.S.C. 829(a) and must be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of October 6, 2014. No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22-1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015.

GUIDANCE FOR NEW HYDROCODONE IMPLEMENTATION
Frequently Asked Questions.

The new rescheduling went into effect October 6, 2014. As of that date, any prescription for hydrocodone products issued on or after October 6, 2014 will be a C II prescription and all regulations regarding C II controlled drugs will apply. Of course that means no refills on the prescription; no prescriptions phoned-in, unless an emergency; the prescription may not be signed by a physician's assistant or a certified nurse practitioner or nurse midwife; there are limits on the specific items recorded on the prescription which may be altered by the pharmacist; the exemptions for long term care facilities and for a hospice apply.

"Upon the effective date of this final rule, any person who handles hydrocodone (HCPs) will be subject to the CSA's (controlled substance act) schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engaging in research, conducting instructional activities, and conducting chemical analysis, of schedule II controlled substances" (http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm)

Prescriptions for hydrocodone products filled before October 6, 2014 and having refills, may be refilled for no more than 5 total refills; refills may not occur more than 6 months after the original filling of the prescription and no refill may occur after April 8, 2015. For the life of this prescription, it is being treated as a C III controlled drug. The pharmacy software must have the ability to still fill hydrocodone as a C III drug.

The computer system in the pharmacy must have the ability to record and document the handling of the prescription and refill as a C III refill. If the computer system can only document the prescription as a C II, then refills or prescription transfers are not allowed. In that case, all prescriptions must be treated as new C II prescriptions.

Transfer of C III prescriptions from before October 6, 2014 with refills remaining. This is one of the most confusing parts of the new regulation. If the receiving pharmacy has a computer system which can record refills at a C III level, and if the prescription is treated as a transfer throughout the process, a prescription may be transferred to another pharmacy and the refills remaining may be dispensed from the second pharmacy. However, if the receiving pharmacy created a "new" prescription rather than handling the prescription as a C III transfer, then the new prescription would be a C II and there would be no refills.

The DEA website, http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm *makes the following statement. Note that it states refills may be dispensed in accordance with 21 CFR 1306.25, which is the policy on transferring of C III drugs.*

"Prescriptions. All prescriptions for HCPs must comply with **21 U.S.C. 829**(a) and must be issued in accordance with **21 CFR part 1306** and subpart C of **21 CFR part 1311** as of October 6, 2014. No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills. Any prescriptions for

HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with **21 CFR 1306.22-1306.23**, **1306.25**, and **1306.27**, if such dispensing occurs before April 8, 2015."

Manufacturer labeling, quotas and repackaging. DEA has stated that "All labels, labeling, and packaging for commercial containers of HCPs must comply with **21 U.S.C. 825** and **958**(e), and be in accordance with **21 CFR part 1302** as of October 6, 2014, except with respect to exchanges for purposes of relabeling/ repackaging." There will not be a similar requirement for having only products labeled as C II controlled drugs in retail pharmacies. Retail pharmacies may have in stock hydrocodone products labeled as either C II or C III. However, a pharmacy or wholesaler may send hydrocodone products back to the manufacturer for relabeling from a C III to a C II. This relabeling will be allowed if it occurs before December 8, 2014. A DEA form 222 or invoice would be used to record the transfer and reflect that the transfer occurred pursuant to the authority contained in this final rule.

No manufacturer may produce hydrocodone products after October 6, 2014 without obtaining an individual manufacturing quota. Products being returned for relabeling shall not be considered part of that quota.

Concern for safe storage of C II drugs. Retail pharmacies are not required by the Controlled Substance Act or DEA regulations to place schedule II controlled substances in a vault or safe. In accordance with **21 CFR 1301.75**(b), pharmacies may disperse schedule II controlled substances throughout their stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

Inventory: Although the time has passed, the law required that all registrants are required to inventory their hydrocodone products before business hours on October 6, 2014.They'll also need to keep a copy of this inventory in an easily retrievable file.