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# Client Alert

Special Matters & Government Investigations Practice Group

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## DEA Issues Proposed Rule Up-Scheduling Hydrocodone Combination Products from Schedule III to Schedule II

*Summary*

On February 27, 2014, the Drug Enforcement Administration (DEA) proposed an up-scheduling for hydrocodone combination products under the Controlled Substances Act (CSA) from Schedule III to Schedule II.

If the proposed rule is finalized, all of the entities and individuals who handle or prescribe hydrocodone combination products will be subject to the myriad regulatory controls governing Schedule II controlled substances.

Interested persons may submit written comments to DEA before midnight Eastern Time on April 28, 2014. The comments submitted and the identifying information of the commenter will be made part of the public record.

*Background*

Under the CSA, controlled substances are classified into one of five schedules based on their potential for abuse, their currently accepted medical use, and the degree of dependence they may cause. Currently, single-entity hydrocodone products are classified in Schedule II, but hydrocodone combination products that contain 15 milligrams or less of hydrocodone per dosage unit, or 300 mg or less of hydrocodone per 100 milliliters, are classified in Schedule III.

On December 16, 2013, following public hearings and solicitation of comments by the Food and Drug Administration, the Department of Health and Human Services submitted a scientific and medical evaluation to the DEA Administrator in support of a recommendation to reschedule hydrocodone combination products. Based upon HHS's evaluation and supporting data, and DEA's own analysis, DEA concluded that hydrocodone combination products have a high potential for abuse and should be rescheduled to Schedule II.

*Implications*

DEA's proposal will apply the increased regulatory controls for Schedule II substances to all hydrocodone products. These controls include[1]:

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- Increased security requirements for storage and handling, including storage in a safe or vault
- Revised labeling and packaging requirements
- Manufacturing quotas
- Ordering via DEA Form 222s
- Additional recordkeeping responsibilities, including exact counts for inventories
- Limitations on oral and faxed prescriptions
- Limitations on partial fills
- No refills

Because products containing hydrocodone are so widely prescribed, the rescheduling will impact a large number of entities—manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics.

Despite expressly acknowledging the large volume of these products in circulation and the broad effect of the rescheduling, DEA does not appear to fully grasp the impact of its proposal in terms of the time and financial investment that may be required for registrants to come into compliance. For example, some facilities may not be readily reconfigured to provide sufficient secure storage for the volume of hydrocodone combination products maintained, and the burden of conducting exact counts for these products will be significant. Written comments regarding these economic impacts may be critical to encouraging DEA ultimately to modify certain requirements for these products. At the least, DEA may provide an expanded timeline for implementing the rescheduling or grace periods for compliance with certain requirements.

DEA's proposed rule and its regulatory analysis also do not address the potential disruption of daily operations. For example, limits on prescriber authority for Schedule II substances—especially on mid-level practitioners' authority to prescribe these products[2]—may have a substantial impact on workflow in physician and clinic settings. In addition, mail order pharmacies that rely on the exemption in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 may be dissuaded from continuing to dispense hydrocodone combination products because Schedule II prescriptions do not fall within that exemption.

Some industry members may have experience with heightened requirements for hydrocodone products. At least one state (New York) has up-scheduled hydrocodone combination products.[3] Other states have added certain restrictions to address potential diversion.[4] But no state has mandated the full spectrum of federal Schedule II requirements (i.e., ordering via DEA Form 222s).

Given the volume of hydrocodone combination products that are manufactured, distributed, and dispensed, the proposed rescheduling will undoubtedly impact the day-to-day activities of every entity that handles these products. There may be good reasons for DEA to consider some flexibility when implementing this proposed rule. Industry members who are concerned about the potential effects of the rescheduling should act quickly to gather data and submit their comments to DEA before the April 28 deadline.[5]

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[1] 27 Fed. Reg. 11,037–45 (Feb. 27, 2014) (referring, *passim*, to 21 U.S.C. §§ 801–971 and 21 C.F.R. Parts 1300–1321).

[2] *See, e.g.*, O.C.G.A. § 43-34-25(k) (advanced practice registered nurse may only prescribe controlled substances in Schedules III–V); Ala. Code § 20-2-63(a) (physician assistant may only prescribe controlled substances in Schedules III–V).
[3] N.Y. Public Health Law § 3306.
[4] *See, e.g.*, 63 Okla. Stat. Ann. § 2-309(B)(3) (no refills); Tenn. Code Ann. § 53-11-308(e) (maximum of 30-day supply for opioids and benzodiazepines).
[5] Confidential business information may be submitted with comments and protected from public disclosure, provided the commenter complies with specific requirements set forth in the Federal Register Notice. 27 Fed. Reg. at 11038 (Supplementary Information: Posting of Public Comments).