KING & SPALDING

Client Alert

Special Matters & Government Investigations Practice Group

August 28, 2014

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

Summary

On August 22, 2014, the Drug Enforcement Administration (DEA) published a final rule upscheduling hydrocodone combination products (HCPs) under the Controlled Substances Act (CSA) from Schedule III to Schedule II.

The entities and individuals who handle or prescribe HCPs have only 45 days—until October 6, 2014—to come into full compliance with the increased regulatory controls that apply to Schedule II substances.

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. Prior to this final rule, single-entity hydrocodone products were classified in Schedule II, but HCPs that contain 15 milligrams or less of hydrocodone per dosage unit, or 300 mg or less of hydrocodone per 100 milliliters, were classified in Schedule III.[1]

In February, DEA issued a notice of proposed rulemaking giving notice of the potential rescheduling and inviting industry comment.[2] DEA received over 500 responses addressing the rescheduling itself as well as the method and timing of the rescheduling. DEA addressed and dismissed comments opposed to the rescheduling, concluding that HCPs are appropriately placed in Schedule II. It also declined requests to temporarily or permanently relax certain of the Schedule II restrictions on HCPs either.[3]

A number of industry members also asked for "sufficient time" to implement Schedule II restrictions through the supply chain and suggested an implementation period of six to twenty-four months with the opportunity for individual extensions. In response, DEA recognized 30 days as the standard implementation period and granted an additional 15 days here. It noted that "45 days to implement all schedule II handling requirements may

For more information, contact:

Catherine M. O'Neil
+1 404 572 2704
coneil@kslaw.com

Steve Cummings
+1 404 572 2753
scummings@kslaw.com

Shannon Cox
+1 404 572 4805
scox@kslaw.com

Coleen P. Schoch
+ 1 404 572 2708
cschoch@kslaw.com

King & Spalding
Atlanta
1180 Peachtree Street, NE
Atlanta, Georgia 30309-3521
Tel: +1 404 572 4600
Fax: +1 404 572 5100

www.kslaw.com

be perceived as short by some," but that the risk of drug diversion to the public health prevented it from extending the time any further.[4]

Implications

The burden of implementing these changes will be significant, and the time period for compliance is short. Entities handling HCPs have only 45 days to come into full compliance with all of the increased regulatory controls for Schedule II substances for all hydrocodone products. These controls include[5]:

- 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 222;
- Increased recordkeeping responsibilities, including exact inventory counts;
- Limitations on oral and faxed prescriptions;
- Limitations on partial fills;
- No refills; and,
- State-specific requirements, including those regarding mid-level practitioner prescribing and triplicate prescriptions

DEA noted that federal labeling requirements for commercial containers do not apply to dispensers. Dispensers may therefore continue to dispense HCPs from commercial containers labeled prior to the effective date as Schedule III until their stock is depleted. Dispensers also have the option to return these Schedule III-labeled HCPs upstream "in a similar manner to the return of expired controlled substances" using a DEA Form 222.

Manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, hospitals, and clinics must act quickly to modify their distribution and/or ordering practices for HCPs and expand existing Schedule II policies and procedures to all HCPs. They must also resolve any physical storage limitations to satisfy the requirement for increased security. Even actors who move quickly must prepare for disruptions in the supply chain, as some entities will undoubtedly respond more nimbly than others.

* * *

---

[1] 21 C.F.R. § 1308.13(e)(1).
[2] Notice of Proposed Rulemaking, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 27 Fed. Reg. 11,037 (Feb. 27, 2014).
[3] Final Rule, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49,661 (Aug. 22, 2014) (to be codified at 21 C.F.R. 1308).
[4] 79 Fed Reg. at 49,674–75.
[5] 27 Fed. Reg. 11,037–45 (referring *passim* to 21 U.S.C. §§ 801–971 and 21 C.F.R. Parts 1300–1321).