Drug Enforcement Administration (DEA) Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

Summary: on August 22, 2014, the Drug Enforcement Administration (DEA) published the Final Rule moving all hydrocodone combination products (HCPs) from Schedule III to Schedule II, effective 45 days from issuance, October 6, 2014. This Final Rule imposes the regulatory controls and sanctions applicable to Schedule II substances on those who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with, or possess) or propose to handle HCPs.

Effective date: October 6, 2014. In accordance with the Administrative Procedure Act, generally, DEA scheduling actions are effective 30 days from the date of publication of the final rule in the *Federal Register*. In order to ensure the continued availability of HCPs for legitimate medical use, while also ensuring they are not subject to misuse, abuse, and diversion, the DEA is establishing an effective date 45 days from the date of publication of this final rule. After careful consideration to the risk to public health and safety related to the diversion and abuse of HCPs, the DEA believes this 45-day period is a reasonable amount of time for registrants to comply with the handling requirements for a schedule II controlled substance and was established upon a full consideration of the totality of circumstances specific to HCPs.

Products affected: with the exception of Zohydro™ ER, all pharmaceuticals containing hydrocodone currently on the market in the United States are HCPs and are subject to this rulemaking. 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 HCPs approved as cough suppressants include Hycodan®, Mycodone®, Tussionex®, Pennkinetic®, Tussigon®, and several generics, plus additional combination products such as hydrocodone and ibuprofen (Vicoprofen®). Once the Final Rule becomes effective, all Schedule II requirements will become applicable to HCPs, including, but not limited to, the requirements related to DEA registration, security protocols, labeling and packaging, inventory, and recordkeeping and reporting.

Inventory and Labeling: the DEA estimates that 45 days is a reasonable amount of time for manufacturers and distributors to deplete existing inventory of HCPs. The DEA anticipates manufacturers to begin developing inventory of HCPs with schedule II labels prior to the effective date of the rule to have stock ready to be distributed upon effect of this rule. The packaging and labeling requirements for manufacturers and distributors do not apply to dispensers. Dispensers with HCPs in commercial containers labeled as schedule III may continue to dispense these HCPs after the implementation of this rule.

Prescriptions and Refills: no prescription for HCPs issued on or after October 6, 2014 shall be authorized for any refills. Although the CSA prohibits refills of prescriptions for schedule II controlled substances, a practitioner may issue multiple schedule II prescriptions in order to provide up to a 90-day supply of medication. Any prescriptions for HCPs that are issued before October 6, 2014 and authorized for refilling may be dispensed, if such dispensing occurs before April 8, 2015.

Electronic Prescriptions of Controlled Substances (EPCS): Schedule II prescriptions may be prescribed electronically in 47 states and the District of Columbia (MT currently does not allow EPCS while KS and VT allow only schedules III-V). Pharmacies that are not currently receiving electronic prescriptions for controlled substances (EPCS) but want to be ready by October 6 should immediately contact their pharmacy software vendor and request activation. A list of pharmacy software vendors certified for EPCS is available on Surescripts EPCS page.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX