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DEA FINAL RULE RESCHEDULES HYDROCODONE COMBINATION PRODUCTS FROM SCHEDULE III TO SCHEDULE II

EXECUTIVE SUMMARY

On August 22, 2014, the Drug Enforcement Administration ("DEA") released its final rule rescheduling hydrocodone combination products ("HCPs") from Schedule III to Schedule II of the Controlled Substances Act ("Final Rule"). This Final Rule went into effect on October 6, 2014 and applies to all persons who manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with or possess HCPs. As such, the Final Rule may affect operational processes throughout the health care supply chain, including manufacturers, distributors, pharmacies (retail, institutional and compounding), physician offices and post-acute care facilities.

BACKGROUND

The Controlled Substances Act ("CSA") and its implementing regulations are designed to prevent, detect and eliminate the diversion of controlled substances that have a potential for abuse and dependence. Under the CSA, controlled substances are classified into one of five schedules based on (i) its potential for abuse; (ii) the degree of dependence the substance may cause; and (iii) whether it currently has an accepted medical use in the United States. Schedule I substances are substances that have no currently accepted medical use and have a high potential for abuse. Schedule II substances include substances that have a currently accepted medical use and have a high potential for abuse. Substances with a progressively reduced potential for harm and abuse are further classified in Schedules III through V.

When the CSA was originally enacted, the DEA classified hydrocodone as a Schedule II substance; however, the DEA classified HCPs, which contain both hydrocodone and specified amounts of other substances such as acetaminophen or aspirin, as Schedule III drugs under the assumption that such combination drugs had a lesser likelihood of being abused. In 1999, the DEA received a petition from a physician to reschedule HCPs from Schedule III to Schedule II due to increased misuse and abuse of such drugs. For the past fifteen years, the DEA, in conjunction with the FDA and HHS, has conducted a scientific and medical evaluation of the health benefits and risks of HCPs and concluded that HCPs have a high potential for abuse. As such, the DEA published a Notice of Proposed Rulemaking on February 27, 2014 to reschedule HCPs from Schedule III to Schedule II of the CSA. The DEA finalized this recommendation in a Final Rule published on August 22, 2014. This Final Rule went into effect on October 6, 2014.

EFFECTS ON THE HEALTH CARE SUPPLY CHAIN

The DEA's decision to reschedule HCPs from Schedule III to Schedule II affects the entire drug supply chain, as it applies to "all persons who manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with, or possess" HCPs. Some of these effects include the following:

Registration. Registrants authorized to handle Schedule I or II controlled substances will now have to use official DEA Form 222 to for each "distribution" of HCPs, rather than simple invoices or packing slips as with Schedule III drugs.[1]

Security. Manufacturers and distributors will have to store HCPs in locked vaults rather than in steel cages.[2] However, pharmacies and institutional practitioners may continue to store HCPs in a securely locked, substantially constructed cabinet.[3]

Labeling and Packaging. Under the Final Rule, it is now unlawful for commercial containers of HCPs to be distributed without bearing the label properly identifying them as Schedule II (C-II) controlled substances.[4] However, a registrant may transfer legacy commercial containers of HCPs bearing the C-III label back upstream to manufacturers in order to have such containers correctly relabeled as C-II controlled substances. Registrants transferring HCPs upstream must still utilize DEA Form 222, as required in accordance with law.[5] It is important to note that the Final Rule's requirements pertaining to labeling of commercial containers only apply to manufacturers and distributors and then only after HCPs distributed on or after 45 days after August 22, 2014, as the DEA has indicated that it will not enforce requirements related to HCP C-II labeling of commercial containers of controlled substances from which drugs are dispensed. As such, dispensers need not

return HCPs that are incorrectly labeled as "C-III" and may continue to dispense such products after the rescheduling takes effect.

Quotas. As of October 6, 2014, a registrant required to obtain an individual manufacturing quota may not manufacture HCPs unless it has received an individual manufacturing quota for such quantities of HCPs.[6] Similarly, a registrant required to obtain a procurement quota shall not procure HCPs unless a procurement quota is granted for such quantities of HCP to be procured. On the other hand, if HCPs were returned to a manufacturer that is authorized to produce both Schedule II and Schedule III substances, then the manufacturer may relabel/repackage HCPs without obtaining a procurement quota for such activity, provided (i) the manufacturer returns the same quantity and strength of HCPs back to the registrant; and (ii) a DEA Form 222 records the transfer and reflects that the transfer occurred pursuant to the authority contained in the Final Rule. All such relabeling/repackaging of HCPs must be completed before **December 8, 2014**; otherwise, the manufacturer will need to obtain a procurement quota to carry out such activities. Distributors, however, may continue to return any incorrectly labeled HCPs to manufacturers after this date.[7]

Inventory. Under existing regulations, all DEA registrants must take an inventory of all stocks of a controlled substance on hand as of the effective date of a rule adding the substance to any schedule of the CSA, including the rescheduling of a substance.[8] As such, all registrants that currently have HCPs in stock should conduct an inventory of HCPs if they have not done so already. Dispensers, researchers and reverse distributors should note that while they were previously able to make an estimate of tablets or capsules in a commercial container that had been opened (unless such container held more than 1,000 tablets, in which case an exact count was required) when HCPs were a Schedule III substance, such registrants must now make an exact count of the contents of any open commercial containers when reporting their inventory of HCPs, pursuant to inventory requirements for Schedule II substances.[9]

Conflicts with State Laws. Some states impose additional safeguards and requirements on Schedule II controlled substances. Any limitations imposed by state law that do not conflict with or contravene federal requirements will apply, in addition to those corresponding requirements under federal law.[10]

PRACTICAL TAKEAWAYS:

- All registrants should conduct an inventory of HCPs pursuant to existing regulations; however, dispensers, researchers and reverse distributors should particularly note inventory requirements for Schedule II drugs that require an exact count of such products.
- Manufacturers and distributors should review all inventory of HCPs to ensure that the labeling/packaging is properly classified as a Schedule II substance;
- All persons who handle HCPs should ensure appropriate physical security controls are in place;
- Manufacturers should communicate with downstream distributors to coordinate relabeling/repackaging of HCPs prior to December 8, 2014;
- Registrants and registrant employees should be adequately trained with respect to HCPs as Schedule II controlled substances (e.g., ordering, registration scope);
- All persons who handle HCPs should review applicable laws in the state or states in which they manufacture, distribute or dispense HCPs to determine whether any additional state requirements apply.

If you have any questions or would like additional information about this topic, please contact:

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[1] See generally 21 C.F.R. §1305

[2] 21 C.F.R. §1301.72

[3] 21 C.F.R. §1301.75(b)

[4] 21 C.F.R. §1302.05 ("All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule shall comply with the requirements of §1302.03, on or before the effective date established in the final order for the transfer or addition.")

[5] 21 C.F.R. §1305.03

[6] 21 C.F.R. §1303.21

[7] 21 C.F.R. §1307.12

[8] 21 C.F.R. §1304.11(d)

[9] 21 C.F.R. §1304.11

[10] 21 C.F.R. §1307.02