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CLIENT ADVISORY

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DEA's Rescheduling of Hydrocodone Combination Products Will Lead to Stricter Controls

On Friday, August 22, 2014, the Drug Enforcement Agency ("DEA") issued a Final Rule rescheduling hydrocodone combination products ("HCPs") from Schedule III into Schedule II. The Final Rule will become effective on October 6, 2014, by which time all parties involved in the manufacturing, distribution, prescribing, and dispensing of HCPs will have to comply with the more stringent regulatory controls placed on Schedule II controlled substances. Hydrocodone by itself has always been listed as a Schedule II drug, but products that contained both hydrocodone and specified amounts of other substances, such as acetaminophen or aspirin, had been listed in Schedule III, which requires less onerous prescribing and control requirements. This change will also affect such products as Vicodin and Lortab. The DEA has long been considering the rescheduling of HCPs based upon the potential for abuse and diversion of drugs containing hydrocodone.

The reclassification into Schedule II will impact the practices of all practitioners primarily including practitioners with prescriptive authority and pharmacists, but ultimately impacting all industries involved in the manufacture, supply, and distribution of HCPs.

Specifically, prescribers will no longer be able to authorize refills for HCPs and will be limited to prescribing a 30-day supply. However, the DEA noted that prescribers can issue multiple prescriptions for up to a 90-day supply. This change has caused concerns among practitioners as it will likely necessitate additional practitioner visits to allow for additional prescriptions. Further, while verbal prescriptions will be allowed in emergency situations, prescribers will no longer be able to phone or fax in prescriptions for HCPs. The practice of mid-level practitioners such as nurse practitioners or physician assistants may also be impacted if their state scope of practice limits their ability to prescribe Schedule II controlled substances or their current practice agreement with a supervising or collaborating physician similarly limits their prescriptive authority by not allowing mid-levels to issue prescriptions for Schedule II drugs.

The rescheduling will also change the process required to order and transfer HCPs between DEA registrants, such as from a distributor to a pharmacy. Previously, because HCPS were listed in Schedule III, DEA registrants could transfer HCPs through simple invoices, packing slips, or other similar documentation. But now, all registrants will have to use the official DEA Form 222 or its electronic equivalent to place an order or distribute HCPs.

Further, the new classification will place added burdens on manufacturers and distributors who will have to store HCPs in secure vaults rather than locked cages and will have to label all HCPs with a "C-II" designation. The DEA noted, however, that the packaging and labeling requirements applicable to manufacturers and distributors do not apply to dispensers such as pharmacies. Therefore, the DEA specified that dispensers with HCPs in commercial containers labeled as Schedule III may continue to dispense these medications after the effective date of the final rule. Further, only manufacturers and distributors, and not retail pharmacies, are required to place Schedule II drugs in a locked vault. Retail pharmacies may disperse HCPs throughout their stock of non-controlled substances in a manner so as to obstruct the theft or diversion of the HCPs.

If you have questions regarding the DEAs final rule to reclassify HCPs from Schedule III into Schedule II please feel free to contact Clay Landa, clanda@hdjn.com, or Mary Malone, mmalone@hdjn.com. They can also be reached by phone at (804) 967-9604. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.

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