DEA Reschedules Hydrocodone Combination Medications

Background
To address the opioid epidemic that has been plaguing our nation, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. The FDASIA required the Food and Drug Administration (FDA) to hold a public meeting to evaluate rescheduling hydrocodone combined products, as well as evaluate both the health risks and health benefits of these drugs. In its December 2013 report, HHS concluded that individuals are using hydrocodone combined products in amounts sufficient to create a hazard to their health or the safety of others, that individuals are taking HCPs on their own initiative rather than on the basis of medical advice from a licensed medical doctor, and that there is significant diversion of hydrocodone combined products.1

Based on HHS’ recommendation and in alignment with single ingredient hydrocodone products that are currently schedule II drugs (e.g. Zohydro ER), the Drug Enforcement Agency (DEA) published its final rule on August 22, 2014, reclassifying all hydrocodone combination medications from schedule III to schedule II drugs. This rule is to become effective within 45 days.1 Movement to a higher schedule signifies recognition of an increased risk of abuse as well as a greater severity of psychological or physical dependence when the medication is abused.2

Our Stance and Impact to You
Hydrocodone combined with acetaminophen (e.g. Lortab®, Norco®, Vicodin®, and generic drugs) is the most common opioid prescribed in workers’ compensation. Rescheduling of hydrocodone combined products to class II is expected to reduce overall utilization as well as inappropriate use due to limitations involved with prescribing. Unlike schedule III medications, which can be phoned in to the pharmacy and can be refilled up to five times, prescriptions for schedule II drugs must be in writing, and no refills are allowed on the same prescription.

When the final rule becomes effective on October 1, 2014, all remaining refills on prescriptions for hydrocodone combination products will be voided by dispensing pharmacies. Claimants will need to obtain a new written prescription from their healthcare providers.

For questions regarding this eAlert or to learn more about Healthcare Solutions’ Clinical Rx Services, please contact your dedicated Account Executive.

Sources

Disclaimer
This alert is offered as a general summary of information retrieved from a variety of sources, including scientific literature and clinical experience. We seek to provide useful, current reference material, but do not claim to provide a comprehensive review and cannot guarantee the accuracy of information presented. Opinions are those of individual authors, and do not necessarily represent the recommendation or endorsement of Healthcare Solutions. This communication does not constitute medical advice.