Clinical Pearls

MEDICATION THERAPY SOLUTIONS, INC.

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DEA ISSUES FINAL RULING ON HYDROCODONE RESCHEDULING COMBINATION PRODUCTS

**EFFECTIVE OCTOBER 6, 2014*

On August 22, 2014, the DEA issued a final rule which reschedules **hydrocodone** combination products **from schedule III to schedule II of the Controlled Substances Act**. This imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, conduct chemical analysis with, or possess) or propose to handle hydrocodone combination products.

REVIEW OF DEA DRUG SCHEDULES	
Schedule I	• Drugs with no currently acceptable medical use and high abuse potential. • The most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence.
Schedule II	• Drugs with high potential for abuse (less than Schedule I), with use leading to severe psychological or physical dependence. • ***Must be written by a physician on a triplicate form, and no refills are allowed***
Schedule III	• Drugs with a moderate to low potential for physical and psychological dependence. • Less abuse potential than schedule I and II drugs.
Schedule IV	• Drugs with a low abuse potential and low risk of dependence.
Schedule V	• Drugs with lower potential for abuse than schedule IV and consist of preparations containing limited quantities of certain narcotics. • Generally used for antidiarrheal, antitussive, and analgesic purposes.

Senior Care Pharmacy concerns about DEA's rescheduling of hydrocodone combination products:

- ✓ Delays to pain-relief will increase for post-acute and long-term care patients.
- ✓ Opioid abuse is not prevalent in LTC settings due to regulation by consultant pharmacists and provider pharmacies.
- ✓ Limited options exist for non-schedule II pain medications.
- ✓ Many patients in LTC facilities live with chronic pain and need relief in a timely manner.
- ✓ Schedule II prescriptions must be written by a doctor every month and no refills are allowed, making it more difficult for the patients to obtain their pain meds.

What is Pain?

Acute pain: *recent onset, transient, and usually from an identifiable cause*
Chronic or persistent pain: *ongoing or recurrent pain, lasting beyond the usual course of acute illness or injury or more than 3 to 6 months, and which adversely affects the individual's well-being.*
Chronic pain classifications:

- *Nociceptive – due to ongoing tissue injury*
- *Neuropathic – resulting from damage to the brain, spinal cord, or peripheral nerves*
- *Mixed or undetermined causes*

Classes of medications for treatment of pain:

- *Non-opioids: aspirin, NSAID (BEERs LIST), acetaminophen*
- *Opioids: morphine, codeine, hydrocodone, oxycodone, methadone*
- *Tramadol (not an opioid but works primarily on the same receptors as opioids)*
- *Adjuvant analgesics: may be helpful for specific types of pain*
  - *Some antidepressants – amitriptyline, nortriptyline, venlafaxine, duloxetine –for neuropathic pain, migraines, fibromyalgia, RA*
  - *Anti-seizure meds – gabapentin, pregabalin, topiramate, lamotrigine, carbamazepine –for nerve-related pain*
- *Other: Drugs with no direct pain-relieving properties - drugs to treat insomnia, anxiety, depression, and muscle spasms*
  - *Baclofen, cyclobenzaprine, methocarbamol, diazepam, lorazepam, SSRIs*

DEA PLACES TRAMADOL INTO SCHEDULE IV CATEGORY
EFFECTIVE AUGUST 18, 2014

Effective August 18, 2014, all manufacturers will be required to print the designation "C-IV" on every bottle, and it is unlawful for commercial containers of tramadol to be distributed without that designation. In addition, all DEA registrants will be required to take an inventory of all tramadol stock. Tramadol will now be treated as any other controlled drug.

Zohydro ER (hydrocodone bitartrate extended-release)

Drug: The only single-entity (not containing acetaminophen) hydrocodone product available (Schedule II)
Indication: management of pain severe enough to require daily, around-the-clock long-term treatment and for which alternative treatment options are inadequate.
Dosage forms: 10mg, 15mg, 20mg, 30mg, 40mg, and 50mg capsules.
Approved on October 25, 2013

TEST YOUR KNOWLEDGE! (multiple choice)

1. After the new laws go into effect, which of the following prescriptions would be allowed to be **called in** by a physician (or designated agent)?
A. Norco 5/325 1 tab po q4-6hr
B. Tramadol 50mg 1 tab po q4-6hr
C. Zohydro ER 10mg 1 cap po q12hr
D. Hydrocodone/APAP 10/325 1 tab po q4-6hr

2. Which of the following is a **serious** adverse effect of tramadol?
A. Constipation
B. QT prolongation
C. Abdominal hemorrhage
D. Seizures

3. How can a schedule II drug be dispensed by a pharmacy for a LTC facility? ***(select all that apply)***
A. Prescription written by a doctor
B. Faxed prescription from a doctor indicating it is for a "LTCF"
C. Prescription called in by a nurse
D. Emergency supply called in by a physician

4. What is the maximum amount of acetaminophen ingestion per day does the FDA recommend for a healthy patient?
A. 3000mg
B. 3500mg
C. 4000mg
D. 5000mg

Answers: 1.B; 2.D; 3.A,B,D; 4.A