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State: NA
DEA's Proposed Tougher Opioid Control Seen Beneficial, Expensive: Top [2014-03-21]

By Mark Larson, Reporter
The Drug Enforcement Administration's proposal to reclassify hydrocodone-combination products as a more strictly regulated Schedule II controlled substance will mark a big step toward controlling the opioid overprescribing rampant in workers' compensation for years, but could also bring huge administrative costs to the industry, analysts say.

The agency may complete the public hearing process and approve the rule by this fall, say industry observers, with an industry compliance likely mandated by mid-2015. An unofficial version of the Feb. 27 notice of proposed rulemaking can be viewed on the DEA's website here.

The change, said PMSI's brief, will bring stricter administrative requirements for the use and handling of specific HCPs, such as registration, labeling and packing, prescribing and dispensing provisions. States can also impose their own additional prescribing and dispensing restrictions. These changes would impact formularies, clinical escalation alerts and adjudication edits, said PMSI. What's more, the company said that any processes tied to the Schedule II status of drugs would need to be applied to HCPs should they be reclassified.

HCPs are pharmaceuticals containing specified doses of hydrocodone, which by itself is already a Schedule II substance, in combination with another drug, and they are commonly prescribed by workers' compensation physicians for pain relief and treatment.

Kevin Tribout, executive director of government affairs for medical-management firm PMSI, said he expects a general increase in awareness of the problem to come from the federal government turning its attention to it. "We'd like people in workers' compensation to start talking about it, pharmacy benefits managers, doctors, pharmacies, to get involved in the development of solutions," he said. "If they do that, it's going to have a huge impact on workers' compensation."

But Tribout said the reclassification could also cause problems for figuring out new treatment protocols for injured workers needing pain relief if at some point they've used up their limit and can't get a prescription refill. "If dispensing of HCPs is curbed to patients using them for pain, how do you stop prescribing them before an addiction stage begins?" he said. Prescription refills could be disallowed after 30 days of treatment, he said. But weaning patients off the pain drugs, he added, "is the tough piece" of dealing with stricter controls of HCPs.
Phil Wells, chief clinical compliance officer for myMatrixx, a pharmacy benefit management firm based in Tampa, said Thursday he wonders whether doctors will cut back on their overprescriptions of HCPs even if they're more strictly controlled as Schedule II drugs.
In the 1970s and 1980s, he said, physicians were more careful about the dangers of prescribing Schedule II

drugs than they are today. Oxycodone, he said, is a heavily prescribed generic pain reliever that is already a Schedule II opioid. The brand name version of it is Oxycontin.

"Schedule II doesn't restrict Oxycodone," he said. "If it did, we wouldn't have this problem."

Wells said he favors HCPs becoming Schedule II drugs, but added, "I'm fearful it's going to have little impact," on curbing the overprescribing/patient pain med addiction problem.

The federal Controlled Substances Act, passed in 1970, he said, is largely ignored. "It's no longer working to protect the public," he said. "We should not have a problem with prescription drugs."

Wells praised controls in Connecticut's workers' compensation system requiring a second doctor's opinion before opioids can be prescribed and credited the rules for a decline of opioid use in that state. He called on the American Medical Association to step into the opioid overprescription problem to promote solutions.

When the AMA campaigned several years ago about the dangers of taking too many antibiotics, doctors listened and were convinced to change their treatments, Wells said.

But Wells added if opioids are cut off from patients addicted to them, people are likely to turn to the street to get a cheaper, easily obtainable and more powerful substitute: heroin.

That's why, he said, the weaning of opioid-addicted patients must be addressed in solving the back end of the problem. Not only are detox programs needed, he said, but so is psychological counseling, all of which are expensive to set up and run.

"Addiction just doesn't go away," he said.

Michael Gavin, president of Prium, a medical cost-containment company, said Thursday he thinks the Schedule II classification of HCPs will work to curb physician overprescribing of opioids as pain treatments to injured workers.

He predicted reclassification will drive huge administrative expenses in the workers' compensation industry. "But we still have to do it," he said.

"This is sending a notice to physicians that this is a dangerous drug," said Gavin. "They can no longer phone in prescriptions for it." Office examinations will be required and prescriptions written from them, he said. "They're going to have to change their prescription patterns in response to this."

HCP overprescribing "far and away" exceeds that of opioids already classified as Schedule II, said Gavin. He praised a provision of New York's law that exempts from HCP controls hospices and assisted-living facilities, where there is typically a legitimate need for pain med prescription renewals.

The federal Department of Health and Human Services initially recommended that HCPs be reclassified, according to a government affairs brief posted online Tuesday by PMSI, a workers' compensation pharmacy service provider. The DEA evaluated available data, said PMSI, and concluded from its research that HCPs:

- Have a high potential for abuse, similar to that of Schedule II substances.
- Have a currently accepted medical use in treatment in the United States.
- May lead to severe psychological or physical dependence when abused, similar to Schedule II substances.

The federal controlled-substance classifications are the national minimum. New York's "I-Stop" legislation reclassified hydrocodone combinations as Schedule II drugs in 2012. Many other states, like the federal government, classify HCPs as Schedule III drugs with less controls, but PMSI says "there has been a noticeable

focus recently on placing stricter controls" on hydrocodone in other states.