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Pharmacies and Suppliers Beware: It Is Not Just the Pill Mills They Are After

DEA's recent position against a national pharmacy chain and a wholesale distributor expands the proactive monitoring and auditing requirements for pharmacies and wholesale distributors to include site visits and possibly medical necessity reviews.

On February 29, the U.S. District Court for the District of Columbia lifted a temporary restraining order preventing the enforcement of an Immediate Suspension Order (ISO) issued by the U.S. Drug Enforcement Administration (DEA). The ISO suspending Cardinal Health Inc.'s (Cardinal's) controlled substance distribution license for its Lakeland, Florida, facility can now be enforced. In issuing its decision, the court agreed with DEA's assertion that drug distributors have an affirmative obligation to monitor for and investigate evidence of diversion. The decision has implications for both distributors and pharmacies, as DEA's position expands the proactive monitoring and auditing requirements for pharmacies and wholesale distributors to include site visits and possibly medical necessity reviews.

Background

DEA investigated Cardinal's Lakeland, Florida, facility and two pharmacies run by a major national pharmacy chain as part of its ongoing efforts to combat Florida's prescription drug abuse epidemic. On February 2 and 3, DEA served an ISO to Cardinal, alleging that the distributor failed to implement controls to monitor for and detect diversion. For instance, the DEA investigation found that Cardinal shipped 50 times as much oxycodone to its four top pharmacies in Florida as it did to its other retail customers.

DEA also served ISOs to two locations of a national retail pharmacy chain due to alleged failures in monitoring the prescribing and dispensing of controlled substances, stating that both pharmacies filled prescriptions in excess of the legitimate needs of the pharmacies' patients. The DEA found, for example, that while the average pharmacy orders 69,000 units of oxycodone per year, the two pharmacies in Florida collectively ordered substantially more units of oxycodone. Therefore, DEA alleged that the pharmacies "knew, or should [have] known," that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.

The February 2012 ISO is not the first time Cardinal has received an ISO related to the distribution of controlled substances. In December 2007, DEA issued an ISO to Cardinal's Lakeland, Florida, facility "due to the distribution of hydrocodone to 'rogue' internet pharmacies." The December 2007 ISO resulted in Cardinal paying a $34 million fine and agreeing to an Administrative Memorandum of Agreement (MOA) that required Cardinal to "maintain a compliance program designed to detect and prevent diversion of controlled substance as required under the Controlled Substances Act and applicable DEA regulations."

Implications for Distributors and Pharmacies

If DEA's expressed position in the Cardinal hearings is upheld, pharmacies and wholesale distributors now have

an affirmative obligation to monitor for and investigate evidence of diversion, or put their DEA license at risk. DEA has long had a "suspicious orders reporting" program. But now, according to DEA and the court, pharmacies and wholesale distributors that hold DEA registrations are obligated to police themselves and their customers and proactively investigate drug diversion.

According to the U.S. Department of Justice (DOJ), wholesale distributors are DEA's first line of defense and have an obligation to ensure, through site visits, audits, and other proactive efforts, that the controlled substances they distribute are not being abused. During Cardinal's preliminary injunction hearing, DOJ stated, and the court agreed, that wholesale distributors "have an obligation to police themselves."

Pharmacies will also need to monitor patient profiles and controlled substance prescriptions patterns to detect patterns of diversion or abuse. While historically there has been a deference by pharmacists to a physicians' authority to prescribe, under DEA's position pharmacists will be required to be more proactive and use their professional judgment to question the legitimate medical purpose behind a controlled substance prescription. Whether DOJ and DEA will use same policy standards for pharmacies that they highlighted in the Cardinal hearing remains to be seen. While it waits for the hearing, the pharmacy chain has agreed to stop dispensing oxycodone in the two Florida pharmacies and to notify 22 high-prescribing Florida physicians that it will no longer fill their prescriptions for controlled substances. If DOJ and DEA do use the same policy standards, pharmacies may be required to put additional proactive procedures in place for reviewing prescription patterns and patient medical records.

Finally, DEA has made clear that it is not focusing on just independent or small chain pill mill facilities. In DEA's February 6 press release relating to the ISOs, DEA emphasized that its "recent efforts go beyond 'Mom and Pop' businesses." DEA is also focusing on large and small chain distributors, prescribers, and pharmacies that dispense and distribute controlled substances. Therefore, all pharmacies and distributors should have in place compliance procedures and training modules that relate to medical necessity reviews and auditing procedures for controlled substance prescriptions.

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