DEA Enforcement Update: Purdue Pharma, Red Flags, and Possible New Requirements for Handling Suspicious Orders

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Recent U.S. Drug Enforcement Administration (DEA) enforcement activity continues to focus on the ongoing effects of the nation's opioid addiction crisis. Enforcement actions by the Department of Justice (DOJ) on behalf of the DEA as well as the agency's administrative registration revocation proceedings reflect the vigor of the government's enforcement work and reveal its continuing focus on investigating alleged wrongdoing by both business organizations and individuals dealing with controlled substances.

This white paper, brought to you by the experts at Thompson Controlled Substances, tracks the latest DEA enforcement trends, analyzes important recent cases and settlements, and outlines an important proposed agency rule on how to handle suspicious controlled substance orders.

I. DOJ's $8 Billion Global Settlement with Purdue Pharma L.P.

In November 2020, a federal bankruptcy court in New York approved an $8 billion global settlement between the opioid manufacturer Purdue Pharma L.P. and the DOJ (*In re Purdue Pharma L.P.*, No. 7:19-bk-23649-RDD (Bankr. S.D.N.Y.)).

The settlement included the company's agreement to plead guilty to a criminal charge of defrauding the United States in part by impeding the operations of the DEA for nearly 10 years "in order to maximize profits from the sale of its opioid products."

The action by the U.S. Bankruptcy Court for the Southern District of New York advances the resolution of criminal and civil investigations into the company and individual shareholders from the Sackler family that had focused on the company's marketing of its opioid drugs.

The global settlement, announced in October 2020, included criminal penalties totaling more than $5.5 billion, the largest ever levied against a pharmaceutical manufacturer.

As part of the settlement, Purdue Pharma agreed to plead guilty in the U.S. District Court for the District of New Jersey to one count of dual-object conspiracy to defraud the United States and to violate the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as two counts of conspiracy to violate the federal Anti-Kickback Statute (*United States v. Purdue Pharma L.P.*, No. 2:20-cr-1028-MCA (D.N.J.)).

To resolve the criminal charges, the company agreed to pay a criminal fine of $3.544 billion and to pay $2 billion in criminal forfeiture.

The company also agreed to pay $2.8 billion to resolve civil liability under the False Claims Act. In addition, members of the Sackler family agreed to pay $225 million to resolve civil false claims liability.

The DOJ stressed that the resolutions "do not include the criminal release of any individuals, including members of the Sackler family, nor are any of the company's executives or employees receiving civil releases."

Conversion to Public Benefit Company

Under the global resolution, Purdue Pharma would emerge from bankruptcy as a public benefit company (PBC) owned by a trust or a similar entity "designed for the benefit of the American public, to function entirely in the public interest," federal enforcement officials said.

The PBC would continue to "endeavor to deliver legitimate prescription drugs," the DOJ said, but it also "will aim to donate, or provide steep discounts for, life-saving overdose rescue drugs and medically assisted treatment medications to communities." Proceeds from the trust "will be directed toward state and local opioid abatement programs," the department added.

Because of the value that state and local governments would realize through the PBC, the DOJ said, the department was "willing to credit up to $1.775 billion against the $2 billion forfeiture amount." The company was to pay the remaining $225 million of the criminal forfeiture on the effective date of the bankruptcy.

Plea Agreement

Under the terms of a 96-page plea agreement, Purdue Pharma admitted that between May 2007 and March 2017 it conspired to defraud the United States by impeding the lawful function of the DEA by telling the agency that it maintained an effective anti-diversion program, as required by the Controlled Substances Act.

However, in fact, according to the DOJ, the company "continued to market its opioid products to more than 100 health care providers who the company had good reason to believe were diverting opioids and by reporting misleading information to the DEA to boost Purdue's marketing quotas" — information consisting of prescription data that included prescriptions written by physicians that the company knew to be engaging in diversion.

According to a 93-page criminal information filed against Purdue Pharma, the company provided the DEA with figures that it claimed constituted the total current sales and prescription trends for its opioid products, but failed to inform the agency that those sales figures included prescriptions written by prescribers who the company knew were engaging in diversion or were willfully blind to their unlawful conduct.

The government also alleged that Purdue Pharma participated in the unlawful diversion of its opioid products by promoting its products to health care providers who wrote medically unnecessary and unlawful prescriptions for its drugs that were subsequently dispensed through pharmacies.

In support of its annual requested quota allocation of Schedule II controlled substances, the company provided the DEA with data concerning the quantity and sales volume of prescriptions for its controlled substances but knowingly and intentionally failed to inform the DEA that "a significant portion of the prescriptions reported (valued at over $1.17 billion between May 2007 and February 2018) were written by … prescribers that Purdue Pharma either knew or believed to be engaged in diversion."

The company's participation in conspiracy to violate the FD&C Act took the form of facilitating the dispensing of OxyContin and other Purdue Pharma opioid products without a medical purpose and thus without lawful prescriptions.

The charges of conspiracy to violate the Anti-Kickback Statute focused on two company practices:

- Between June 2009 and March 2017, Purdue Pharma paid two doctors through its speaker program to induce them to increase the number of prescriptions that they wrote for the company's opioid drug products.

- Between April and December 2016, Purdue Pharma paid Practice Fusion Inc., an electronic health records (EHR) company, for referring, recommending or arranging for the ordering of the company's extended-release opioid pain medications, including OxyContin, Butrans and Hysingla. In January 2020, Practice Fusion agreed to pay $145 million to resolve civil and criminal allegations that it solicited and receive illegal kickbacks from Purdue Pharma to adjust its EHR software in a way that produced alerts to health care providers that would encourage them to prescribe the company's extended-release opioids.

Civil Settlements

Civil settlement with Purdue Pharma. Under the civil settlement with Purdue Pharma, the federal government will have an allowed, unsubordinated, general unsecured bankruptcy claim for recovery of $2.8 billion.

The payment was to be paid to resolve allegations that between 2010 and 2016 the company caused false claims for reimbursement to be filed with Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Program and the Indian Health Service.

According to the DOJ, the false reimbursement claims resulted from Purdue Pharma's promotion of its opioid drug products to health care providers who the company knew were prescribing the products for unsafe, ineffective and medically unnecessary uses and whose prescribing practices often led to drug abuse and diversion.

"For example," the DOJ alleged, "Purdue learned that one doctor was known by patients as 'the Candyman' and was prescribing 'crazy dosing of OxyContin,' yet Purdue had sales representatives meet with the doctor more than 300 times."

Federal officials identified three alleged kickback schemes aimed at inducing sales of Purdue Pharma's opioid drugs:

- The company paid physicians kickbacks in the form of purported reimbursement for giving educational talks to other providers and for serving as consultants.

- It paid kickbacks to Practice Fusion for adjusting its EHR software to encourage providers to prescribe Purdue Pharma's extended-release opioid drugs.

- It contracted with specialty pharmacies to fill prescriptions for its opioid drugs "that other pharmacies had rejected as potentially lacking medical necessity."

Civil settlement with the Sackler family. The government alleged that, despite knowing that the legitimate market for Purdue Pharma's opioid drug products had contracted, five members of the Sackler family who were targets of the DOJ's civil investigation asked company executives "to recapture lost sales and increase Purdue's share of the opioid market," according to the department.

Also, beginning in 2013, the five Sacklers approved a Purdue Pharma marketing program called "Evolve to Excellence," the DOJ said. The program allegedly directed company sales representatives to intensify their marketing of OxyContin to "extreme, high-volume prescribers who were already writing 25 times as many OxyContin scripts as their peers, causing health care providers to prescribe opioids for uses that were unsafe, ineffective and medically unnecessary, and that often led to abuse and diversion."

Company 'Accepts Responsibility'

In a statement, Purdue Pharma said that it "accepts responsibility" for the misconduct detailed in the plea agreement. "Importantly," the company said, "the overwhelming majority of these settlement funds will be directed to state, local and tribal governments to address the opioid crisis."

The company also said that it had entered into the civil settlement "to avoid the delay, uncertainty and expense of protracted litigation."

Purdue Pharma Chairman Steve Miller said that the company "deeply regrets and accepts responsibility for" the criminal misconduct. He noted that the settlement agreement "will pave the way for Purdue to submit a plan of reorganization to the bankruptcy court" that will transfer the company's assets to the PBC, which he said "ultimately will deliver more than $10 billion in value to claimants and communities."

"Purdue today is a very different company," Miller said. "We have made significant changes to our leadership, operations, governance and oversight."

He noted that the company had stopped promoting opioids to health care professionals, eliminated its sales force, appointed a new president and chief executive officer, accepted the resignation of all Sackler family members from its board of directors, and agreed to have an independent monitor review its compliance with a voluntary injunction "that further restricts the company's promotion of its opioid medications."

Sackler Family Statement

In a separate statement, members of the Sackler family who had served on the company's board said that they had "acted ethically and lawfully."

"As members of the board," they said, "we adopted rigorous policies requiring Purdue to be in full compliance with the law. The board relied on repeated and consistent assurances from Purdue's management team that the company was meeting all legal requirements."

The Sackler family members also said that the proposed resolution "has been valued at $10-$12 billion — more than double all Purdue profits the Sackler family retained since the introduction of OxyContin."

They also said that no member of the family had been involved in the conduct outlined in the company's plea agreement or had served in a management role at the company during the relevant time period.

Criticism from States, Congress

In a letter to Attorney General William P. Barr, the attorneys general of 25 states said that they opposed the proposal to preserve Purdue Pharma's "infamous" OxyContin business as a public trust.

"A business that killed thousands of Americans should not be associated with government," they said. "Instead, the business should be sold to private owners, so the government can enforce the law against it with the same impartiality as for any other company."

Also in letters to Barr, dozens of Democratic House members and 15 Democratic and independent members of the Senate criticized the proposed PBC arrangement, saying that it would force state and local governments "to assume an indefinite obligation to direct the operations of an opioid manufacturer" and improperly align the governments' interests with increasing the sale of opioids.

The DOJ noted that its global settlement did not resolve claims that states may have against Purdue Pharma or members of the Sackler family.

II. Recent DEA Enforcement and Revocation Actions Citing Red Flags for Diversion

(1) Georgia Pharmacist Owner Accused of Ignoring Red Flags for Diversion, Failing to Maintain Records

A pharmacist and pharmacy in Georgia were charged with dispensing thousands of doses of prescription opioids despite the presence of red flags indicating that the prescriptions were illicit, the DEA announced in February 2020 (*United States v. Chip's Discount Drugs, Inc.*, No. 2:20-cv-00010-LGW-BWC (S.D. Ga.)).

A civil complaint filed in the U.S. District Court for the Southern District of Georgia alleged that pharmacist Rogers Wood, owner of Chip's Discount Drugs in Hazlehurst, Georgia, knew or should have known that many of the prescriptions filled were not legitimate.

According to prosecutors, the red flags that were ignored included numerous patients traveling long distances to get prescriptions filled, the same patients receiving simultaneous prescriptions for similar drugs, prescriptions for the same drugs in multiple strengths, daily doses higher than medically necessary, a disproportionate level of cash sales, and prescriptions for drug combinations well-known to be commonly abused.

Specifically, according to federal prosecutors, the pharmacy dispensed more than 350,000 units of controlled substances prescribed by Dr. Frank Bynes Jr., who in February 2020 was sentenced to serve 240 months in prison after being found guilty by a federal jury on 13 counts of unlawful dispensation of controlled substances and three counts of health care fraud.

The pharmacy dispensed the drugs despite "obvious evidence Bynes was operating a pill mill," the government said. The red flags included the following:

- Most patients traveled between four and six hours to obtain prescriptions for commonly abused controlled substances from an internal medicine doctor without any specialty.

- More than 90 percent of Bynes' patients received a monthly supply of the highest strength of oxycodone — double the opioid potency that clinicians are advised to avoid under Centers for Disease Control and Prevention guidance.

- Most of Bynes' patients received multiple types of immediate-release opioids at the same time.

- Most of Bynes' patients received the so-called "holy trinity" drug cocktail of opioids, benzodiazepines and carisoprodol favored by opioid addicts.

- The medications were "consistently and disproportionately" the highest available strength.

- Multiple members of the same household received similar dangerous prescriptions, including one family of three that received more than 17,500 dosage units of controlled substances from the pharmacy in less than two years.

Prosecutors also alleged that the pharmacist and pharmacy could not account for more than 9,000 oxycodone and hydrocodone pills.

Dispensing drugs in violation of the Controlled Substances Act carries a civil penalty of up to $64,820 per violation, and failing to maintain and provide accurate prescription records carries a civil penalty of up to $15,040 per violation.

The pharmacy and Wood agreed in March 2020 to pay up to $2,153,383 in civil penalties to resolve the allegations.

(2) West Virginia Pharmacy Sentenced on Money Laundering Charges Arising From Conspiracy with Pain Clinic

An Alum Creek, West Virginia, pharmacy was sentenced in June 2020 to pay $250,000 toward community restitution and forfeiture after pleading guilty to one count of money laundering in connection with a conspiracy between the company and a pain clinic that was "operating as a pill mill," according to the DOJ. The pharmacy dispensed compound opioids "for no legitimate medical purpose and outside the bounds of professional medical practice," the department said (*United States v. Meds2Go Express Pharmacy, Inc.*, No. 2:19-cf-00299 (S.D. W. Va.)).

Meds2Go Express Pharmacy Inc. was charged with money laundering in a criminal information filed with the U.S. District Court for the Southern District of West Virginia in December 2019.

The information charged that between July 2014 and March 2015 the pharmacy conducted financial transactions including "purchasing powders and other raw materials" to illegally manufacture controlled substances in violation of 21 U.S.C. §841 and furthering a conspiracy to dispense and manufacture controlled substances in violation of 21 U.S.C. §846.

The company pleaded guilty to the money laundering charge two weeks after the information was filed. It also agreed to shut down its operations under the terms of a December 2019 plea agreement.

The West Virginia crime victim's compensation fund was to receive 65 percent of the $250,000, with the rest going to the state Department of Health and Human Resources Bureau of Behavioral Health and Health Facilities.

The company had faced the possibility of a maximum criminal penalty of up to $900,000, twice the value of the property involved in the illegal transaction, or twice the gross pecuniary gain or loss resulting from the conduct, whichever was greater.

'No Legitimate Medical Purpose'

Meds2Go admitted that it filled prescriptions written by physicians employed by Hope Clinic "despite its knowledge that there was no legitimate medical purpose for the prescriptions and that they were prescribed outside the usual course of medical practice," the DOJ said.

The pharmacy ignored "numerous" red flags that should have prevented it from filling the Hope Clinic prescriptions, federal prosecutors said, including:

- an "abnormally high" number of prescriptions for oxycodone and other widely abused, highly addictive controlled substances;
- prescriptions for patients who were prescribed controlled substances for long periods of time;
- requests for refills of drugs before earlier prescriptions should have run out;
- "obvious signs" that patients were drug addicts;
- patients who travelled long distances and who were from out of state;
- prescriptions from "multiple" Hope Clinic physicians who issued prescriptions to the same patient;
- prescriptions for "numerous" family members who were all patients of the clinic and who came to the pharmacy at the same time;
- the refusal of insurance companies to pay for prescriptions from the clinic; and
- patients who paid only with cash.

Illegal Compounding

Meds2Go also admitted that it illegally manufactured its own oxycodone and methadone due to patient demand. The company compounded pills "in mass quantities" at its locations in Alum Creek and Charleston, West Virginia, the DOJ said.

Because of the "excessive amount" of prescriptions for controlled substances coming from Hope Clinic, Meds2Go was unable to obtain enough oxycodone and methadone from its distributors, according to the U.S. Attorney's Office.

To meet the demand, the pharmacy "bypassed purchase restrictions from the distributor by setting up and purchasing compounding equipment, training its employees to compound pills on a mass scale, purchasing powders and other raw materials, and manufacturing pills containing oxycodone and methadone," the DOJ said. The compounded drugs were sold through cash transactions to patients who had prescriptions written by Hope Clinic.

The investigation into Meds2Go was conducted by the FDA and by the Department of Health and Human Services Office of Inspector General.

(3) Pharmacy Agrees to Pay Civil Monetary Penalties in Dispute Over Allegedly Invalid Prescriptions

A Mingo County, West Virginia, pharmacy agreed to pay more than $88,000 in civil monetary penalties in response to DOJ allegations that it violated the Controlled Substances Act by filling invalid prescriptions.

Adkins Pharmacy Inc. also entered into a three-year compliance agreement with the DEA under which the company agreed to increased reporting and oversight requirements.

U.S. Attorney for the Southern District of West Virginia Mike Stuart announced the settlement in May 2020.

As outlined in the settlement agreement reached by Adkins Pharmacy and the DOJ, the government alleged that between January 2014 and December 2015 the pharmacy filled prescriptions written by physicians associated with Hitech Opioid Pharmacovigilance Expertise Clinic P.L.L.C. even though the pharmacy "knew or should have known that [the] prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice."

The pharmacy's actions violated 21 U.S.C. §842(a)(1), according to federal enforcement officials.

The pain management clinic had three offices in West Virginia and one in Virginia. In December 2018 the DOJ indicted 12 persons associated with the clinic for allegedly operating a pill mill that distributed oxycodone without a legitimate medical purpose.

Rodney Adkins, a pharmacist who owned the pharmacy, was a party to the civil settlement and was responsible along with the pharmacy for payment of the civil money penalties. There was no admission of liability or fault by Adkins or the pharmacy, the settlement agreement specified.

The investigation into Adkins Pharmacy "indicated that the pharmacist-in-charge at the pharmacy should have known that patients had presented illegitimate prescriptions that should not have been filled," the U.S. Attorney's Office said.

"The diversion of prescription opioids fueled an epidemic and devastated a countless number of West Virginia families," Stuart said. "When pharmacies ignore red flags indicative of illegitimate opioid prescriptions for the sake of profits, we will use every available criminal and civil enforcement tool to hold them accountable."

The investigation was conducted by the DEA, the Department of Health and Human Services Office of Inspector General and the FDA's Office of Criminal Investigations.

Stuart's office said that the settlement resulted from the U.S. Attorney's Healthcare Fraud Abuse, Recovery and Response Team (ARREST), described as "an innovative approach linking civil and criminal enforcement efforts together in a comprehensive attack on the opioid epidemic and health care fraud."

(4) Protracted Revocation Proceeding Ends with Loss of Pharmacy Registration

A Bessemer, Alabama-based pharmacy lost its DEA registration following a four-year revocation proceeding (*Heavenly Care Pharmacy*, 85 Fed. Reg. 53402, Aug. 28, 2020).

The DEA served an order to show cause (OSC) on Heavenly Care Pharmacy in August 2016. The OSC alleged that the pharmacy's continued registration would be inconsistent with the public interest.

Specifically, the OSC alleged that the pharmacy:

- failed to exercise its corresponding responsibility to assess the legitimacy of prescriptions that it filled, as required by 21 C.F.R.§1306.04(a), and failed to dispense controlled substances within the bounds of the pharmacy profession, as required by 21 C.F.R. §1306.06;

- failed to maintain required records and have them available for inspection, as required by 21 C.F.R. Part 1304, 21 C.F.R. Part 1305 and Alabama law; and

- inaccurately reported its dispensing data to the Alabama Prescription Drug Monitoring Program.

The OSC alleged that the conduct threatened the public health and safety and called for revocation of the pharmacy's registration.

Later, the government added an allegation that the pharmacy provided materially false responses in a registration renewal application filed on Sept. 8, 2016.

Hearing and Review

In August 2017, a hearing was held before a DEA administrative law judge (ALJ). Following the hearing, the ALJ recommended revocation of the pharmacy's registration.

On review, the DEA deciding official (DO) agreed that the record established, by substantial evidence, two independent grounds for the revocation of registration:

- continued registration was inconsistent with the public interest; and

- the pharmacy materially falsified its renewal application.

Further, as did the ALJ, the DO found that the pharmacy's acceptance of responsibility for the proved violations was insufficient and that, even if it were sufficient, the pharmacy did not offer adequate remedial measures.

The material falsification arose when the pharmacy applied to renew its registration while the proceeding was pending. In the renewal application, the pharmacy answered “No” to the question: “Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?” That answer was untrue because revocation proceedings were ongoing at the time when the answer was provided, the DEA said.

Diversion Red Flags

Substantive violations related to the filling of prescriptions included filling numerous prescriptions that raised red flags, including:

- evidence of drug cocktails (multiple drugs of similar type for similar purposes);
- multiple customers filling prescriptions from the same prescriber for the same drugs (“pattern prescribing”);
- customers with the same last name and street address presenting the same prescriptions within a short period of time;
- customers traveling unusual distances;
- doctor shopping;
- pharmacy shopping;
- therapeutic duplication; and
- unusual increases in drug quantities.

Prior DEA decisions have found that prescriptions with the red flags that were at issue with Heavenly Care Pharmacy were so suspicious as to support a finding that the pharmacists who filled them violated the agency's corresponding responsibility rule due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy.

Based on these violations and substantial record-keeping and inventory violations, the DO issued an order revoking the pharmacy’s existing registration and denying prospectively any application to modify or renew the registration. The order of revocation became effective on Sept. 28, 2020.

(5) Alleged Illegal Acts by Pharmacist in Charge Prompts DEA Revocation Action Against Texas Pharmacy

In a DEA registration revocation action targeting a Cedar Hill, Texas, pharmacy, the alleged illegal acts at issue were committed by the pharmacist in charge, the spouse of the pharmacy’s owner (*Morning Star Pharmacy and Medical Supply 1*, 85 Fed. Reg. 51045, Aug. 19, 2020).

The government alleged that Morning Star Pharmacy filled more than 200 controlled substance prescriptions outside the usual course of professional practice, in violation of 21 C.F.R. §1306.06 and in contravention of its corresponding responsibility under 21 C.F.R. §1306.04(a), as well as Texas law.

Among many red flags allegedly ignored or not sufficiently resolved were the following:

- prescriptions for highly abused controlled substances such as hydrocodone, alprazolam, promethazine with codeine, and carisoprodol;
- prescriptions written to individuals who travelled long distances and/or used unusual routes to obtain their prescriptions and fill them at the pharmacy;
- prescriptions from individuals obtaining the same or similar combinations of controlled substances from the same small number of providers;
- prescriptions for highly abused drug cocktails, such as hydrocodone and alprazolam, hydrocodone and promethazine with codeine, and hydrocodone and carisoprodol; and
- prescriptions for controlled substances that were purchased with cash.

The pharmacy also allegedly failed to document specific information as legally required either on the hard copies of the prescriptions or in the pharmacy's electronic patient profiles.

The government alleged that the prescriptions at issue presented two or more red flags and that the pharmacy filled the prescriptions without resolving the red flags. By filling the prescriptions with these red flags without properly investigating, documenting and resolving the red flags, the agency said, the pharmacy fell below the minimum standards of the practice of pharmacy in Texas and was outside the usual course of professional practice of a pharmacy in Texas.

At the revocation hearing, the pharmacy asserted that it had investigated the circumstances of some of the prescriptions. The DEA DO concluded that such responses were inadequate. The DO found that some prescriptions displayed red flags including pattern prescribing, cash payments and drug cocktails, and that the pharmacists at the pharmacy knew or should have known that the prescriptions raised red flags.

The DO also found that some prescriptions that were filled were facially invalid because they did not list the patient's address or the prescriber's DEA registration number. Further, even if the red flags on the prescriptions were resolvable, there was no credible evidence that the pharmacy addressed or resolved them.

The DO placed no weight on contrary evidence presented by the pharmacy because the pharmacy did not maintain contemporaneous documentary evidence in accordance with Texas standards of practice to support its claim that it resolved the red flags before filling the prescriptions and because testimony presented at the hearing by the pharmacy was not credible.

The legal basis for revocation rested primarily on factors two and four of the five factors for revocation set out in 21 U.S.C. §823(f):

- Factor two relates to a registrant’s experience in dispensing controlled substances (21 U.S.C. §823(f)(2)).
- Factor four relates to compliance with federal and state laws relating to the regulation of controlled drugs (21 U.S.C. §823(f)(4)).

In sum, the DO found that the pharmacy filled controlled substance prescriptions for dozens of patients in violation of their corresponding responsibility and Texas law. The pharmacy also violated numerous federal and state record-keeping requirements related to controlled substances, and it knowingly violated DEA regulations by employing a doctor in a position in which he had access to controlled substances after the pharmacy had been denied a waiver that would have allowed such employment.

The DO concluded that the pharmacy engaged in misconduct that supported the revocation of its registration and held that the government had established a prima facie case that continued registration would be inconsistent with the public interest.

On the question of sanctions, where a prima facie showing has been made that continued registration is inconsistent with the public interest due to violations pertaining to controlled substance dispensing and record-keeping, the burden shifts to the respondent to show why it can be entrusted with the responsibility carried by its registration. The respondent is required not only to accept responsibility for the established misconduct, but also to demonstrate what corrective measures have been undertaken to prevent the reoccurrence of similar acts.

Here, the pharmacy did not acknowledge record-keeping problems, let alone the more serious violations of federal law, leading to the DO's conclusion that revocation was warranted.

The DO agreed with the ALJ that there was nothing in the record suggesting that the pharmacy had accepted responsibility for its actions. On the contrary, the DO concluded, the egregiousness of the conduct and the interests of specific and general deterrence supported a sanction of revocation.

The DO noted that the pharmacy had filled approximately 200 prescriptions that contained red flags of diversion and abuse sufficiently flagrant that they provided substantial evidence that the pharmacists knowingly filled prescriptions that lacked a legitimate medical purpose. The red flags were so egregious, the ALJ had found, that they supported a conclusion that the pharmacy was involved in the diversion of controlled substances.

The DO concluded that a balancing of the statutory public interest factors, coupled with consideration of the pharmacy's failure to accept responsibility, the absence of any evidence of remedial measures to guard against recurrence, and the agency's interest in deterrence, supported the conclusion that the pharmacy could not continue to be entrusted with a registration.
The DEA revocation order was effective Sept. 18, 2020.

(6) Pharmacy, Medical Equipment Company Lose DEA Registrations After Ignoring Red Flags of Diversion

The DEA has revoked the registrations of a pharmacy and a medical equipment company based in Melbourne, Florida, finding that the companies ignored multiple red flags of diversion over a 17-month period (*Suntree Pharmacy and Suntree Medical Equipment, L.L.C.*, 85 Fed. Reg. 73753, Nov. 19, 2020).

On Oct. 5, 2016, the DEA issued an OSC that proposed the revocation of and denial of any pending application to modify or renew the registrations held by the companies, which were registered as retail pharmacies, because continued registration would be inconsistent with the public interest under the Controlled Substances Act.

Specifically, the OSC alleged that from October 2013 through March 2015 the pharmacies filled more than 200 controlled substances prescriptions outside the usual course of pharmacy practice in violation of 21 C.F.R. §1306.06 and §1306.04(a).

The OSC further alleged that the pharmacies' failure to exercise their corresponding responsibility was evidenced by repeatedly filling of controlled substance prescriptions that contained multiple red flags of diversion or abuse without addressing or resolving those red flags and under circumstances indicating that the pharmacists involved were willfully blind or deliberately ignorant of the prescriptions' illegitimacy.

The OSC listed the red flags of diversion that the pharmacies allegedly did not resolve before filling prescriptions, including:

- prescriptions for highly abused narcotics;
- prescriptions written to individuals traveling long distances;
- prescriptions from groups of individuals who traveled long distances, from the same doctor, and presented at the same time;
- prescriptions for multiple drugs designed to treat the same condition in the same manner;
- prescriptions constituting obvious early refills; and
- prescriptions for costly narcotic medications that the customer repeatedly purchased with cash.

The OSC also listed 22 patients whose prescriptions indicated red flags.

Furthermore, the OSC alleged that the pharmacies dispensed controlled substances to a physician who wrote prescriptions to himself in violation of Florida law, and that they violated 21 C.F.R. §1306.04(b) in dispensing controlled substances for "office use."

The OSC also alleged other violations of Florida state law, including violation of the requirement that a pharmacist filling a prescription determine in the exercise of her or his professional judgment that the order is valid under standards set by the state.

The state required that, before filling a new or refilling an existing prescription, a pharmacist must review the patient record for therapeutic appropriateness. Also, state law required the maintenance of retrievable records, including pharmacist comments relevant to the individual's drug therapy and any related information.

In April 2017, the DEA held a three-day hearing on the agency's allegations. The ALJ found that the record showed by substantial evidence that the pharmacies committed acts that rendered their continued registration inconsistent with the public interest.

The record also showed that the pharmacies filled hundreds of prescriptions without fulfilling their corresponding responsibility to resolve red flags and acted outside of the usual course of professional practice in Florida, in violation of federal and state law.

The DO in the case, DEA Acting Administrator Timothy J. Shea, concurred and concluded that revocation of the registrations and denial of any pending applications to renew or modify the registrations were appropriate sanctions.

The DEA's order was to be effective Dec. 21, 2020.

III. DEA Proposes New Rules for Handling Suspicious Orders

In November 2020, the DEA proposed revisions to its regulations relating to suspicious orders of controlled substances (85 Fed. Reg. 69282, Nov. 2, 2020).

The proposed changes would clarify the procedures that a registrant must follow for orders received under suspicious circumstances, the agency said.

Under the current 21 C.F.R. §1301.74(b), a registrant must design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant must also inform the DEA Field Division Office in his or her area of suspicious orders when the registrant discovers them. Under the current regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Two Options

Under the proposed rule, in response to an order received under suspicious circumstances, a registrant authorized to distribute controlled substances would have a choice of proceeding under one of two options (under what the agency called a "two-option framework"). The options are:

- to immediately file a suspicious order report through a DEA centralized database, decline to distribute pursuant to the suspicious order, and maintain a record of the order and any due diligence related to the suspicious order; or

- before distributing pursuant to the suspect order, to conduct due diligence to investigate each suspicious circumstance surrounding the order and maintain a record of the registrant's due diligence regarding the order. The registrant would have seven calendar days to dispel each suspicious circumstance surrounding the order. If the suspicious circumstances are dispelled within that time frame, the order may be filled, and the order would not need to be reported to the DEA. Otherwise, the registrant would be required to submit a suspicious order report to the DEA centralized database and keep records pertaining to the suspicious order.

New Definitions

Part 1300 of the DEA regulations would be amended to provide the following definitions relevant to the two options:

- "due diligence" in resolving suspicious orders would be defined as "a reasonable and documented investigation into persons and orders (coupled with other appropriate investigations, including previous investigations into persons and orders) that includes, but is not limited to, verification that a person (or a person submitting an order) holds the appropriate DEA registration, verification that a person (or a person submitting an order) holds all licenses required by the state(s) in which a person (or a person submitting an order) conducts business with respect to controlled substances, examination of each suspicious circumstance surrounding an order, and examination of all facts and circumstances that may be relevant indicators of diversion in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances";

- an “order” would mean any communication by a person to a registrant proposing or requesting an order of a controlled substance, regardless of how it is labeled by the person or the registrant, and regardless of whether a distribution is made by the registrant (an exception would be provided for “simple price/availability inquiries, standing alone”);

- an “order received under suspicious circumstances” would be an order meeting the definition of a “suspicious order”; and

- a “suspicious order” would include, but not be limited to, an order of unusual size, an order deviating substantially from a normal pattern, or an order of unusual frequency.

Required Reports

Reports submitted to the DEA’s centralized database would be required to contain the following information:

- the DEA registration number of the registrant placing the order for controlled substances;

- the date the order was received;

- the DEA registration number of the registrant reporting the suspicious order;

- the National Drug Code number, unit, dosage strength, and quantity of the controlled substances ordered;

- the order form number for Schedule I and Schedule II controlled substances;

- the unique transaction identification number for the suspicious order; and

- the information and circumstances that rendered the order “actually suspicious.”

Systems for Identifying Suspicious Orders

The security controls for nonpractitioners mandated in a revised 21 C.F.R. §1301.74(b) would require a registrant to design and operate a system to identify suspicious orders or controlled drugs. The system would be required to comply with federal and state privacy laws.

In addition to identifying orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency, the system would be required to be designed and operated to identify suspicious orders “based on facts and circumstances that may be relevant indicators of diversion in determining whether a person (or a person submitting an order) is engaged in, or is likely to engage in, the diversion of controlled substances.”

The DEA was expected to consider stakeholder comments and finalize the rule after the comment period closed in early January 2021.

IV. What's on the Horizon

As the massive Purdue Pharma settlement reflects, the government's enforcement of compliance requirements can target not only business organizations but also the individuals who run them. With their increasingly sophisticated ability to track and analyze prescription and dispensing data, federal officials can be expected to continue to direct the full force of the government's investigative and enforcement authorities to help stop noncompliance with DEA mandates.

The growing body of documented red flags that companies and individuals should recognize in fulfilling their responsibilities under DEA regulations to help prevent the diversion of controlled substances can help organizations develop systems and best practices to meet those requirements — and to avoid becoming targets of enforcement actions themselves.

The scope and implementation of a new rule specifying the DEA's requirements for handling orders for controlled substances are likely to create new compliance challenges. Companies and individuals will need to study the final rule carefully and track how the DEA applies the new requirements to make sure that they are complying with the agency's evolving regulatory expectations.

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