DEA Enforcement Update: DEA, DOJ Continue To Target Pharmacies for Noncompliance

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Through Drug Enforcement Administration (DEA) administrative procedures and Department of Justice (DOJ) civil and criminal actions, federal enforcement officials continue to closely scrutinize pharmacies and pharmacists in the United States for alleged violations of Controlled Substances Act (CSA) requirements.

As always, it is important for pharmacy professionals to be aware of the alleged violations being investigated by DEA and DOJ officials — including alleged failures to resolve red flags of abuse and diversion when filling prescriptions for controlled substances, alleged violations of CSA recordkeeping mandates, and other alleged wrongdoing — that have resulted in the revocation of DEA registrations and the imposition of civil and criminal penalties.

This white paper, brought to you by the experts at Thompson Controlled Substances, tracks and analyzes recent DEA and DOJ enforcement actions involving the dispensing and storage of controlled substances and other important recent cases and settlements — all cautionary tales that should encourage pharmacies and pharmacists to scrutinize their operations to ensure compliance with complex and exacting federal requirements.

Pharmacy Loses DEA Registration After Failing To Resolve Red Flags Identified by Texas Pharmacy Board

The DEA revoked the registration of a Houston-based pharmacy under the CSA following allegations that over an 11-month period it violated the Texas standard of care for dispensing pharmacies by failing to address and resolve red flags of abuse or diversion identified by the state's board of pharmacy (*Blue Mint Pharmacy; Decision and Order*, 88 Fed. Reg. 75326 (Nov. 2, 2023)).

In a July 26, 2022, order to show cause and immediate suspension of registration (OSC/ISO), the government notified Blue Mint Pharmacy that its DEA certificate of registration was immediately being suspended, alleging that the pharmacy's continued registration would be "an imminent danger to the public health and safety" and proposing a revocation of the pharmacy's certificate.

A consultant had told the DEA that, based on her review of the pharmacy's prescription monitoring program data for the period from February 2021 through March 2022, the pharmacy had repeatedly filled prescriptions for 14 patients without addressing or resolving red flags of abuse or diversion in violation of the Texas standard of care for pharmacy practice and thus had acted outside the usual course of professional practice.

State list of red flags. In particular, the consultant took note of the Texas State Board of Pharmacy "Red Flag Checklist," which is available on the pharmacy board's website and is provided during pharmacy compliance inspections.

Among the red flags of abuse or diversion on the pharmacy board's checklist were:

- pattern prescribing — when "a pharmacy dispenses a reasonably discernable pattern of substantially identical prescriptions for the same controlled substances, potentially paired with other controlled substances, for numerous persons, including a lack of individual drug therapy in prescriptions issued by the practitioner";

- prescriptions for controlled substances commonly known to be abused, such as opioids or muscle relaxants;

- prescriptions for controlled substances at the highest strength and/or in large quantities;

- patients obtaining similar controlled substance prescriptions from multiple practitioners;

- multiple patients sharing the same address and obtaining similar controlled substance prescriptions from the same prescriber; and

  patients consistently paying for controlled substance prescriptions with cash rather than through insurance.

The consultant also stated that pharmacists in Texas must document how they address and resolve any red flags and must have prevention techniques in place to deter the dispensing of fraudulent controlled substance prescriptions, such as contacting doctors to verify prescriptions, searching the Texas Medical Board website, talking with patients, and checking patient identification cards.

Analysis of prescriptions. For example, with respect to prescriptions issued to three patients, the consultant noted, the prescriptions filled by Blue Mint Pharmacy had been issued by the same physician, who prescribed the same controlled substances in identical or substantially similar quantities to multiple patients; the drugs prescribed — hydrocodone/acetaminophen and carisoprodol, which were known to be abused — were prescribed in large quantities and at the highest dosage; the three patients shared the same address; and all three paid cash for all the prescriptions. According to the consultant, there was no evidence that the pharmacy had addressed these red flags.

Also, according to the consultant, for four other patients, who all shared an address and three of whom shared a phone number, the controlled substance prescriptions were issued by the same practitioner; the drugs — hydrocodone/acetaminophen and carisoprodol — were prescribed in large quantities and at the highest dosage; and all four had paid cash for all the prescriptions. Again, the consultant said, there was no evidence that the pharmacy had addressed the red flags.

The consultant made similar accusations with respect to seven other patients.

DEA evaluation. In reaching its revocation decision, the DEA focused on two of the five factors that it must consider when determining whether a registration would be inconsistent with the public interest and thus could form the grounds for revoking a registration:

- the registrant's experience in dispensing or conducting research with respect to controlled substances; and

- compliance with applicable state, federal or local laws relating to controlled substances (21 U.S.C. §823(g)(1)(B), (E)).

"Here," the DEA determined, "the record demonstrates that [the pharmacy] repeatedly filled prescriptions for controlled substances for multiple patients without adhering to Texas' operational standards for pharmacists filling prescriptions and without addressing or resolving numerous and blatant red flags of abuse and/or diversion."

"Because [the pharmacy's] conduct clearly violates the Texas standard of case — thus

rendering its dispensing outside the usual course of professional practice — and clearly violates the various federal and state regulations," the DEA continued, "the agency hereby sustains the government's allegations that [the pharmacy] repeatedly violated federal and state law relating to controlled substances."

The DEA found that the two statutory factors weighed in favor of revocation of the pharmacy's registration and that the pharmacy's continued registration would be inconsistent with the public interest. Moreover, the agency found, the pharmacy failed to provide sufficient evidence to rebut the government's prima facie case against it.

The government having established grounds to revoke the pharmacy's registration, the burden shifted to the pharmacy to show why it could be entrusted with the responsibility carried by a DEA registration, and it was the pharmacy's responsibility to accept responsibility and demonstrate that it had undertaken corrective matters.

"Here, [the pharmacy] did not request a hearing, submit a corrective action plan, respond to the OSC/ISO, or otherwise avail itself of the opportunity to refute the government's case," the agency said. "As such, [the pharmacy] has made no representations as to its future compliance with the CSA nor made any demonstration that it can be entrusted with registration."

On this basis, the DEA ordered the revocation of the pharmacy's registration, effective Dec. 4, 2023.

Court Shutters Pain Clinic, Dissolves Pharmacy, Imposes Civil Penalties To Resolve CSA Allegations

A federal district court in Florida ordered a Tampa-area pain management clinic and pharmacy to close and ordered the businesses' owners and the clinic's former physician to pay a total of $600,000 in civil penalties to resolve allegations that they unlawfully dispensed opioids and other controlled substances in violation of the CSA (*United States v. Bacaner*, No. 8:21-cv-00391 (M.D. Fla.)).

In a civil complaint filed in February 2021 in the U.S. District Court for the Middle District of Florida, the DOJ sought injunctive relief and civil monetary penalties against Dr. Tobias Bacaner, Theodore Ferguson and Timothy Ferguson, the joint owners of Paragon Community Healthcare Inc., which operated as Paragon Clinic, and of Cobalt Pharmacy.

The government had alleged that while he was employed by the pain clinic Bacaner issued prescriptions for opioids without a legitimate medical purpose and outside the usual course of professional practice; that the Fergusons, who managed the clinic, profited from the unlawful prescribing while ignoring obvious signs of drug abuse and diversion; and that the three individuals used their jointly owned pharmacy to unlawfully fill prescriptions issued by the pain clinic without scrutinizing the prescriptions to determine their legitimacy.

Under a stipulated judgment and permanent injunction approved by the court July 26, 2022:

- Bacaner was to pay $500,000 in civil penalties, and the physician was barred from prescribing, administering, dispensing or distributing controlled substances;
- the Fergusons and Paragon were to jointly pay $100,000 in civil penalties;
- Paragon Clinic was ordered to permanently close;

- restrictions were placed on the Fergusons' ability to own or work in the future at entities that administer, dispense or distribute controlled substances; and

- Cobalt Pharmacy was to be permanently dissolved. The pharmacy had closed shortly before the government filed its February 2021 complaint.

Details of allegations. The government had alleged that through the clinic and the pharmacy the three co-owners had unlawfully issued and filled prescriptions for controlled substances in violation of the CSA.

The DOJ had alleged that Bacaner had written prescriptions for "potent and dangerous opioids despite obvious signs of immediate peril to his patients from those drugs"; the Fergusons had profited from the physician's "dangerous and unlawful prescribing"; and the pharmacy had allegedly charged "inflated cash prices" to fill the opioid prescriptions that Bacaner had prescribed.

Restrictions on Bacaner. The stipulated judgment and permanent injunction issued against the physician barred him from:

- prescribing or dispensing controlled substances;

- holding, applying for or seeking renewal of a DEA registration for himself, another individual or any legal entity;

- managing, owning, controlling, operating or serving on the board of any entity that dispenses or distributes controlled substances;

- working as an employee or independent contractor for a pain management clinic, pharmacy or any other entity that dispenses or distributes controlled substances (except for a company with more than 50 employees);

- owning, operating, managing or having an equity interest in any property where controlled substances are dispensed or distributed (except for a private employer stock plan or publicly traded company); and

- engaging in any conduct with respect to controlled substances that violates the CSA.

Pain clinic closed. The court also permanently enjoined Paragon from operating as an ongoing business. The court gave the company 90 days to dissolve or wind up its operations, "after which Paragon shall permanently close."

The clinic was also barred from dispensing or distributing controlled substances; managing or owning any entity that dispenses or distributes controlled substances; managing, employing or contracting with any individual or agent that dispenses or distributes controlled substances; applying for or seeking renewal of a DEA registration; and assigning, transferring or referring current or former Paragon patients to any other pain management clinic.

Restrictions on co-owners. The Fergusons were barred from owning or working for any pain management clinic or pharmacy that dispenses or distributes controlled substances. They would be permitted to work for an entity that dispenses or distributes controlled substances if (1) the company has more than 50 employees or (2) the company has fewer than 50 employees, they provide the employer a copy of the court's stipulated judgment and permanent injunction, and they are not involved with controlled substances at the company.

The Fergusons were allowed to continue in their current roles at the pain clinic during the period when the company's operations were being dissolved or wound up.

Cobalt Pharmacy shut down. The stipulated judgment and permanent injunction for Cobalt Pharmacy permanently enjoined it from operating as an ongoing business; managing or operating any entity, including a pain management clinic or pharmacy, that deals with controlled substances; managing, employing or contracting with any individual or agent who deals with controlled substances; dealing with controlled substances itself; or applying for or seeking renewal of a DEA registration.

Each stipulated judgment and permanent injunction stated that the defendants had not admitted any fact, application of law, or liability with respect to the government's allegations.

The case was investigated by the Tactical Diversion Squad in the DEA's Tampa District Office.

Consent Agreement Restricts Dispensing of Controlled Substances by Texas Pharmacy, Pharmacist

A San Antonio pharmacy and its pharmacist-in-charge agreed to pay a $275,000 civil penalty and to enter into a consent agreement restricting their dispensing of controlled substances following years of alleged violations of DEA requirements (*United States v. Zarzamora Healthcare L.L.C.*, No. 5:22-cv-00047 (W.D. Tex.)).

Under the terms of a consent agreement and final order entered in the U.S. District Court for the Western District of Texas on Oct. 10, 2023, Zarzamora Healthcare L.L.C. doing business as Rite-Away Pharmacy & Medical Supplies #2 and the company's pharmacist-owner, Jitendra Chaudhary, were enjoined from dispensing certain opioid prescriptions, including combination opioid and benzodiazepine prescriptions.

In a civil complaint filed in the district court in January 2022, the DOJ alleged that the company and Chaudhary had knowingly dispensed controlled substances without a valid prescription, outside the usual course of the professional practice of pharmacy, and based on purported prescriptions that were not issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.

Rite-Away and Chaudhary also altered records required to be kept under the CSA and maintained a drug-involved premises for the unlawful distribution of controlled substances, the department said.

DEA inspections. According to the complaint, at the conclusion of a September 2014 inspection, DEA diversion investigators alleged CSA recordkeeping violations at Rite-Away's facility, including the absence of required information in "numerous" controlled substances prescriptions and alleged inventory control violations.

The pharmacy and Chaudhary were notified of the alleged violations in an Oct. 10, 2014, DEA Warning Letter. Later that month, Chaudhary responded to the DEA, acknowledging the violations and stating that corrective actions had been taken.

During a second inspection, conducted in August 2018, DEA diversion investigators again allegedly found "numerous inaccurate records that showed significant discrepancies between a physical count of controlled substance doses and Rite-Away's written inventory logs."

For one audit period of approximately a year, the physical inventory at the pharmacy was short by 44,958 dosage units across five different controlled substances when compared with records furnished by Rite-Away to the DEA, according to the complaint.

Also during the August 2018 inspection, a limited sample of prescription records allegedly revealed that the pharmacy had filled 50 prescriptions for controlled substances even though the written prescriptions did not conform to "basic requirements" of 21 C.F.R. §1306.05.

Representatives of the DEA and the U.S. Attorney's Office for the Western District of Texas met with Chaudhary and his legal counsel in April 2019. During the meeting, the pharmacist "was expressly told" that filling prescriptions that lacked information required by Section 1306.05 constituted a violation of the CSA, the DOJ said.

In August 2019, a Texas State Board of Pharmacy inspector visited the Rite-Away facility and allegedly noted that numerous controlled substance prescriptions lacked information required under Section 1306.05.

On Oct. 16, 2019, the DEA notified Chaudhary through his counsel that the following day its agents would pick up the original hardcopy prescriptions identified during the August 2018 inspection as lacking required information. When DEA diversion investigators arrived on Oct. 17, 2019, they allegedly "observed [Rite-Away] employees in the process of deliberately altering controlled substance prescriptions, including the specific 50 prescriptions sought by the investigators." Moreover, the investigators allegedly found an additional 192 altered prescriptions that were defective under Section 1306.05.

Alleged red flags. The complaint also detailed alleged instances in which Rite-Away and Chaudhary "knowingly filled prescriptions for controlled substances that raised obvious 'red flags' of potential abuse or diversion."

The DOJ said that the pharmacy and the pharmacist "deliberately ignored or were willfully blind to circumstances indicating that controlled substance prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice."

Among the alleged red flags were the following:

- filling prescriptions for unusually large quantities or strengths of a drug, including prescriptions for high dosages of opioids in amounts far exceeding the daily morphine milligram equivalent (MME) dosage recommended by the Centers for Disease Control and Prevention;

- pattern prescribing — prescribers repeatedly writing prescriptions for the same drugs, quantities and strengths for many patients, including (1) physicians prescribing the same drugs, quantities and strengths for his or her patients; (2) patients receiving the same controlled substances "over and over again with no adjustment to or change in therapy"; and (3) multiple individuals residing at the same household receiving the same or substantially similar controlled substance prescriptions, indicating a lack of individual treatment;

- prescribers routinely prescribing controlled substances known to be frequently abused drugs, including opioids, benzodiazepines, muscle relaxers, psychostimulants and cough syrups containing codeine or combinations of these drugs;

- prescriptions issued with a nonspecific diagnosis or with no diagnosis, and prescriptions omitting the intended use;

- patients traveling unusually long distances from their home addresses or their prescribers' addresses to the pharmacy, "including travel past many other pharmacies";

- patients presenting prescriptions for controlled substances from multiple prescribers, indicating "doctor shopping," or multiple physicians reissuing the same or similar high-dose opioid therapy in excessive durations; and

- prescriptions for immediate-release opioids on a schedule or for a length of time — in contrast to having an extended-release opioid accompany an immediate-release opioid, which is typical in legitimate pain management practice.

The complaint alleged multiple violations of the CSA, including recordkeeping violations, altering records furnished to the government, filling facially invalid prescriptions, filling prescriptions outside the usual course of pharmacy practice or in violation of a pharmacy's corresponding responsibility (21 C.F.R. §1306.04); and operating a drug-involved premises from which controlled substances were unlawfully distributed.

The DOJ called for the court to impose civil penalties and to enter a preliminary and permanent injunction to prevent future violations.

Motion for preliminary injunction. The government filed a separate motion for preliminary injunction on Jan. 21, 2022, based on many of the same allegations, on the sworn declarations of three DEA investigators and a pharmacy expert and on evidentiary exhibits filed with the motion.

However, three days after the motion was filed, the court denied the motion for preliminary injunction under Federal Rule of Civil Procedure 65(a)(1) because the DOJ had not provided notice of the filing to either the pharmacy or Chaudhary.

Moreover, the court refused to issue a temporary restraining order under Federal Rule of Civil Procedure 65(b)(1), which could be issued without notice to the defendants, because the DOJ had not satisfied the requirements for (1) an affidavit or verified complaint clearly showing that immediate and irreparable injury, loss or damage would result before the defendants could be heard in opposition and (2) certification of the efforts made to give notice and the reasons why notice should not be required.

On March 1, 2022, the parties filed a stipulated preliminary injunction placing specific restrictions on the dispensing of controlled substances by Rite-Away and Chaudhary.

Consent agreement. The Oct. 10, 2023, consent agreement set specific restrictions on the dispensing of controlled substances by the pharmacy and Chaudhary, including, except as specified:

- filling no controlled substance prescription more than two days before completion of the intended duration of the previous fill;

- restrictions on filling concurrent prescriptions of opioids and gabapentin and of opioids and benzodiazepines to a single patient;
- filling one or more opioid prescriptions for the same patient that together exceed 90 MME per day;
- dispensing more than one immediate-release opioid prescription to the same patient;
- dispensing single-entity opioids in excess of 15 mg; and
- dispensing Schedule II controlled substances to a patient paying in cash or otherwise paying out-of-pocket unless certain conditions were met.

The consent agreement also required periodic comprehensive reviews of Rite-Away's dispensing of controlled substances and the pharmacy's compliance with the CSA and its implementing regulations, including reviews of dispensing records and the filing of periodic detailed certification reports with the DEA identifying any noncompliant fillings of prescriptions by the pharmacy.

Chaudhary was also specifically barred from falsifying or directing the falsifying of CSA-mandated records and barred for a period of seven years from serving as the pharmacist-in-charge at any pharmacy other than the Rite-Away pharmacy.

The government noted that the claims in the complaint that were resolved by the injunction were merely allegations and that there had been no determination of liability.

Pharmacy Operator Agrees to $250,000 Settlement of Alleged Dispensing, Recordkeeping Violations

A company that owns and operates retail pharmacies in the Kansas City metropolitan area agreed to pay $250,000 to resolve allegations that one of its pharmacies violated civil provisions of the CSA governing the dispensing of prescriptions and the maintenance of pharmacy records.

The DEA and the U.S. Attorney's Office for the District of Kansas announced Sept. 14, 2023, that Kansas City, Kansas-based Four B. Corp., doing business as Balls Food Stores, agreed to the settlement. The company owned Olathe, Kansas-based Price Chopper Pharmacy.

According to the government, between February 2019 and June 2022 the pharmacy violated the CSA and its implementing regulations by dispensing controlled substances before receiving prescriptions, by improperly dispensing partially filled prescriptions, and by failing to maintain inventory records for controlled substances.

The DOJ noted that in passing the CSA, Congress "took steps to create 'a closed system' of distribution for controlled substances in which the handling of the substances is subject to intense governmental regulation" — in part "to prevent the diversion and abuse of legitimate controlled substances while still ensuring an adequate supply of those substances to meet the medical and scientific needs of the country."

Efforts to prevent the abuse and misuse of controlled substances are "futile unless those who dispense these substances will make pharmacies take heed of the Department of Justice's commitment to enforcing these rules," said U.S. Attorney Kate E. Brubacher.

"How pharmaceutical medications are dispensed is something we have to take seriously, because it can so easily result in someone getting hurt from the drugs," said Kimberly Daniels, a DEA Diversion Program manager and the lead for the program in Missouri, Kansas and southern Illinois. "One of the many responsibilities that pharmacies have is ensuring medications are dispensed only after receiving legitimate prescriptions. Then they must track the prescriptions they disperse. When they fail to do that, DEA must take action."

The case was investigated by the Kansas City Field Office of the DEA's Diversion Control Division.

The DOJ stressed that the claims resolved by the settlement were allegations only and that there had been no determination of liability.

Austin Pharmacy Resolves Allegations of Violating DEA Self-Certifying Mandate for Ephedrine Sales

An Austin, Texas, pharmacy agreed to pay a civil penalty of $200,000 to resolve allegations that it violated various provisions of the CSA, including the requirement for self-certifying that its employees were trained in the requirements for selling ephedrine, pseudoephedrine and phenylpropanolamine products over the counter.

According to the U.S. Attorney's Office for the Western District of Texas, People's Pharmacy Inc., which did business as Peoples Rx, operated five retail pharmacies and a compounding laboratory in the Austin area.

A routine inspection in June 2022 conducted by DEA diversion investigators allegedly revealed that the company had violated the agency's recordkeeping requirements, had improperly dispensed controlled substances for office use, and had issued prescriptions without authorization.

The investigators also allegedly determined that the company had not complied with the self-certification requirements of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which regulates the nonprescription sale of cough, cold and allergy products that include ingredients that can serve as precursor chemicals used to illicitly manufacture methamphetamine and amphetamine.

"Retail provisions of the CMEA include daily sales limits and 30-day purchase limits, placement of product out of direct customer access, sales logbooks, customer ID verification, employee training, and self-certification of regulated sellers," the DOJ said in announcing the settlement Aug. 16, 2023.

The DEA San Antonio District Office Diversion Control Unit investigated the matter. The U.S. Attorney's Office stressed that the claims resolved by the settlement were allegations only and that there had been no determination of liability.

Company statement. In an emailed statement, Peoples Rx said that it had "agreed to settle these allegations to resolve the findings of the DEA audit and to avoid further distraction to business operations." The company also stressed that there had been no determination of liability as part of the settlement.

"The DEA audit found no diversion of controlled substances However, it revealed some deficient recordkeeping which was immediately remedied through additional training of pharmacists and pharmacy staff. Regarding the oversight in completing

the annual self-certification required to sell over-the-counter pseudoephedrine products, Peoples Rx uses a secondary screening tool in its point-of-sale system that helps prevent the improper sale of these products and keeps complete records of the sales, which indicated that there were no irregular or questionable purchases of those products during the time period at issue."

"Peoples Rx has taken steps and will continue to improve its recordkeeping and compliance program through additional training of staff and by adding an inspection role to ensure the proper paperwork is being completed fully and accurately in compliance with the protocols required by the DEA," said a Peoples Rx spokesperson.

Consent Decree Resolves Allegations That Maryland Pharmacy, Pharmacist Ignored Red Flags of Diversion

A Maryland pharmacy accused of knowingly filling fraudulent prescriptions over a period of four years and ignoring red flags indicating that the prescriptions were not legitimate agreed to voluntarily surrender its DEA registration under the terms of a consent decree of permanent injunction (*United States v. Upton Care Pharmacy, Inc.*, No. 8:23-cv-01397-PJM (D. Md.)).

In addition, the company's pharmacist-in-charge agreed to pay a $100,000 civil monetary penalty and to surrender his state pharmacy board license for cause and not reapply for a license for three years.

"Critical gatekeeping responsibilities." According to a complaint filed by the DOJ in the U.S. District Court for the District of Maryland May 24, 2023, North Bethesda, Md.-based Upton Care Pharmacy Inc. and Abtin Youssefi-Rashti "assumed critical gatekeeping responsibilities under the [CSA] to prevent the diversion of controlled substances."

However, the government alleged, between 2018 and 2022, when the pharmacy was shuttered, Upton Care and Youssefi-Rashti "filled hundreds (if not thousands) of invalid prescriptions exhibiting one or more red flags indicating that the prescriptions were likely illegitimate."

The DOJ said that more than 300 people traveled more than 180 miles to have their prescriptions filled at Upton Care, "passing any number of pharmacies along the way."

Moreover, according to the department, Youssefi-Rashti regularly filled controlled substance prescriptions for customers who paid cash even though they had insurance available to pay for the prescriptions. He also allegedly dispensed prescriptions for both opioids and stimulants — "a dangerous and potentially lethal combination" — to the same patient concurrently.

In addition, the government said, Youssefi-Rashti routinely dispensed opioid prescriptions that provided dosages of upwards of 1,800 daily MME. The Centers for Disease Control and Prevention generally recommend that primary care clinicians avoid daily dosages of opioids over 90 MME.

Also, according to the complaint, Youssefi-Rashti dispensed buprenorphine without naloxone — "a frequently abused and diverted controlled substance" — without having reliable documentation from the prescriber that the patient was pregnant, was a nursing mother, or had experienced an adverse reaction to naloxone.

The DOJ said that, despite the presence of these red flags, among others, the pharmacist "took no efforts to determine whether the prescriptions were legitimate" or to resolve the red flags otherwise.

Mandatory self-certification. The government also alleged that although in February 2019 Upton Care completed the annual self-certification required of regulated sellers of scheduled listed chemical products under 21 U.S.C. §830(e)(1)(B)(1), the pharmacy's self-certification was not renewed until July 2022.

"Between March 1, 2020, and July 11, 2022," the DOJ alleged in the complaint, "the … pharmacy was without the required self-certification." Many times during that period, the department said, the pharmacy and Youssefi-Rashti sold products containing ephedrine, pseudoephedrine or phenylpropanolamine.

The complaint alleged two counts of unlawful dispensing of controlled substances in violation of the CSA. One count alleged that Youssefi-Rashti "knowingly filled prescriptions without resolving one or more red flags indicating that such prescriptions were not written for a legitimate medical purpose or in the usual course of professional treatment." The government alleged that Upton Care was "vicariously liable for these knowing deficiencies."

The other count alleged that Youssefi-Rashti knowingly dispensed and sold pseudoephedrine and ephedrine products without the required self-certification. Again, the government said, the pharmacy was vicariously liable for the "knowing deficiencies."

Terms of the consent decree. Under the terms of the 11-page consent decree, which was approved by the district court May 30, 2023, Upton Care and Youssefi-Rashti are required to use data available through the Maryland prescription drug monitoring program, the pharmacy's patient record system or patient profile system, patient prescriptions, and other available records to identify the red flags presented by prescriptions for dosages in excess of 90 daily MME and by patients paying with cash despite having insurance that would pay for their prescriptions.

Before filling prescriptions raising those two red flags, the pharmacy and the pharmacist must document in detail any indications of abuse or diversion and the steps they take to ensure that each prescription is valid and has been issued for a legitimate medical purpose and that the prescription will not be abused or diverted for illegitimate purposes.

The consent decree also prohibits Upton Care and Youssefi-Rashti from filling certain prescriptions, including (1) prescriptions for a combination of an opioid and a stimulant and (2) prescriptions for buprenorphine without naloxone unless there is reliable prescriber documentation that the prescription is justified.

If the DEA determines that the pharmacy or the pharmacist has violated any requirement of the consent decree or that they have not implemented the corrective actions outlined in the consent decree, the agency may order them to stop ordering, distributing or dispensing controlled substances immediately.

The DOJ noted that the consent decree did not constitute an admission of liability by either Upton Care or Youssefi-Rashti.

Warning to pharmacies, pharmacists. "The court's approval of this consent decree should remind pharmacists and pharmacies of their corresponding responsibility to confirm the legitimacy of the prescriptions that they fill," the DOJ said in announcing the consent decree.

The department stressed that it "intends to use all tools at its disposal — both criminal and civil — to combat the controlled substances epidemic which continues to plague our country."

The investigation was conducted by the DEA Washington Division's Office of Diversion Control along with the Montgomery County (Md.) Police Department and the FBI's Baltimore Field Office.

Maryland Court Approves Another Consent Decree Settling Alleged Violations by Pharmacist, Pharmacy

For the fourth time in two years, federal enforcement officials in Maryland used a court-approved consent decree of permanent injunction to resolve allegations that a pharmacy has dispensed controlled substances in violation of the CSA (*United States v. Beckman's Greene Street Pharmacy, Inc.*, No. 1:23-cv-01630-LKG (D. Md.)).

Cumberland, Maryland-based Beckman's Green Street Pharmacy Inc. and its pharmacist-in-charge, John Beckman, were to be subject to the remediation and compliance requirements of the consent decree for four years, at which time they may petition the U.S. District Court for the District of Maryland for relief from the decree's mandates.

DOJ allegations. In a complaint filed in the district court June 16, 2023, the DOJ alleged that since 2017 Beckman and Beckman's Pharmacy had "knowingly filled fraudulent prescriptions for controlled substances, ignoring red flags that should have acted as warning signs that the prescriptions were not legitimate," the government said in announcing the consent decree.

The DOJ alleged that they "would often dispense dangerous combinations of controlled substances which are known to be pursued by drug abusers but which seriously increase the risk of respiratory distress, overdose and death, and did so without noting any reasonable explanation for these dangerous combinations."

These included the "extremely dangerous" so-called "holy trinity" combination of an opioid, a benzodiazepine, and carisoprodol, and a combination of an opioid with buprenorphine, a drug used to treat opioid dependence.

According to the government's complaint, Beckman and the pharmacy "dispensed opioids to more than 10 patients who subsequently died within 10 days of the prescription" for such combinations.

Among other alleged violations of the CSA were the following:

- prescribing buprenorphine without naloxone, an abuse-prevention component;
- dispensing prescriptions for controlled substances paid for with cash, even though the patients had prescription drug insurance coverage;
- dispensing controlled substances to patients who lived long distances away from the pharmacy and/or their prescribers; and
- dispensing prescriptions to patients "many times" that caused their MME levels to exceed the Centers for Disease Control and Prevention's recommended levels of 90 daily MME — with one patient's levels being "upwards of 1,000 MME" and at least 50 patients' levels topping 300 MME.

Terms of the consent decree. Under the terms of the consent decree, which the district court approved July 5, 2023, Beckman and the pharmacy were to pay a $120,000 civil monetary penalty.

They are also enjoined from dispensing any prescriptions for controlled substances unless the dispensing would comply with:

- 21 U.S.C. §842 (a list of prohibited acts under the statute);
- 21 C.F.R. §1306.04 (requiring a controlled substances prescription to be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice, and establishing a corresponding responsibility for the pharmacist to ensure that the prescription is legitimate);
- 21 C.F.R. §1306.06 (requiring the pharmacist to act in the usual course of his or her professional practice and to be individually registered with the DEA or employed at a registered pharmacy); and
- any Maryland statutes and regulations dealing with dispensing controlled substances.

When presented with a controlled substance prescription, they must review online data for the patient available through Maryland's prescription data monitoring program, and they must determine from that information, the pharmacy's patient record or patient profile system, other available information, the prescription itself, and other circumstances whether the prescription is legitimate.

They also will be required to identify red flags of abuse and diversion, document any indications of abuse or diversion, document the steps they have taken to ensure that the prescription was valid and was issued for a legitimate medical purpose, and document that the prescription would not be abused or diverted for illegitimate purposes. Only then can Beckman and the pharmacy dispense the prescriptions that signaled the red flags.

The red flags listed in the consent decree are:

- patients appearing too frequently with requests for prescription refills that are more frequent than medically indicated or directed;
- patients receiving prescriptions for controlled substances with counteracting physiological effects, such as depressants and stimulants;
- patients receiving prescriptions for opioids and benzodiazepines who may be taking the medications simultaneously;
- patients presenting prescriptions written in the names of other persons;
- patients who have traveled a long distance to the prescriber or the pharmacy;
- a number of people bearing similar prescriptions from the same prescriber and appearing at the pharmacy simultaneously or within a short time;
- patients who are not regular patrons of the pharmacy or residents of the community showing up with prescriptions from the same prescriber;
- prescribers writing "significantly more" prescriptions or prescriptions in larger quantities, compared to practitioners in the area with the same specialty; and
- patient living more than 30 miles from the pharmacy or more than 40 miles from the prescriber.

The consent decree specifies that the red flags to be identified by Beckman and the pharmacy are not limited to those listed in the consent decree.

Moreover, the consent decree specifically forbids dispensing:

- a daily dosage in excess of 90 MME unless the patient has legitimate documentation of a current hospice diagnosis or end-of-life care;
- the "holy trinity" combination of drugs;
- a prescription for buprenorphine without naloxone, unless there is reliable documentation from the prescriber that the patient is pregnant, a nursing mother, or someone who has had an adverse reaction to naloxone;
- an early refill for any controlled substance;
- any controlled substance paid for with cash despite the fact that the patient has insurance available to pay for the prescription; and
- any controlled substance if the patient is an employee of the pharmacy.

Also, once every calendar quarter Beckman and the pharmacy must send the DEA copies of all their documentation of abuse or diversion and of the steps that they took to ensure that the prescriptions were legitimate, as well as documentation that a patient could qualify for prescriptions resulting in daily dosages over 90 MME.

If the DEA determines that Beckman or the pharmacy has failed to comply with the consent decree, it may notify the party of the noncompliance and order the party to take corrective action, including ordering the party to immediately cease ordering, distributing or dispensing controlled substances.

Renewed warning to pharmacists, pharmacies. The DOJ said that the district court's approval of the consent decree "should again remind pharmacists and pharmacies of their corresponding responsibility to confirm the legitimacy of the prescriptions that they fill, and that [the department] intends to use all tools at its disposal — both criminal and civil — to combat the controlled substances epidemic which continues to plague our country."

The government noted that the consent decree was not an admission of liability by Beckman or Beckman's Pharmacy, nor a concession by the United States that its claims were not well founded.

New York Pharmacy Pays $65,000 Penalty, Adopt Employee Screening and Recordkeeping Reforms

A Catskill, New York, pharmacy agreed to pay a $65,000 penalty and to comply with recordkeeping and employee screening practices specified in a memorandum of agreement entered into with the DEA to resolve allegations that the business failed to maintain records required under the CSA.

Based on a January 2022 inspection, the DEA alleged that Greene Pharma L.L.C., which did business as Greene Medical Arts Pharmacy, had failed to keep adequate records on its receipt and disposition of certain controlled substances, including oxycodone, hydrocodone, alprazolam, methylphenidate and buprenorphine.

Following a subsequent audit conducted by the company, Greene Pharma allegedly was unable to account for 200 oxycodone tablets, 144 buprenorphine films, and two buprenorphine tablets. The pharmacy concluded that the missing drugs "were likely stolen by an employee who had not been adequately screened before employment," the Office of the U.S. Attorney for the Northern District of New York said in announcing the settlement June 22, 2023.

The DEA also allegedly found that the company had failed to maintain records required under the CSA, including pseudoephedrine logs and Controlled Substance Ordering System (CSOS) electronic order forms.

The DOJ said that the settlement resolves the government's allegations that Greene Pharma caused controlled substances to be distributed without a valid prescription and that the company failed to keep CSA-required records.

Under the memorandum of agreement, as a condition of maintaining its DEA registration certificate, the pharmacy "must perform employee background checks and maintain complete and accurate records pertaining to the receipt and sale of controlled substances," the DOJ said.

The investigation was conducted by the Diversion Group of the DEA Albany District Office.

CVS Agrees To Pay $70,000 To Resolve Allegations That Its Pharmacists Filled Forged Prescriptions

In a civil settlement, CVS agreed to pay $70,000 to resolve allegations that it violated the CSA in New Hampshire by filling forged prescriptions for Adderall, Ritalin and Xanax, the DOJ announced June 23, 2023.

According to the U.S. Attorney's Office for the District of New Hampshire, the investigation into the company's prescription filling practices resulted from criminal investigations into two individuals who had filled prescriptions at multiple CVS pharmacies in the state.

Theodoros Bahtsevanos pleaded guilty in June 2019 to two counts of misuse of a DEA registration number and one count of possession of five or more false identification documents. He allegedly had presented numerous prescriptions and had them filled while using fictitious names (*United States v. Bahtsevanos*, No. 1L19-cr-00002-JL (D.N.H.)).

A January 2019 indictment listed nine aliases that Bahtsevanos allegedly had used along with false driver's licenses purportedly issued by other states. In April 2020, Bahtsevanos was sentenced to three years of probation on the three counts. A criminal fine was waived due to the defendant's inability to pay.

In July 2020, Jane Mastrogiovanni pleaded guilty to 10 counts of obtaining controlled substances by fraud, forgery, deception or subterfuge. The government had alleged that she used forged prescriptions to obtain controlled substances. In February 2021, she was sentenced to three years of probation following the transfer of her case to the U.S. District Court for the District of New Jersey (*United States v. Mastrogiovanni*, No. 2:20-cr-00374-KM (D.N.J.)).

Based on an investigation led by the DEA, the DOJ alleged that the pharmacists at CVS should have known that they were presented with invalid prescriptions that should not have been filled.

"Pharmacies have a legal responsibility to ensure that controlled substances are dispensed only pursuant to valid prescriptions," U.S. Attorney Jane E. Young said. "When pharmacies ignore red flags that a prescription is fraudulent, they miss a critical opportunity to prevent prescription drugs from being misused or diverted for unlawful uses or into the black market."

DEA Special Agent in Charge Brian D. Boyle said, "Pharmacies are responsible for handling controlled substances responsibly and staying in compliance with the [CSA]. Any violation of that will not be tolerated. We are committed to working with our law enforcement and regulatory partners to ensure that these rules and regulations are followed."

CVS statement. In an emailed statement, CVS said that the settlement "avoids the time and expense of litigation concerning 41 allegedly forged prescriptions, none of which were for opioid medications, that were filled between five to seven years ago at certain CVS Pharmacy locations in New Hampshire."

"We actively worked with law enforcement upon becoming aware of the alleged forgeries," the company said. "This agreement is not an admission of liability or wrongdoing."

Pharmacy Pays Its Remaining $3.5 Million in Assets as Civil Penalty To Resolve Alleged CSA Violations

A Lakewood, Colorado, pharmacy and its former owner and pharmacist-in-charge agreed to pay a $3.5 million civil penalty to resolve allegations brought by the DOJ that the pharmacy unlawfully dispensed opioids, dangerous drug combinations and other controlled substances between January 2014 and July 2020.

The multimillion-dollar civil penalty requires the business "to pay all its remaining assets," the U.S. Attorney's Office for the District of Colorado noted in a March 27, 2023, statement.

In addition, People's Pharmacy agreed to permanently forgo holding a pharmacy license or a DEA registration, thereby preventing it from dispensing controlled substances in the future. Mahnaz Abharian, the pharmacy's former owner, also agreed that she would not dispense controlled substances again in the future.

According to the DOJ, the pharmacy violated the CSA by unlawfully filling prescriptions despite the presence of red flags indicating that the prescriptions were not issued for legitimate medical purposes. Among the red flags were prescriptions written for exceptionally high opioid dosages and for dangerous drug combinations.

The government alleged that the pharmacy's CSA violations "resulted in serious harms, including both overdose deaths and the unlawful diversion of prescription drugs onto the street," the DOJ said.

In announcing the settlement, U.S. Attorney Cole Finegan said, "When a pharmacist ignores red flags indicating that a prescription lacks a legitimate medical purpose and fills the prescription anyway, there can be deadly consequences."

"We will protect our community by vigorously pursuing pharmacies and pharmacists that fail to follow the law," Finegan added, "just as we do with prescribers who issue unlawful prescriptions."

DEA Rocky Mountain Division Acting Special Agent in Charge David Olesky said, "People's

Pharmacy perpetuated the opioid crisis by ignoring red flags and knowingly and unlawfully dispensing oxycodone that led to addiction and in some cases death. Pharmacists have a corresponding responsibility to ensure the legitimacy of the prescriptions they fill."

The DOJ stressed that the claims against People's Pharmacy and Abharian were allegations and that the pharmacy and its former owner had not admitted any liability.

The matter was investigated by the DEA's Rocky Mountain Division.

Inspection of Tacoma Pharmacy Reveals Alleged CSA Administrative Violations, Leads to $80K Settlement

A June 2021 DEA inspection of a Tacoma, Washington, pharmacy led to a settlement agreement under which the business was to pay $80,000 to resolve allegations that it violated administrative requirements of the CSA.

During the inspection of Lincoln Pharmacy, the DEA allegedly found that the business failed to appropriately track controlled substances coming to the pharmacy.

For example, the U.S. Attorney's Office for the Western District of Washington said in announcing the settlement Feb. 28, 2023, the pharmacy "failed to maintain records on substances such as oxycodone and hydrocodone between March 2020 and June 2021."

Moreover, according to the government:

- the pharmacy's inventories of scheduled drugs were inadequate;
- the business failed to keep records of the delivery dates and quantities received for some scheduled drugs that the pharmacy received;
- some controlled substances that the business received were not secured; and
- the pharmacy failed to keep secure the private key — the part of the pharmacy's digital certificate known only to the business's owner — that the business used to sign for electronic orders of controlled substances.

In agreeing to the settlement agreement, the pharmacy did not admit any liability, the DEA said.

"The [CSA] has requirements for medical professionals and pharmacies so that certain narcotic substances are carefully tracked," U.S. Attorney Nicholas W. Brown said. "Those requirements are designed to allow DEA to monitor the distribution of these drugs to try to combat abuse and addiction and the harms that follow."

"The DEA will hold those medical practitioners accountable who fail to comply with the [CSA] in order to deter pharmaceuticals from being abused," DEA Acting Special Agent in Charge Jacob D. Galvan said. Galvan works with the agency's Seattle Field Division.

Kansas Pharmacy Pays $3 Million for Self-Reported Violations of Emergency Dispensing Requirements

A long-term care pharmacy based in Lenexa, Kansas, agreed to pay $3 million to resolve

allegations that it violated the CSA by dispensing controlled substances to nursing and long-term care facility residents without valid prescriptions.

The settlement also resolved allegations that the pharmacy was wrongfully reimbursed by Medicare and Medicaid for the illegally dispensed prescriptions.

According to the DEA and the Office of the U.S. Attorney for the District of Kansas, PharmScript of KS L.L.C., a wholly owned subsidiary of PharmScript Holdco L.L.C., provided drug services to patients in skilled nursing facilities and residents in assisted living facilities in Kansas and Missouri.

CSA mandates. Under the CSA, pharmacists may dispense opioid pain medications and other Schedule II controlled substances without a written prescription only in emergency situations. Under those circumstances, the pharmacist may dispense only the quantity of drugs needed to treat a patient during the emergency period. Afterwards, the emergency prescription must be reduced to writing and signed by an authorizing physician within seven days of the issuing.

"Failure to meet the emergency dispensing requirements results in an illegal dispensing of controlled substances without a valid prescription," the DOJ said in announcing the settlement.

Between October 2019 and March 2021, the DOJ alleged, the firm dispensed Schedule II controlled substances for purported emergencies when the quantities of the controlled substances dispensed were larger than what was adequate for the emergency period.

The company also allegedly failed to obtain written prescriptions within seven days after the verbal authorizations, according to the government. Other controlled substances allegedly were also dispensed without a valid written prescription and when there had been no verbal authorization by a physician.

In addition, the DOJ alleged that PharmScript was improperly paid by the Medicare and Medicaid programs for dispensing controlled substances without valid prescriptions.

The company self-reported the CSA violations to the DEA, which subsequently conducted an investigation along with the Department of Health and Human Services Office of Inspector General and the U.S. Attorney's Office.

"Because opioids are highly addictive," said Michael A. Davis, the special agent in charge of the DEA division that leads agency investigations in Kansas and Missouri, "doctors and pharmacies have a duty to ensure they are prescribing controlled substances according to law to protect their patients' health and safety. PharmScript's dispensing practices were so egregious, it warranted a significant civil penalty."

The DEA and the U.S. Attorney's Office announced the settlement Dec. 13, 2022.

DEA Revokes Registration of Texas Pharmacy in Face of Owner's Denials That Prescriptions Presented Red Flags

The DEA revoked the registration of a Lewisville, Texas, pharmacy following an agency hearing at which, when presented with accusations that the pharmacy filled controlled substance prescriptions without resolving evident red flags of diversion and abuse, the pharmacy's owner and pharmacist in charge asserted that there had been no red flags to resolve (*Lewisville Medical Pharmacy; Decision and Order*, 87 Fed. Reg. 59456 (Sept. 30, 2022)).

A June 9, 2021, DEA OSC/ISO alleged that from at least March 2018 through at least March 2021, Lewisville Medical Pharmacy "repeatedly filled prescriptions for Schedule III through V controlled substances in the face of obvious and unresolved red flags of drug abuse and diversions" in violation of federal and Texas law.

Among the red flags allegedly left unresolved by the pharmacy, according to the OSC, were:

- pattern prescribing — prescribing the same controlled substance in identical or substantially similar quantities to multiple individuals, indicating a lack of individualized therapy;
- distance — traveling abnormally long distances to fill a controlled substance prescription;
- cash payment — permitting an individual to avoid the scrutiny associated with the use of insurance as part of the payment process; and
- shared addresses — multiple persons with the same address presenting the same or substantially similar controlled substance prescriptions from the same practitioner.

Testimony at hearing. At the pharmacy's request, a DEA administrative law judge (ALJ) conducted a four-day video teleconference hearing in November 2021.

An expert on Texas pharmacy law testified during the hearing that the applicable standard of pharmaceutical practice in the state "is for the resolution of red flags to be documented before the controlled substance prescription is filled."

The ALJ also heard the testimony of the pharmacy's owner and pharmacist in charge, who attempted to justify the legitimacy of the controlled substances prescriptions that the pharmacy filled. He acknowledged that he did not document the existence or resolution of any red flag on those prescriptions, since, he said, there were no red flags associated with the prescriptions, meaning that there was "nothing to document."

In April 2022, the ALJ recommended the revocation of the pharmacy's DEA registration.

DEA administrator's analysis. Despite the owner's repeated denials that the controlled substance prescriptions at issue "even included a red flag," the DEA administrator noted, "substantial record evidence of any one of the founded controlled substance prescription violations is sufficient for the agency to revoke [the pharmacy's] registration."

"Texas law explicitly lists and clearly articulates what red flags are," she said, "making the identification of red flags on controlled substance prescriptions a process largely devoid of professional analysis or judgment, and … the applicable standard of practice requires the resolution of those red flags and the documentation of the red flags' resolutions before the controlled substance prescription is filled."

According to Texas law, the DEA administrator noted, pharmacists "shall make every reasonable effort to ensure that any prescription drug order … has been issued for a legitimate medical purpose by a practitioner in the course of medical practice" (22 Tex. Admin. Code §291.29(b)).

Further, according to Texas law, a "pharmacist shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility." Moreover, Texas

administrative law lists “red flag factors” that are “relevant to preventing the nontherapeutic dispensing of controlled substances” and that “shall be considered by evaluating the totality of the circumstances rather than any single factor” (22 Tex. Admin. Code §291.29(f)).

Red flags identified under Texas law. As the DEA administrator acknowledged, for example, a pharmacy’s “dispens[ing]” a “reasonably discernible pattern of substantially identical prescriptions for the same controlled substance … for numerous persons, including a lack of individual drug therapy in prescriptions issued by the practitioner,” is listed in Texas law as a red flag (22 Tex. Admin. Code § 291.29(f)(1)).

Other red flags explicitly identified in Texas law are “multiple persons with the same address [who] present substantially similar controlled substance prescriptions from the same practitioner” and “persons [who] consistently pay for controlled substances with cash or cash equivalents more often than through insurance” (22 Tex. Admin. Code § 291.29(f)(11), (12)).

“Prior agency decisions consistently find that controlled substance prescriptions with these red flags are so suspicious as to support a finding that the pharmacists who filled them violated their corresponding responsibility due to actual knowledge of, or willful blindness to, the prescriptions’ illegitimacy,” the DEA administrator said.

“The testimony of [the pharmacy’s] owner and [pharmacist in charge], during which he spoke at length about why red flags, that are explicitly listed in Texas law as such, are not red flags, is record evidence that [the pharmacy] was willfully blind to red flags on the prescriptions it filled,” the administrator concluded.

No rebuttal of government’s case. The DEA administrator concluded that the pharmacy had not successfully rebutted the government’s prima facie case that the pharmacy violated applicable law by filling controlled substance prescriptions without resolving and documenting the resolution of the red flags on them.

“The testimony of [the pharmacy’s] owner and [pharmacist in charge] is replete with unsupported and undocumented assertions about why controlled substance prescriptions evidencing what Texas law labels as ‘red flag factors’ are not red flags at all, typically then followed by the incantation that, if there is no red flag, there is nothing to document,” the administrator said.

For instance, she noted, according to a customer’s profile, a prescription from the customer showed “a pretty bad drug interaction,” but the owner testified, “You don’t necessarily have to document that …. I know we say, ‘document, document,’ but a lot of things are expected as a plan of care for patients that are very important that are not documented.”

The owner also testified that “there was really nothing to document because, typically, with red flags, the things we want to document is if you think the prescription is fraudulent.”

Moreover, she observed, he testified that a controlled substance prescription for codeine cough syrup is medicine for a “communicable disease …. I don’t think any pharmacist would really see that as a red flag” — even though Texas law lists prescriptions for cough syrups containing codeine as a “red flag factor” (22 Tex. Admin. Code §291.29(f)(3)).

The DEA administrator found that most of the owner and pharmacist in charge’s testimony “evidences, at least, a deep and endemic misunderstanding of Texas and federal law.”

Moreover, when asked what the pharmacy was “doing differently regarding documentation” following the DEA OSC, the pharmacy official’s response appeared to be

"more indicative of an attempt to avoid law enforcement attention in the future rather than of an accurate understanding of Texas and federal legal requirements, to recognize, resolve, and document the resolution of red flags, and a commitment to comply with them."

Through its owner and pharmacist in charge, the administrator concluded, the pharmacy had not unequivocally accepted responsibility and had not convinced the agency that the pharmacy could be entrusted with a registration. Consequently, she ordered that the pharmacy's DEA registration be revoked, as the government requested.

The order was effective Oct. 31, 2022.

Pharmacy Inventory Service Providers Pay CSA Penalty Following Employee Diversion Incidents

Two affiliated pharmacy inventory service providers agreed to pay a $158,760 penalty to resolve allegations that they caused violations of the CSA when their employees were implicated in the theft of controlled substances from pharmacies in four states.

RGIS L.L.C. and Retail Services WIS Corp. (WIS) provided inventory teams to retail store clients throughout the United States, including retail pharmacies. Company policies permitted only well-respected employees to be assigned to pharmacy inventory teams. The companies required employees assigned to these teams to undergo drug tests and criminal background checks, and the firms maintained a zero-tolerance policy for theft.

Nevertheless, according to the DOJ, employees of the two companies were involved in stealing controlled substances from several pharmacies.

In July 2017, an RGIS employee stole Vicodin pills while creating an inventory at a retail pharmacy in Schenectady, New York, the DOJ said. RGIS terminated the employee, the government alleged, but it later rehired him. In 2020, the same employee allegedly was implicated in stealing narcotics from three pharmacies in Fort Edward, Saratoga and Glens Falls, New York.

"RGIS employees were also implicated in stealing narcotics from pharmacies in Kentucky, North Carolina and Louisiana," the DOJ said in announcing the settlement on Sept. 30, 2022. "In addition, WIS employees were implicated in stealing narcotics from pharmacies in Dallas, Duncanville and Little Elm, Texas."

Enhanced employee scrutiny. In addition to paying the civil settlement amount, the two companies agreed to add procedures to ensure the proper scrutiny of employees assigned to inventory pharmacies and to make the results of the scrutiny available to their pharmacy clients.

However, the DOJ warned, "the pharmacy clients, as DEA registrants, are ultimately responsible for supervising all personnel on the premises and preventing the diversion of controlled substances."

The investigation was led by the DEA's Albany Diversion Group with help from the Tactical Diversion Squads in Dallas; Albany, New York; and Charleston, West Virginia. Also assisting were the New York State Police, the Glens Falls Police Department, and the Little Elm Police Department.

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