DEA Enforcement Update: Pharmacies Under Compliance Scrutiny for Their Handling of Controlled Substances

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U.S. pharmacies continue to be targeted by Drug Enforcement Administration (DEA) enforcement actions, through civil allegations and criminal prosecutions brought by the Department of Justice (DOJ) as well as through the DEA's administrative registration revocation proceedings.

Alleged failures to resolve red flags of drug abuse and diversion, alleged violations of DEA recordkeeping requirements, and a range of other alleged wrongdoings continue to bring close DEA and DOJ scrutiny of the actions (or inactions) of pharmacies, pharmacists and their employees.

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

Pharmacy's Repeated Filling of Prescriptions Despite Unresolved Red Flags Leads to DEA Registration Revocation

The DEA revoked the certificate of registration held by a Rayford, Texas, pharmacy following allegations that the business repeatedly filled prescriptions for 17 patients in the face of unresolved red flags of abuse and diversion (*Rayford ACP; Decision and Order*, 87 Fed. Reg. 56705 (Sept. 15, 2022)).

The agency found through an administrative procedure that each of the controlled substance prescriptions at issue was outside of the usual course of professional practice of pharmacy in Texas and in violation of the pharmacy's corresponding responsibility under 21 C.F.R. §1306.04(a).

According to the DEA's findings, the pharmacy dispensed controlled substances on numerous occasions without documenting the resolution of various red flags, including drug cocktail prescribing for 11 patients, therapeutic duplication for 12 patients, early refills for two patients, and long distances for two patients.

For example, the agency determined, the pharmacy dispensed at least 39 prescriptions to one patient without documenting the resolution of multiple red flags, including combination prescribing, therapeutic duplication and/or early refills.

Regarding two patients, the pharmacy conceded that it "did not appropriately exercise its corresponding responsibility" because it dispensed controlled substances without documenting the resolution of red flags for combination prescribing.

The DEA also established that the pharmacy dispensed at least 19 prescriptions for controlled substances to another retail patient who lived approximately 60 miles from the pharmacy without documenting the resolution of the red flag of traveling a long distance.

The pharmacy dispensed two short-acting opioids along with a benzodiazepine, which raised red flags for both therapeutic duplication and cocktail prescribing, the agency found. In addition, the pharmacy dispensed hydrocodone six days early along with alprazolam, which raised red flags for both early refills and cocktail prescribing.

Federal, state requirements. "Both federal and Texas law impose an independent, corresponding responsibility on pharmacists to ensure that a prescription is issued for a legitimate medical purpose and within the usual course of professional practice," the agency said.

"In this matter," the DEA determined, "the government did not allege that [the pharmacy] dispensed the subject prescriptions having actual knowledge that the prescriptions lacked a legitimate medical purpose. Instead, the government alleged that [the pharmacy] violated the corresponding responsibility regulation for each of the patients at issue in this matter by repeatedly dispensing controlled substances without addressing or resolving clear red flags."

"Agency decisions have consistently found that prescriptions with the same red flags at issue here were so suspicious as to support a finding that the pharmacists who filled them violated the agency's corresponding responsibility due to actual knowledge of, or willful blindness to, the prescriptions' illegitimacy," the DEA said.

The DEA also noted that Texas law "explicitly states that the geographical distance between the practitioner and the patient or between the pharmacy and the patient is a reason to suspect that a prescription may have been authorized in violation of the practitioner's standard of practice" (22 Tex. Admin. Code §291.29(c)(4)).

The state's administrative code also requires early refills to be identified and resolved and the resolution to be documented before the drug is dispensed (22 Tex. Admin. Code §291.33(c)(2)(A)(i)(X)).

Consequently, the DEA found, Rayford ACP's failure to document the resolution of a red flag violated Texas law.

Violations denied. Although the pharmacy admitted that it violated its corresponding responsibility with respect to two patients, it denied that one patient's prescription presented a red flag based on distance "in spite of clear Texas law to the contrary," the agency said. The pharmacy also "consistently" denied that the controlled substance prescriptions for its hospice patients presented any red flags, according to the DEA, despite one pharmacy official's expert testifying to the contrary.

"A registrant's acceptance of responsibility for misconduct is not adequate when the registrant does not understand what the law requires," the agency noted.

The DEA also noted that the pharmacy's misconduct "was far from a one-time occurrence." Consequently, the agency determined, the sanction of registration revocation was appropriate.

The DEA order was effective Oct. 17, 2022.

Undercover Pharmacy Transactions Lead to Temporary Restraining Order Against Florida Pharmacist

A Hudson, Florida, pharmacist was prohibited from filling prescriptions for opioids and other controlled substances under a temporary restraining order (TRO) issued in August 2022 by a federal district court (*United States v. Esalomi*, No. 8:22-cv-01725-TPB-JSS (M.D. Fla.)).

The case illustrates the scrutiny under which a pharmacist can come through investigations of prescribers suspected of violating Controlled Substance Act (CSA) requirements and through undercover investigations of the pharmacist's transactions involving controlled substances.

Details of complaint. A complaint for injunctive relief and civil penalties filed by the DOJ in August 2022 in the U.S. District Court for the Middle District of Florida alleged that the pharmacist, Nathaniel Esalomi, "has both fueled and profited from the opioid epidemic by repeatedly dispensing powerful opioids prone to abuse in violation of the CSA through the guise of Apexx Pharmacy, which he owns and runs as the sole pharmacist."

The government said that in transactions with undercover law enforcement officials, Esalomi "repeatedly filled prescriptions for controlled substances that he knew were not legitimate in exchange for cash" and "repeatedly filled prescriptions in the name of dead patients and falsely recorded that these patients were present in the pharmacy when the drugs were dispensed."

Physician investigation. According to the complaint, the investigation into Esalomi stemmed from a May 2022 report of potentially fraudulent prescriptions for promethazine with codeine cough syrup, a Schedule I controlled substance, being filled at pharmacies in three Florida counties by "a known drug trafficker." The purported prescriptions were issued by a Tampa area physician.

By the following month, law enforcement officials had learned that the physician "writes prescriptions in exchange for cash, charging $450 for an oxycodone prescription and $650 for a promethazine-codeine prescription." The physician allegedly issued the purported prescriptions "based on the information provided on a driver's license but without seeing or having a doctor-patient relationship with the person depicted in the license."

Law enforcement officials then conducted two undercover transactions in which the physician "wrote more than a dozen prescriptions for controlled substances to individuals [that the physician] had never met or examined, based on nothing more than text message[s] containing images of the purported patients' driver's licenses," according to the complaint. The physician allegedly provided the prescriptions "in exchange for thousands of dollars in cash."

Undercover pharmacy transactions. On July 7, 2022, according to the complaint, two undercover law enforcement officials took six of the prescriptions to Apexx Pharmacy to be filled. The prescriptions were for identical quantities of oxycodone 30 mg tablets, promethazine-codeine and suboxone.

"Esalomi filled these six prescriptions despite having actual knowledge or being willfully blind to the fact that they were not legitimate," the complaint alleged.

Moreover, according to the DOJ, Esalomi attempted to conceal the illegitimate nature of the prescriptions by creating "four additional prescriptions for the noncontrolled substances azithromycin, docusate sodium (stool softener), cyclobenzaprine (muscle relaxant) and ibuprofen" — prescriptions that had not been issued by a physician but that Esalomi allegedly added to the order "to conceal the illegitimate prescriptions among prescriptions for medications subject to less law enforcement scrutiny."

"The exceedingly high price that Esalomi charged for the prescriptions also demonstrates his knowledge that they were not legitimate," the government also alleged. According to the DOJ, a person would be willing to pay the $650 that he allegedly charged for each 473 ml bottle of promethazine-codeine — far above the market price when the drug is dispensed for a legitimate purpose — only because the drug was not intended for a legitimate medical use, "such as having an expectation to ultimately sell the controlled substance on the street for a much higher price."

Later that day, two other undercover law enforcement officers visited Apexx Pharmacy to fill other prescriptions written by the physician. The prescriptions were also for oxycodone 30 mg tablets and promethazine-codeine, according to the complaint. Once again, Esalomi allegedly filled the prescriptions.

During the visit, the DOJ reported, when one of the undercover officers, Joseph Pelz, provided a Massachusetts driver's license, Esalomi requested a Florida address. In the presence of Esalomi, Pelz turned to the other undercover officer, Jason Gates, and asked if he could use the address shown on Gates' undercover driver's license. Pelz then filled out a patient form at the pharmacy counter in Esalomi's presence using that address. "Esalomi knew that this was a ruse," the DOJ alleged, "and stated, 'Because of out-of-state, I will have problems."

In fact, according to the DOJ, Esalomi's request for Pelz to alter his address "was designed to evade law enforcement detection," because the out-of-state address or customers traveling long distances to obtain controlled substance prescriptions "are well-known red flags that a prescription may not be legitimate," and a prescription linked to an out-of-state address would be recorded in the Florida Electronic Online Reporting of Controlled Substances Evaluation (E-FORCSE) system and might be reviewed by law enforcement officials.

As during the first undercover visit that day, Esalomi allegedly again created additional prescriptions for the same four noncontrolled substances to supplement each order as if they had been issued by the physician. Also, Esalomi allegedly once again charged "the excessive price" of $650 for each of the two bottles of promethazine-codeine.

When Gates produced "a stack of cash" and told Esalomi that he had only $1,650 rather than the total charge of $1,816 for his prescriptions, Esalomi allegedly accepted the $1,650, saying, "When you come back next time, you pay me … can I trust you?" Pelz and Gates returned on July 14 and paid Esalomi $180 for the prior transaction. Esalomi allegedly accepted the payment.

Also during the July 14 visit, the two undercover officials presented eight more prescriptions for promethazine-codeine and oxycodone written by the physician, none of which were for the two officers' undercover identifies. Esalomi agreed to fill the prescriptions, and Pelz gave Esalomi four driver's licenses corresponding to the individuals named on the prescriptions. Esalomi instructed Pelz to fill out patient forms for the prescriptions, instructing Pelz to forge the signature of each of the four purported patients on the forms.

When the two officials returned later that day to pick up the prescriptions, Esalomi told then that, because the four new patients did not have a history of filling controlled substance prescriptions in the Florida data monitoring program (PDMP), Esalomi would need to see the patients in the pharmacy.

The following day, Pelz and Gates returned to the pharmacy with additional undercover officers associated with the driver's licenses that had been presented to Esalomi on July 14. Each of the additional officers filled out a patient form.

One of the additional officers used a Miami address. Esalomi said that the officer needed to use a local address, saying, "Miami is just too far for me." Gates told the officer to use the address on Gates's undercover license, and Esalomi allegedly approved the change. Esalomi also allegedly told the group that he needed telephone numbers from everyone and that having everyone use Gates's phone number would be acceptable. The group then left the pharmacy.

Pelz and Gates returned about an hour later to pick up everyone's prescriptions. Esalomi told them that the prescriptions would cost $3,632 — again charging the excessive price of $650 for the promethazine-codeine. Pelz paid Esalomi $3,640, and Esalomi then provided two bags to Gates. The bags contained four bottles each of the two controlled substances as well as four bottles each of the same noncontrolled substance medications, prescriptions for which Esalomi fraudulently created as though the medications had been prescribed by the same physician.

"The exchanges of illegitimate prescriptions for cash … were essentially drug deals, in violation of 21 U.S.C. §842(a)(1)," the DOJ alleged in the complaint.

Prescriptions allegedly filled for deceased patients. The government also alleged that Esalomi had filled prescriptions for at least three patients who were deceased at the time.

For example, according to the DOJ, one patient died on July 21, 2019, but between July 19, 2021, and July 21, 2022, Esalomi allegedly "filled at least 23 prescriptions for hydromorphone, 20 prescriptions for oxycodone, two prescriptions for alprazolam, and one prescription for promethazine with codeine syrup for [the patient]. Each time he filled the prescriptions, Esalomi falsely indicated that [the patient] came to the pharmacy in person."

Esalomi was charged with three counts of violating the CSA (21 U.S.C. §842(a)(1), 21 U.S.C. §843(f)(1) and §882(a), and 21 U.S.C. §856).

Motion for TRO. In its motion for a TRO and preliminary injunction, also filed in August 2022, the government told the court that the injunctive relief was needed "to immediately stop Esalomi's illegal activity."

The government also asked for the TRO to be granted without prior notice, saying that advance notice "would provide Esalomi an opportunity to conceal or destroy relevant evidence" in "a parallel criminal investigation."

The court granted the TRO and later extended the TRO "until the motion for preliminary injunction can be heard and resolved by the court."

In September 2022, the district court entered a stipulated preliminary injunction that replaced the TRO. The preliminary injunction barred Esalomi from serving as a manager, owner or operator of any entity that dispenses or distributes controlled substances, from applying for or seeking renewal of a DEA certificate of registration on his own behalf or on behalf of a corporation, and from altering or destroying any record related to his dispensing of controlled substances, including at Apexx Pharmacy.

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 in July 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 was ordered to permanently close;
- restrictions were placed on the Ferguson's 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 bars 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 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 DEA's Tactical Diversion Squad in the agency's Tampa District Office.

Pharmacy Pleads Guilty to Illegal Opioid Distribution, Kickbacks, Agrees To Pay $50 Million in Penalties

A Fort Lee, New Jersey, pharmacy pleaded guilty in August 2022 to conspiring to illegally distribute prescription fentanyl and other opioids and providing illegal kickbacks to health care providers. The pharmacy also entered into a civil settlement agreement with the DOJ to resolve alleged violations of the False Claims Act and the CSA (*United States v. Dunn Meadow L.L.C.*, No. 2:22-cr-00517-JXN (D.N.J.)).

Dunn Meadow L.L.C., doing business as Dunn Meadow Pharmacy, was a retail pharmacy that functioned as a mail-order pharmacy, marketing controlled substances throughout the United States. The company referred to itself as a "specialty pharmacy" and claimed to specialize in pain management medications — specifically, prescription opioids.

The pharmacy contracted to purchase drugs from companies that manufactured and marketed highly addictive and dangerous transmucosal immediate release fentanyl (TIRF) medications.

Alleged illegal practices. The government alleged that between 2015 and 2019 Dunn Meadow "dispensed prescription TIFT medications and other controlled substances knowing that the prescriptions were not for a legitimate medical purpose."

According to a criminal information filed in August 2022 in the U.S. District Court for the District of New Jersey, the company filled prescriptions for patients exhibiting suspicious or drug-seeking behavior, including patients who "repeatedly requested early refills, paid thousands of dollars for their prescriptions, or requested that prescriptions be sent to suspicious or inappropriate locations including hotels, casinos and elementary schools."

For example, in December 2015 the pharmacy's employees using the company's instant messaging system allegedly referred to one patient as a "drug addict" and noted that the patient pretended to have lost two boxes of TIRF medications. Dunn Meadow allegedly continued to fill TIRF prescriptions for the patient until about January 2018.

In a March 2016 instant message, Dunn Meadow's pharmacist-in-charge allegedly asked another pharmacy employee why a patient would want to pay more than $9,000 in cash for a TIRF product. "The other employee responded, 'because she's an addict :),'" the information reported. "The pharmacist-in-charge replied, 'OK … 'splains dat!'" The pharmacy filled the patient's prescription.

The company also allegedly filled controlled substance prescriptions written by prescribers who wrote prescriptions that the pharmacy knew were not written for a legitimate medical purpose.

In September 2016, the government alleged, the pharmacist-in-charge told his staff that he had removed alerts from patient profiles in the business's computer system for "multiple" patients and reinstated their TIRF prescriptions.

"In response," the information stated, "the other pharmacy employee asked the pharmacist-in-charge: 'So what happened within less than 24 hours that I now have to redo orders …? Did the M.D. all of a sudden become "good" or did these [patients] develop cancer overnight?'"

The pharmacy also allegedly failed to adequately confirm the diagnoses or clinical profiles of patients for whom it was filling prescriptions for fentanyl and other controlled substances.

Moreover, it allegedly dispensed controlled substances "based on patient information obtained from sales representatives from opioid manufacturers, including sensitive clinical information such as diagnoses." The DOJ said that the pharmacy "relied on the opioid manufacturers' sales representatives rather than confirming the appropriateness of the controlled substance directly with the prescribers."

The pharmacy also allegedly engaged in a practice of filling prescriptions for controlled substances without receiving an original prescription. According to the information, "Dunn Meadow maintained a 'send without original' ('SWO') list, which consisted of the names of certain prescribers across the United States who were important, high-value prescribers of controlled substances, including fentanyl." The DOJ said that the pharmacy authorized its employees to fill and ship any controlled substance prescription for any patient of any prescriber on the SWO list without receiving a prescription.

Supplier warnings. The DOJ said that compliance officials working for companies that supplied the pharmacy with controlled substances warned Dunn Meadow about "the suspicious and problematic prescribing habits and histories of some of these prescribers …. Notwithstanding these warnings, Dunn Meadow continued to fill prescriptions written by those prescribers."

By February 2016, two suppliers had stopped selling controlled substances to Dunn Meadow. One of the suppliers warned the pharmacy that it had "serious concerns about Dunn Meadow's history of filling prescriptions for controlled substances written by prescribers whose prescribing practices were highly suspicious and indicative of controlled substance diversion," the government said.

The pharmacy subsequently submitted at least three applications to other suppliers in an attempt to continue to purchase controlled substances. The government alleged that the applications "falsely represented that no supplier had ever suspended, ceased or restricted controlled substance sales to Dunn Meadow."

Alleged Anti-Kickback Statute violations. The government had also alleged that Dunn Meadow conspired to offer illegal kickbacks to health care providers and drug company sales representatives in violation of the federal Anti-Kickback Statute.

The DOJ said that the unlawful inducements took the form of lunches, dinners and happy hours provided to prescribers and their staffs and to pharmaceutical sales representatives.

In its guilty plea, the pharmacy acknowledged that its violations of the Anti-Kickback Statute "caused a loss to federally funded health care programs of over $4.5 million," the DOJ said.

The district court sentenced Dunn Meadow to probation for a term of two years and ordered the company to pay nearly $4.499 million as criminal restitution and a special assessment of $800.

Civil settlement. Dunn Meadow and its parent company, Allegheny Pharma L.L.C., also entered into a civil settlement with the DOJ to resolve allegations that Dunn Meadow dispensed opioid medications in violation of the CSA.

In a 23-page civil settlement agreement, the government alleged that the pharmacy filled prescriptions that were not issued for a legitimate medical purpose and were outside the usual course of the professional practice of a pharmacy.

The company allegedly "dispensed opioid medications: (a) without valid prescriptions; (b) for unsafe, medically unnecessary uses; and (c) to individuals displaying red flags of abuse and addiction."

According to the government, the red flags included "patients who routinely sought and received early refills; patients who received dangerous combinations of controlled substances

(including the high-risk 'holy trinity' drug combination of at least one opioid, benzodiazepine, and muscle relaxant sought by addicts); patients who received multiple short-acting opioids — including multiple TIRF medications — at the same time; and patients who received excessive quantities and dosages of controlled substances for extended periods of time."

The civil settlement resolved the DOJ's allegations that the company violated the CSA by filling prescriptions for opioids written by prescribers who Dunn Meadow had reason to know were writing prescriptions outside of the usual course of professional practice.

In addition, the government alleged that the pharmacy "knowingly submitted claims for opioid medications to Medicare and TRICARE that were not eligible for coverage because they were for noncovered uses" — such as patients who lacked valid prescriptions, patients suffering addition to opioids for whom the medications were medically unreasonable and unnecessary, and patients who received TIRF medications for uses other than for breakthrough cancer pain.

Dunn Meadow also "knowingly submitted claims for opioid medications to Medicare and TRICARE in violation of the Anti-Kickback Statute," the DOJ alleged in the civil settlement agreement.

The civil settlement stipulated that Dunn Meadow and its parent company did not admit to the government's allegations beyond those reflected in the pharmacy's guilty plea in the criminal action.

Under the terms of the civil settlement agreement, Allegheny Pharma was to pay $225,000 to the federal government as restitution, and Dunn Meadow was to pay 50% of revenues generated in excess of $221,000 after Aug. 31, 2021, if any, in quarterly payments for five years, up to a total settlement amount of $50 million. $9 million of that amount was earmarked as restitution.

The case was investigated by DEA New Jersey Division diversion investigators, special agents of the Department of Health and Human Services Office of Inspector General, special agents of the Department of Defense's Defense Criminal Investigative Service, and special agents of the FBI.

Philadelphia-Area Pharmacy Owner Pleads Guilty to Illegally Distributing Opioids, Health Care Fraud

The owner and pharmacist-in-charge of a Philadelphia pharmacy pleaded guilty to a charge of conspiracy to illegally distribute controlled substances and to commit health care fraud (*United States v. Spivack*, No. 2:22-cr-00166-HB (E.D. Pa.)).

The government alleged that Mitchell Spivack and his coconspirators "filled prescriptions for wholesale quantities of high-dose oxycodone despite obvious alterations to the prescriptions and other red flags indicating that the drugs were not prescribed for legitimate medical purposes."

Following his June 2022 guilty plea, Spivack had faced a maximum possible sentence of five years in prison, a $250,000 fine, three years of supervised release, a special assessment, and an order of restitution.

Conspiracy to distribute controlled substances. According to a 13-page criminal information filed in May 2022 in the U.S. District Court for the Eastern District of Pennsylvania, Spivack was the owner of Verree Pharmacy, a small neighborhood pharmacy in the Fox Chase section of Philadelphia, for more than 30 years.

The DOJ alleged that Spivack and his coconspirators "cultivated Verree's reputation as an 'easy fill' and 'no questions asked' pharmacy for oxycodone and other dangerous and addictive opioid drugs." The DOJ said that by 2016 the pharmacy was the largest purchaser of oxycodone among retail pharmacies in Pennsylvania.

The information alleged that at Verree Pharmacy altered prescriptions were filled without verifying the prescription with the issuing physician. "Despite the fact that prescriptions had been altered," the government alleged, "the oxycodone would be dispensed so long as a customer had sufficient funds to pay for the drugs."

Moreover, the government said, Spivack and the coconspirators "also filled prescriptions for wholesale quantities of high-dose oxycodone, despite the existence of red flags that indicated potential diversion of controlled substances, in which case the prescriptions should not have been filled."

The DOJ also alleged that Spivack and the others "typically required payment in cash for oxycodone prescriptions even when the customer produced proof of insurance." The pharmacy's cash-only policy was intended to help the pharmacy escape scrutiny by health care benefit programs that monitored the amount of oxycodone dispensed to beneficiaries, as well as to generate cash proceeds that could not be traced, according to federal prosecutors.

Spivack and his coconspirators also allegedly created a club through which patients "who paid a premium as 'Narc Members' could expedite the filling of their high-dose oxycodone prescriptions with no questions asked."

The information detailed nine transactions between June 2017 and August 2018 in which Spivack allegedly distributed oxycodone products outside the usual course of professional practice and not for a legitimate medical purpose.

Alleged health care fraud. The DOJ also alleged that Spivak and other employees of Verree Pharmacy submitted "entirely fraudulent" claims to health care benefit programs for prescription drugs that in fact had not been dispensed.

According to the information, prescription drugs for which fraudulent reimbursement claims would be submitted were designated in the comments section of patients' profiles in the pharmacy computer system as "BBDF" — an acronym for "Bill But Don't Fill."

The information detailed five transactions between July 2017 and February 2019 in which Spivack submitted or caused to be submitted fraudulent "BBDF" claims to Medicare for prescription drugs that had not been dispensed.

Spivack was sentenced in October 2022 to a term of 42 months in prison followed by two years of supervised release. He was also ordered to pay $278,566.33 in restitution.

Civil suit. The federal government also pursued a civil suit against Spivack, his company, and pharmacy employees alleging health care fraud and violations of the CSA (*United States v. Spivack, Inc.*, No. 2:22-cv-00343-MAK (E.D. Pa.)).

The suit was originally filed in January 2022 in the U.S. District Court for the Eastern District of Pennsylvania.

A second amended complaint filed in June 2022 alleged that Verree Pharmacy, Spivack, another pharmacist and two pharmacy technicians illegally dispensed controlled substances and committed health care fraud against Medicare and other federal health care programs. The government also alleged that the defendants had caused the submission of false reimbursement claims to Medicare and other federal health care programs and had conspired to do so in violation of the False Claims Act.

"Spivack, the other employees, and Verree Pharmacy — which was the top retail pharmacy purchaser of oxycodone in the entire state of Pennsylvania … — created a destructive enterprise that illegally dispensed unparalleled quantities of opioids and other controlled substances into the Philadelphia community and this district," the complaint alleged.

In August 2022, the DOJ announced that Verree Pharmacy and Spivack had agreed to pay more than $4.1 million to settle the civil suit. The total included the entry of judgment against them in the amount of more than $1.2 million to resolve their False Claims Act liability (with more than $403,000 of that amount designated as restitution) and a civil monetary penalty of more than $2.9 million imposed under the CSA.

N.C. Pharmacy, Two Pharmacists To Pay $300,000 Penalty for Allegedly Ignoring Red Flags for Years

A federal district court in North Carolina entered a consent decree of permanent injunction barring a pharmacy and two pharmacist employees from dispensing opioids and other controlled substances until they have taken specific steps to ensure that the drugs will not be diverted or abused (*United States v. Asheboro Drug Co. Inc.*, No. 1:22-cv-522-CCE (M.D.N.C.)).

The three defendants — Asheboro Drug Co. Inc., an Asheboro, N.C.-based pharmacy; Isaac F. Brady III, a part-owner and pharmacist at the company; and his son, Isaac F. Brady IV, also a part-owner of the company and the pharmacist-in charge — also agreed to pay $300,000 in civil penalties over the course of three years.

Allegations brought by DOJ. In a complaint filed in July 2022 in the U.S. District Court for the Middle District of North Carolina, the DOJ alleged that between January 2016 and at least October 2019 the three defendants "knowingly filled prescriptions for controlled substances that presented significant red flags," which the government said were "obvious indications of drug abuse, drug diversion and drug-seeking behavior."

The defendants "ignored or otherwise failed to take sufficient steps to resolve these red flags before filling the prescriptions," the DOJ alleged.

The DOJ said that Asheboro Drug Co. and its pharmacists cooperated with the government's investigation. According to a settlement agreement negotiated by the parties, the defendants did not admit any liability for the offenses alleged by the government.

Red flags allegedly ignored. Among the red flags that the defendants allegedly ignored were the following:

- ***Dangerous drug combinations/cocktails.*** The pharmacy and the two pharmacists allegedly dispensed combinations of controlled substances, including high-powered opioids combined with benzodiazepines, muscle relaxers and/or stimulants, "despite significant unresolved red flags regarding the prescriptions' medical legitimacy."

Red flags allegedly ignored. Among the red flags that the defendants allegedly ignored were the following:

- ***Long-term, high-dose opioids.*** The government noted in the complaint that opioids are not recommended for the long-term treatment of non-cancer pain, such as the pain caused by osteoarthritis, and that prescribers should be using the lowest effective dosages of opioids. Moreover, it said, pharmacists exercising their corresponding responsibility under 21 C.F.R. §1306.04(a) should question opioid dosages above 50 morphine milligram equivalents (MME) per day and should have substantial justification for dispensing doses exceeding 90 MME.

  Despite these government guidelines, the defendants allegedly filled long-term prescriptions for high-dose opioids "with insufficient or no documentation justifying those dangerous doses."

- ***"Doctor shopping."*** A patient's history of obtaining prescriptions for controlled substances from multiple prescribers is a red flag of diversion or abuse, the DOJ noted in the complaint. That behavior may indicate that a physician stopped writing prescriptions for a person if the physician believed that the person was abusing controlled substances, and that the patient then sought out prescriptions for controlled substances from other prescribers. The behavior may also indicate that the patient is trying to make it harder for any individual prescriber to identify the patient's drug-seeking behavior.

  Despite the defendants' ability to review a person's prescription history through North Carolina's Controlled Substance Reporting System, the DOJ alleged, they "nevertheless dispensed opioids and other controlled substances to doctor-shopping individuals, including people who had received controlled substance prescriptions from as many as nine different prescribers in the past three years," the DOJ alleged.

- ***Family members receiving similar prescriptions.*** Prescriptions for similar combinations of controlled substances written for members of the same family constitute a red flag indicating that the prescriptions may not be legitimate, according to the government. The complaint alleged that the three defendants "dispensed controlled substances, including similar prescriptions, to individuals of the same family" — for example, dispensing similar prescriptions for a husband and his wife "from overlapping physicians, for years."

- ***Early refill requests.*** The defendants allegedly filled prescriptions for patients before their current supplies of drugs from previous prescriptions had been exhausted, even when the patients "exhibited other drug-seeking behavior."

The complaint detailed alleged case histories for five individuals demonstrating the defendants' purported failure to heed these red flags.

"Red-flag doctor." Moreover, according to the government, a physician of whom Asheboro Drug's employees were aware wrote similar or "pattern" prescriptions for all his patients, prescribed opioids long-term, and wrote prescriptions for patients who sought early refills or who appeared at the pharmacy together in groups.

The physician "appeared to 'write anything,'" the complaint alleged, adding, "One employee reported hearing from customers that this doctor only accepted cash and had weekend evening clinics where he prescribed whatever patients wanted."

The pharmacy employees also allegedly knew that the doctor "refused to do physician authorizations," which were required at the time by North Carolina Medicaid "for coverage of daily MME above 120 or greater than 14-day supplies of any opioid."

Nevertheless, the three defendants allegedly filled "a large volume" of the physician's prescriptions "for years" and did not refuse to fill his prescriptions "until after a DEA audit." Between January 2017 and May 2019, the physician "was responsible for more than three times as many prescriptions and dosage units as any other single provider in Asheboro," the complaint reported.

Relief sought. In its complaint, the government called for civil penalties for the defendants' alleged violations of the CSA, which stemmed from filling prescriptions "that were not written for a legitimate medical purpose or were written outside the usual course of professional treatment, as evidenced by the numerous red flags defendants failed to resolve prior to filling such prescriptions."

The DOJ also asked the court to enter a permanent injunction barring the defendants from any dispensing of controlled substances that did not comply with the CSA, DEA regulations, or any North Carolina statutes and regulations dealing with the dispensing of controlled substances.

Consent decree. The 13-page consent decree, entered by the court in July 2022, specified that before dispensing any controlled substance prescriptions, the defendants must review the patient's record in the North Carolina prescription data monitoring program and determine from the database records, the prescription, other available records, and other circumstances surrounding the presentation of the prescription whether the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice.

The defendants will also be required to identify "any indication that the prescribed controlled substance might be abused by the patient or diverted for an illegitimate purpose." The consent decree specifies 10 red flags that the defendants must spot, but also requires their scrutiny not to be limited to the specified red flags.

In addition, the defendants must "document in detail any indicators of abuse or diversion and the steps [they] took to reasonably ensure" that the prescription was legitimate and that the controlled substances dispensed would not be abused or diverted. The specified documentation for each prescription must be submitted to the DEA according to a quarterly schedule.

The consent decree also bars the defendants from filling certain prescriptions, such as daily dosages exceeding 90 MME; any combination of an opioid, a benzodiazepine and carisoprodol; early refills for any controlled substances; any controlled substance for a patient who lives more than 30 miles from the pharmacy; and "any controlled substance paid for with cash despite the fact that the patient has insurance available to pay for the patient's prescriptions."

If there is any noncompliance with the terms of the consent decree, the DEA may order the defendants to correct the noncompliance, including directing them to immediately stop ordering, distributing or dispensing controlled substances.

If the agency shuts down their controlled substance operations, the defendants' DEA registrations will be deemed to have been surrendered for cause, the DEA may have immediate access to the pharmacy premises, and the agency may seize all controlled substances and controlled substance order forms.

No sooner than at least five years after entry of the consent decree, the defendants may petition the district court for relief from the consent decree's requirements. The government will not oppose such a petition "if defendants have maintained a state of continuous material compliance with [the] decree, the CSA and its implementing regulations, and any North Carolina statutes and regulations pertaining to the distribution of controlled substances during the five years preceding defendants' petition."

Health System Pays More Than $4.36 Million, Enter Into Non-Prosecution Agreement Following Diversion Incidents

A Virginia-based regional health care system agreed to pay a civil penalty of over $4.36 million and enter into a four-year non-prosecution agreement with the DOJ to resolve allegations that the health system failed to have effective controls in place to prevent the diversion of dangerous prescription opioids (*In re Sovah Health*, No. 1:22-mc-00009-JPJ-PMS (W.D. Va.)).

Sovah Health consists of a hospital with campuses in Danville, Virginia (formerly Danville Regional Medical Center), and in Martinsville, Virginia (formerly Memorial Hospital of Martinsville and Henry County).

The government alleged that the health system failed to guard sufficiently against the diversion of controlled substances, filled orders for the substances without a system in place to detect suspicious orders, and failed to maintain readily retrievable records of controlled substances.

"The settlement is the third-largest civil penalty ever obtained from a hospital system under the (CSA) and the largest ever in the Fourth Circuit," the Office of the U.S. Attorney for the Western District of Virginia said in announcing the settlement in June 2022.

Diversions by pharmacy technician. The settlement follows two major diversion incidents involving Sovah Health employees.

According to a statement of agreed facts attached to the 11-page non-prosecution agreement, which was filed in the U.S. District Court for the Western District of Virginia, between June 2017 and June 2019 Paulette Toller, a pharmacy technician at the Danville hospital, diverted more than 11,000 Schedule II controlled substances and more than 1,900 Schedule III and Schedule IV controlled substances from the health care system.

Toller later admitted to obtaining hydrocodone, oxycodone and other controlled substances for her personal use.

Her diversions resulted from her exploitation of a flaw in the health system's computer system used to track controlled substances. For each diversion, she would enter information into the system indicating that certain controlled substances were to be moved from a central storage location to a location that was recognized by the computer system but no longer used by the hospital.

"As with all transfers of controlled substances," the statement of agreed facts reported, "a form was generated and printed with a sequential serial number. Such forms were required to be signed by two witnesses and returned and saved by Sovah Health – Danville. The forms were stored in two binders — one for Schedule II controlled substances, the other for all other controlled substances."

"In the instances when Toller diverted medications," the statement continued, "she destroyed the forms and did not place the forms in the location where such forms were to be saved."

Toller pleaded guilty in February 2020 to possessing a controlled substance with the intent to distribute, distributing a controlled substance, and obtaining possession of a controlled substance by misrepresentation, fraud, forgery or deception. In August 2020, she was sentenced to 13 months in federal prison.

Lack of inventory control. During the two-year period during which Toller diverted controlled substances, the Danville hospital did not conduct a full physical inventory of its controlled substances, which would have identified the employee's diversions.

Also, according to the statement of agreed facts, access to the pharmacy and to the controlled substances room within the pharmacy was controlled with a key card. However, a number of employees acknowledged, the controlled substances room door was often left propped open.

Moreover, there was no procedure to ensure that forms were missing from the two binders, such as a check of the forms to determine if a form within the sequence of serial numbers was missing.

In addition, no one reviewed the controlled substance transfer forms to determine whether the transfers had in fact been witnessed. "Several forms indicate transfers were not witnessed, as they bear no signature of a witness," the agreed statement of facts said.

Diversion by registered nurse. A second employee tampered with Schedule II controlled substances stored at the Danville hospital between January and May 2020.

Emilee Poteat stole the active ingredients from fentanyl vials and hydromorphone injectables (Dilaudid) "on a daily basis," the agreed statement of facts reported. She used a syringe to remove the controlled substances and replace them with saline. The vials with which she had tampered remained available to be administered to patients at the hospital.

"Although no patient harm was reported during the time period in which Poteat was tampering with drugs," the statement said, "Sovah Health employees administered medications to patients, even after seeing signs on some of the containers of possible tampering."

Eventually it was discovered that the tops of vials of fentanyl stored in the AcuDose point-of-care drug dispensing machine on one floor of the hospital had been tampered with. The tops of 14 vials of fentanyl had had their tops popped off, and the tops of six other vials fell off when they were touched. "One of the vials had a dry white film around the rim which appeared to be Super Glue," the DOJ reported.

A review of the AcuDose machine revealed that Poteat was the only employee who had accessed the drawer where the tampered vials were found.

On two occasions, Poteat told law enforcement officials that she had not tampered with controlled substances and that she did not use drugs. She also suggested that another hospital employee had used her password to gain access to the AcuDose machine. However, after being terminated by Sovah Health – Danville, she told the Virginia Department of Health Professions that she had a substance abuse problem, that she self-medicated with opioids, and that she had diverted the hospital's fentanyl and hydromorphone for her own use.

Poteat pleaded guilty in May 2021 to one count of tampering with consumer products that affect interstate commerce, one count of reckless disregard for the risk that another person be placed in danger of death or bodily injury, and one count of making false statements.

In February 2022, Poteat was sentenced to 36 months in federal prison.

Details of non-prosecution agreement. The non-prosecution agreement committed the health system to take on additional compliance measures, including:

- allowing the DEA unlimited access to the health system's controlled substance records while a facility is open to the public, including during unannounced inspections;
- allowing DEA personnel to access any Sovah Health facility during those hours, without prior notice and without an administrative inspection warrant;
- maintaining all required controlled substances records so that they are readily accessible upon request for inspection by the DEA;
- installing cameras at automated drug dispensing machines to capture the activity of anyone removing or adding controlled substances;
- using software to monitor discrepancies discovered during employees' blind counts of the controlled substances in dispensing machines, reviewing the discrepancies, and documenting the actions taken to resolve the discrepancies;
- maintaining reports of the disciplinary actions taken against employees who steal, divert or lose controlled substances, and making those reports readily accessible by the DEA upon request;
- promptly investigating theft, loss, tampering or diversion incidents and each potential violation of controlled substance laws, and reporting any incidents or potential violations to the Virginia State Police and the DEA within one business day after the incidents and potential violations are discovered;
- sending the Virginia State Police and the DEA a copy of any report to a regulatory agency that an employee has stolen, diverted or lost a controlled substance or abused or mishandled a controlled substance;
- informing the Virginia State Police and the DEA when an employee has been arrested or charged on controlled-substance-related charges;
- conduct background checks before hiring anyone who will have access to controlled substances;

- not hiring, without obtaining a DEA waiver, any person who would have access to controlled substances and who has been convicted of a controlled-substance-related felony, has had a DEA registration application denied, or has had a DEA registration revoked or surrendered for cause;
- maintaining a mandatory random drug testing program applicable to any employee who has access to controlled substances;
- creating and enforcing a policy of progressive discipline for violations of the health care system's controlled substance policies and procedures;
- conducting an annual physical inventory of all Schedule II-V controlled substances on hand, and providing the results of the inventory to the DEA within 24 hours;
- conducting an accountability audit on at least two Schedule II controlled substance medication formulations quarterly and reporting the audit results to the DEA within two days, with follow-up audits being conducted within 60 days; and
- conducting annual self-evaluations to review compliance with the CSA, DEA regulations and the non-prosecution agreement.

Sovah Health also committed to fully cooperate with any investigations or prosecutions undertaken by the DOJ that are related to controlled substances.

The health system agreed to the entry of a June 2022 order by the district court requiring it to comply with the terms of the non-prosecution agreement. The court said that it may impose "any sanction it deems appropriate" for any violation of the terms of the non-prosecution agreement or the order, including sanctions for criminal contempt of court.

"Today's settlement sends a clear message to all registrants that it is essential to maintain effective controls to prevent the diversion of controlled substances," said Jarod Forget, the DEA Washington Division's special agent in charge. He added that the agency "is dedicated … to hold all DEA registrants accountable."

The investigation into Sovah Health was conducted by the FDA's Office of Criminal Investigations' Metro Washington Field Office, the DEA Roanoke Resident Office Diversion Group, and the Virginia State Police.

Former N.J. Pharmacist Arrested on Charges of Illegally Distributing Oxycodone, Other Opioids

A 62-year-old former pharmacist was arrested in May 2022 on charges that she illegally dispensed huge quantities of oxycodone and other controlled substances to customers and drug dealers for more than three years from a Trenton, New Jersey, pharmacy (*United States v. Ndubizu*. No. 3:22-cr-00234-ZNQ (D.N.J.)).

Florence Ndubizu, formerly the co-owner and pharmacist-in-charge of Healthcare Pharmacy, was charged with one count of conspiracy to unlawfully distribute and dispense and to possess with intent to distribute Schedule II controlled substances, including oxycodone; one count of unlawfully distributing and dispensing a controlled substance; and one count of maintaining a premises for the illegal distribution of a controlled substance.

Grant jury indictment. "From at least as early as 2014 and continuing to on or about Aug. 31, 2017," according to a 34-page grand jury indictment filed in the U.S. District Court for the District of New Jersey, Ndubizu "operated her pharmacy as a criminal enterprise, unlawfully distributing and dispensing tens of thousands of doses of oxycodone and other Schedule II controlled substances for profit."

The indictment, filed in March 2022, was unsealed two months later.

Ndubizu and employee coconspirators who acted at her direction "filled fraudulent prescriptions outside the usual course of professional practice, knowing that the drugs would not be used for a legitimate medical purpose, but instead would be illegally diverted, including to street-level drug dealers," the indictment alleged.

According to the DEA and the DOJ, Ndubizu "purchased and distributed millions of dosage units of oxycodone, including over 800,000 pills in 2014, over 900,000 pills in 2015, over 800,000 pills in 2016, and over 200,000 pills in 2017, until the DEA suspended the pharmacy's registration." The statistics were obtained from the DEA's Automation of Reports and Consolidated Orders System (ARCOS).

During each of those years, Healthcare Pharmacy "was one of the largest purchasers of oxycodone in the state of New Jersey," the agencies alleged.

In August 2017, the DEA served an immediate suspension of registration order on the pharmacy, Ndubizu surrendered the pharmacy's registration five weeks later.

Change in distributors. As part of a conspiracy with pharmacy employees and drug dealers, the government alleged, Ndubizu purchased large quantities of controlled substances from distributors to satisfy the demands of pharmacy customers, whom she knew to be fraudulently obtaining or forging prescriptions. She allegedly knew that customers' purported prescriptions were not issued in the usual course of professional treatment and were not issued for a legitimate medical purpose.

In August 2016, one of the pharmacy's distributors suspended all sales of controlled substances to the pharmacy, the indictment reported. The distributor cited a number of red flags of diversion in the pharmacy's practices, including:

- the high percentage of oxycodone orders when compared with the pharmacy's total orders of controlled substances;
- the high percentage of the pharmacy's patients receiving only oxycodone from the pharmacy;
- the large number of patients paying primarily in cash and receiving combinations of oxycodone 30 mg and methadone 10 mg in large quantities;
- examples of physician shopping among patients receiving controlled substances from the pharmacy;
- the filling of duplicate and/or nonclinical combinations of prescriptions; and
- the filling of prescriptions for patients with excessive quantities of controlled substances prescribed.

The distributor continued to supply noncontrolled substances to the pharmacy. However, within nine weeks, Ndubizu closed the pharmacy's account with the distributor, and a week later she opened a new primary vendor account with another distributor and resumed ordering large quantities of oxycodone products and other Schedule II controlled substances.

Alleged filling of invalid, fraudulent prescriptions. The government also alleged that Ndubizu "filled facially invalid and fraudulent prescriptions at [the pharmacy] for profit." For example, according to the indictment, she and the pharmacy:

- filled prescriptions marked as "VOID," indicating that the purported prescriptions had been photocopied;
- filled prescriptions that did not identify the name of the patient;
- filled prescriptions purportedly from the same physician that bore different physician signatures;
- filled prescriptions that lacked the appropriate watermarks or other indicia that they had been written on a legitimate prescription pad; and
- filled prescriptions on which the customer had altered the prescription by increasing the number of dosage units called for (including cases in which customers had altered prescriptions while in the pharmacy and Ndubizu had been immediately notified about the alterations but ordered the prescriptions to be filled).

"Ndubizu failed to report any of these fraudulent prescriptions to DEA, and instead filled them for profit," the indictment alleged.

In addition, Ndubizu allegedly dispensed Schedule II controlled substances without conducting patient drug utilization reviews or consulting a patient's records in the state's Prescription Monitoring Program database. Approximately 100 of the customers allegedly averaged more than 200 MME of opiates per day, and "multiple" customers received more than 1,000 MME per day.

She also allegedly filled more than 1,000 prescriptions for the dangerous "trinity" combination of an opioid, benzodiazepine and a muscle relaxant, which can put patients at greater risk for potentially fatal overdoses.

Also, according to the indictment, Ndubizu filled more than 10,000 prescriptions from customers who had submitted prescriptions from different doctors for the same drug. More than 30 customers submitted prescriptions for oxycodone and other substances from three or more different physicians — an indication of doctor shopping.

Hundreds of prescriptions also allegedly were filled for out-of-state customers, including "many regular customers traveling from the New York City area and others traveling over 100 miles from other areas of New York state."

Other alleged parts of the conspiracy. Ndubizu also allegedly:

- filled numerous fraudulent prescriptions over several years without calling the prescribing physicians to determine whether the prescriptions were legitimate;

- continued to fill prescriptions for customers who had submitted fraudulent prescriptions in the past;

- filled prescriptions in exchange for cash payments that exceeded a drug's normal retail price;

- failed to report large quantities of missing oxycodone inventory to the DEA;

- instructed non-pharmacist employees to dispense Schedule II controlled substances when no pharmacist was present at the pharmacy;

- instructed employees to fill prescriptions even when circumstances demonstrated that the substances would be diverted — for example, when she instructed employees to sell customers additional prescription bottles "so that customers could subdivide their prescriptions for redistribution"; and

- filled prescriptions for oxycodone products knowing that the drugs would be illegally redistributed — for example, by allowing a customer to sit in the pharmacy "for hours" and purchase oxycodone from other customers immediately after Ndubizu filled their oxycodone prescriptions.

The indictment detailed the undercover operations used by law enforcement officials to observe the pharmacy's practices, including incidents in which undercover agents had prescriptions filled, asked for an additional prescription bottle, placed drugs in the additional bottle, and sold the additional bottle to another undercover agent.

Not guilty plea; possible penalties. In June 2022, Ndubizu pleaded not guilty to all three counts.

Both the conspiracy charge and the unlawful distribution charge brought against Ndubizu carry a maximum potential penalty of 20 years in prison and a $1 million fine or twice the gross gain or loss from the offense, whichever is greater. The drug-involved premises charge carries a maximum penalty of 20 years in prison and a $500,000 file or twice the gross gain or loss from the offense, whichever is greater.

The indictment included a notice to Ndubizu that the government will seek the forfeiture of property derived from her allegedly illegal activity.

The investigation was conducted by DEA diversion investigators, special agents and task force officers with the assistance of IRS Criminal Investigation special agents, officers of the Trenton Police Department, and the Mercer County Prosecutor's Office.

DEA Revokes Registration of Florida Pharmacy for Failing To Act on Red Flags of Abuse, Diversion

The DEA revoked the registration of a Florida pharmacy through an administrative proceeding following allegations that the business "repeatedly filled controlled substance prescriptions for numerous patients without addressing or resolving red flags of drug abuse or diversion" (*George Pharmacy, Inc.; Decision and Order*, 87 Fed. Reg. 21145 (April 11, 2022)).

October 2018 inspection. In August 2019, the DEA issued an order to show cause and immediate suspension of registration to Daytona Beach, Florida-based George Pharmacy Inc. following an on-site inspection conducted by the agency in October 2018.

During the inspection, the pharmacy's owner and pharmacist-in-charge described the process through which the company sought to verify the validity of controlled substance prescriptions, asserting that it was sufficient to check Florida's Prescription Data Monitoring Program (E-FORSCE) for patient information and to check the Florida Department of Health to confirm the validity of the prescribing physician's license.

"As long as the physician's license is legitimate, [the pharmacy] would fill the prescription," the DEA reported. The pharmacist-in-charge "asked the DEA what other red flags would have to be addressed 'if the doctor is legitimate and the script is legitimate,'" the agency said.

DEA officials responded by warning the two pharmacy officials that George Pharmacy had been filling prescriptions for controlled substances in the face of obvious red flags of abuse and diversion, including "the high cash payments made by [the pharmacy's] patients, as well as the long distances traveled by [the pharmacy's] customers to obtain and fill their prescriptions." The agency officials also warned the officials about the large quantities of hydromorphone prescriptions that the pharmacy purchased.

In response, the two pharmacy officials "asked for one more chance and the opportunity to take continuing education classes," the DEA reported.

Administrative subpoena. In November 2018, the DEA served an administrative subpoena on the pharmacy to obtain the business's records and patient profiles. The materials covered by the subpoena included due diligence documentation, prescriptions, electronic dispensing logs and other dispensing files for certain patients covering the period between November 2015 and October 2018.

In March 2019, DEA officials met with the two pharmacy employees and informed them that a Florida pharmacy expert hired by the agency to review the pharmacy's records determined that there were "numerous red flags with many of the prescriptions that [the pharmacy] had filled" and that there was "no documentation supporting adequate resolution of these red flags." The pharmacist-in-charge responded that it had stopped filling prescriptions for the patients whose prescriptions the expert had reviewed.

The DEA officials then told the pharmacy officials that the agency was pursuing administrative action and asked them to surrender the pharmacy's certificate of registration. The pharmacy officials refused to do so.

During its review of the pharmacy's E-FORSCE report, the DEA "identified several additional customers whose prescriptions presented red flags of abuse and diversion, such as large cash payments and long distances traveled." The agency then served additional subpoenas on the pharmacy and performed additional on-site inspections. The additional records obtained were provided to the pharmacy expert for analysis.

"Additional red flags." Through his analysis, the expert "identified additional red flags that pharmacists must address or resolve prior to filling a prescription" because of pharmacists' corresponding responsibility to ensure that a prescription for a controlled substance is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice (21 C.F.R. §1306.04).

The red flags identified by the expert included not only long distances traveled, the DEA reported, but also:

- prescriptions for so-called cocktail medications, such as the "trinity" cocktail of opioids, benzodiazepines and muscle relaxants;

- cash payments at inflated prices, with George Pharmacy's patients willing to pay for their prescriptions at prices that were more than five times what other pharmacies would charge, in order to conceal the fact that the patients were abusing or diverting the drugs;

- inappropriate drug dosages and durations of treatment, such as patients receiving prescriptions for immediate-release opioids for several months at a time — despite the facts that immediate-release medication should be used only to treat short-term acute pain and that patients with legitimate chronic pain should eventually be switched to safer, long-term pain medication; and

- pattern prescribing, in which physicians (1) regularly prescribe common drugs of abuse or diversion in the same dosages and quantities to many patients sharing the same surnames or addresses and (2) use the same diagnosis codes to justify the prescriptions — indicating that the physicians are focused on distributing drugs with high street value rather than on examining their patients and developing individualized treatment plans.

Based on the pharmacy's prescribing histories for 15 patients, the expert concluded that, because of its failure to resolve these red flags, the pharmacy failed to follow the minimum requirements for Florida pharmacists and thereby acted outside the usual course of professional practice in filling each prescription.

DEA administrator's order. In her analysis, the DEA administrator concluded that the government had met its prima facie burden of showing that the pharmacy's continued registration was inconsistent with the public interest.

The pharmacy had first requested an administrative hearing and then filed a motion to terminate the proceedings and cancel the hearing, which a DEA administrative law judge granted. In so doing, the DEA administrator said, the pharmacy had failed to avail itself of the opportunity to refute the government's case.

"In light of the registrant's egregious violations, which go to the heart of the [CSA's] purpose of preventing addiction and recreational abuse of controlled substances," the DEA administrator said, "[the pharmacy's] silence weighs against [its] continued registration."

On this basis, the DEA administrator revoked the pharmacy's certificate of registration and denied any pending applications for renewal or modification of the registration. In addition, the administrator ordered that any controlled substances seized under the order of immediate suspension be forfeited to the government.

The DEA administrator's order was effective May 11, 2022.

S.C. Health Care System To Pay $1 Million To Resolve Alleged CSA Reporting, Recordkeeping Violations

A South Carolina-based health care system agreed to pay $1 million to resolve allegations that it committed reporting, recordkeeping and dispensing violations of the CSA. The violations allegedly led to the illegal diversion of controlled substances by two patients who later pleaded guilty to federal drug distribution charges.

The settlement amount was the largest ever involving allegations of violations of DEA requirements in the state.

The government said that the civil settlement between Prisma Health Midlands and the government was the culmination of a joint investigation by the DEA and the U.S. Attorney's Office for the District of South Carolina that began in November 2018, when the two Prisma patients were arrested. The DOJ alleged that the patients were able to receive some of the illegally distributed controlled substances through Prisma's pharmacy.

According to the government, over a three-year period Prisma failed to notify the DEA of thefts or significant losses of controlled substances as required under the CSA. "As a DEA registrant," the DOJ said, "Prisma has certain recordkeeping and reporting obligations, and one of these is to promptly notify the DEA whenever a theft or significant loss occurs."

Under 21 U.S.C. §830(b)(1)(C) and 21 C.F.R. §1301.76(b), a registrant that is a practitioner must notify the local DEA Field Division Office in writing of the theft or significant loss of any controlled substance within one business day of the registrant's discovery of the theft. The report should be submitted on DEA Form 106 via the DEA's Theft/Loss Reporting Online (TLR) system or directly to DEA diversion authorities on a downloaded fillable PDF version of the form.

The government also alleged that Prisma pharmacists violated the CSA by filling prescriptions for the two patients that were not issued for a legitimate medical purpose.

The health care organization and the government entered into a memorandum of agreement as part of the settlement.

According to DEA Atlanta Field Division Special Agent in Charge Robert J. Murphy, DEA diversion investigators had uncovered recordkeeping discrepancies for the controlled substances that Prisma purchased, maintained and dispensed.

The case was investigated by the DEA, the DOJ Civil Division and the U.S. Attorney's Office.

The government stressed that the conduct outlined in the settlement agreement was merely alleged and that the agreement did not constitute an admission of liability by Prisma.

Co-Owner of Texas Pharmacies Convicted of Illegally Dispensing More than 1.5 Million Controlled Substance Doses

The co-owner of three Texas pharmacies was convicted by a federal district court jury in March 2022 on charges of unlawfully distributing controlled substances and money laundering. According to the DOJ, the co-owner and his coconspirators unlawfully distributed more than 1.5 million dosage units of controlled substances, including more than 1.1 oxycodone and hydrocodone pills (*United States v. Curry*, No. 4:18-cr-00339 (S.D. Tex.)).

Clint Carr, of Cypress, Texas, co-owned and operated CC Pharmacy in Houston and CC Pharmacy 2 and CC Pharmacy 3 in the Austin area. The DOJ said that the pharmacies' staffs were shown at trial to have unlawfully dispensed the controlled substances in bulk for cash, based primarily on forged or stolen prescriptions that had been brought to the pharmacies for filling by drug couriers posing as staff of long-term care facilities.

The pharmacies took in more than $5.5 million from the unlawful sale of the controlled substances, the government alleged. Carr and his coconspirators structured the cash proceeds to avoid reporting requirements, depositing the unlawful proceeds in increments just below $10,000 into accounts held in the names of the three pharmacies.

"Evidence at trial showed that Carr and his coconspirators used these drug proceeds to finance a lavish lifestyle, including the down payment on a $100,000 Ford truck," the DOJ reported.

Carr was found guilty by a jury of the U.S. District Court for the Southern District of Texas on one count of conspiracy to unlawfully distribute and dispense controlled substances, four counts of unlawfully distributing and dispensing controlled substances, one count of conspiracy to launder monetary instruments, and two counts of engaging in monetary transactions in property derived from specified unlawful activity.

The defendant faced a possible maximum penalty of 140 years in prison. In June 2022, Carr was sentenced to 20 years in prison and ordered to forfeit more than $700,000 for operating a pharmacy that illegally dispensed controlled substances and for laundering the criminal proceeds.

Five other coconspirators, including Dustin Curry, the pharmacies' other co-owner, have pleaded guilty to related charges of illegally distributing controlled substances.

Hassan Barnes, the pharmacy's pharmacist-in-charge, was sentenced in July 2022 to 24 months in prison for unlawfully dispensing opioids and other controlled substances. Frasiel Hughey, a supplier-level drug dealer, was sentenced in June 2022 to 20 years in prison for using fake prescriptions to purchase opioids and other controlled substances.

The DEA's Houston Division, including the agency's Austin Resident Office, investigated the case.

N.M. Pharmacy Pays $400,000 Penalty for Alleged Violations of DEA Inventory, Records Requirements

A New Mexico-based pharmacy agreed to pay $400,000 to resolve civil claims brought by the DOJ on behalf of the DEA's El Paso Division Regulatory Diversion Group that the company failed to account for more than 26,000 missing dosage units of controlled substances.

Ready Pharmacy was registered with the DEA as a retail pharmacy and was authorized to dispense controlled substances.

In March 2016, the agency conducted an on-site inspection of the pharmacy that allegedly revealed the inventory discrepancy. Also during the inspection, controlled substances "were discovered unsafeguarded and not properly stored," the DOJ said.

Stipulated judgment. In December 2021, Ready Pharmacy, its pharmacist in charge, and an employee who worked as a pharmacy technician entered into a stipulated judgment

with the DOJ under which the defendants jointly and severally agreed to pay a $450,000 civil penalty in connection with multiple alleged CSA violations (*United States v. Hurab*, No. 1:19-cv-01195-MV-LF (D.N.M.)).

According to a complaint filed with the U.S. District Court for the District of New Mexico in December 2019, the pharmacist in charge and the employee owned Ready Pharmacy I Inc., which the DOJ said had gone by the names Rede Pharmacy Inc., Rede Partnership, Ready Pharmacy and variations of those names.

During the DEA inspection, which was conducted along with the New Mexico Board of Pharmacy (NMBOP), Mahmood Hurab, the pharmacist in charge, provided the investigators the pharmacy's controlled substance inventory from May 2014, the government reported.

The investigators' audit of the inventory revealed that there were 26,078 dosage units for which there was no accounting at the pharmacy. The controlled substances involved included alprazolam, amphetamine/salt combo tablets, carisoprodol, oxycodone, oxycodone with acetaminophen, and zolpidem.

Controlled substances allegedly stored in car. Also during the inspection, Hurab allegedly "showed controlled substances that he had in his car." He allegedly told the investigators that the Schedule II-V controlled substances were expired medications that he intended to return to a pharmaceutical services company. According to the DOJ, NMBOP seized the 635 ½ dosage units that had been in Hurab's car.

The complaint also alleged that Hurab had continued to write and fill invalid prescriptions after his state controlled substance license and his state pharmacist/clinician license had expired. The government alleged 114 instances in which Hurab had written prescriptions after his pharmacist/clinician license had expired.

Among the prescriptions for carisoprodol and alprazolam that had been prescribed to Hurab and dispensed by the pharmacy, the date on one "had been altered from the original date the prescription was issued," according to the DOJ. Also, the government alleged, a carisoprodol prescription had been written for 30 250 mg tablets, but the pharmacy filled the prescription by dispensing 30 350 mg tablets. Moreover, the pharmacy allegedly refilled one of the prescriptions even though the prescription did not allow for refills.

Alleged missing records. Moreover, the DOJ alleged in the complaint, the pharmacy had not retained an October 2015 distributor invoice and 40 written controlled substance prescriptions, and on 44 invoices it failed to record the quantities of controlled substances received and the dates they were received.

The complaint also alleged failures to record the quantity received and/or the date received on three DEA Form 222 orders, to record the patients' addresses on seven prescriptions for controlled substances, and to furnish an inventory, DEA 222 order forms, and other required records for the dosage units found in Hurab's car.

The defendants' actions violated multiple sections of the CSA and its implementing regulations, the government alleged in the complaint.

Ready Pharmacy agreed to pay the $400,000 civil penalty over five years, with an initial payment of $50,000 due within 30 days of the settlement date.

The pharmacy is no longer in operation.

N.C. Pharmacy Agrees To Pay $100,000 Penalty for Allegedly Not Checking Validity of Prescriber's License

A North Carolina pharmacy agreed to pay a civil money penalty of $100,000 to settle allegations that it filled invalid prescriptions for controlled substances without confirming the validity of the prescribing physician's license. The DEA said that the pharmacy's "reckless" actions violated its corresponding responsibility under the CSA and 21 C.F.R. §1306.04(a).

Aspirar Pharmacy L.L.C. and Aspirar Pharmacy of Durham L.L.C. allegedly filled the prescriptions, which had been written by Dr. Sharon Halliday, at its two locations in Cary and Durham.

According to the DOJ, Halliday had obtained a limited medical school faculty license (MSFL) from the North Carolina Medical Board in connection with her work at Duke University. According to the board's website, such a license "is intended to allow North Carolina medical schools to benefit from the expertise, specialized knowledge, or unique skills of physicians who are not otherwise eligible for full licensure in North Carolina."

A physician should file an application for an MSFL if he or she wants to come to the state "for a limited time, scope and purpose, such as to demonstrate or learn a new technique, procedure or piece of equipment, or to educate physicians or medical students in an emerging disease or public health issue."

The license allows a physician to practice medicine "only … to the extent authorized by its sponsoring university," the DOJ said.

The government alleged that while Halliday possessed the MSFL, she prescribed controlled substances outside the scope of medical practice permitted by Duke. Aspirar Pharmacy allegedly filled these invalid prescriptions for Halliday without checking the validity of her license.

In addition to paying the penalty, the pharmacy agreed to enter into a Memorandum of Agreement with the DEA specifying that Aspirar Pharmacy would no longer fill any prescriptions from RAPHA Healthcare Services L.L.C., the drug addiction medicine practice that Halliday owned and operated.

"An essential part of combatting the opioid epidemic is ensuring that pharmacies are held to the same standard as prescribers," said Sharon J. Hairston, the U.S. Attorney for the Middle District of North Carolina. "Pharmacies cannot simply put their head in the sand when filling prescriptions and work under the assumption that the physician complied with their legal obligations."

DEA Special Agent in Charge Robert J. Murphy said that investigators with the agency's Diversion Control Division "did an outstanding job of uncovering the reckless actions of Aspirar Pharmacy in filling prescriptions from a physician operating outside the scope of her limited license."

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

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