

DEA REGISTRANTS PLAY A VITAL ROLE IN PREVENTING DIVERSION

With roughly [64,000 people dying from drug overdoses last year](#) and with nearly one-third of those deaths involving prescription painkillers, the current administration has declared the [opioid epidemic a "National Emergency."](#) Every day more than [1,000 people are treated in emergency departments](#) across the country for misusing prescription opioids. It is estimated that almost [80% of heroin users first struggled with prescription opioid addiction](#). In this sense, prescription painkillers are walking users to heroin's door, across that threshold and into a deadly embrace.

To address a problem of this magnitude and complexity, a balanced, holistic approach is needed from the U.S. Interagency and the entire pharmaceutical controlled substances supply chain. These efforts must protect the public from highly addictive, potentially dangerous drugs while at the same time, ensure patients have access to their legitimate medications.

The pharmaceutical controlled substances supply chain includes approximately [1.7 million Drug Enforcement Administration \(DEA\) Registrants](#) comprised of manufacturers, distributors, pharmacies, practitioners, hospitals, importers, exporters and researchers. Increased enforcement focused on DEA Registrants has brought about civil and administrative actions against Registrants not upholding their regulatory obligations. Several examples of recent enforcement actions include:

- A [national chain pharmacy paid \\$80 million](#) to resolve federal charges alleging their failure to prevent the diversion of prescription opioids.
- A prominent academic medical center paid \$2.3 million to resolve allegations that their lax anti-diversion efforts enabled employees to divert controlled substances.
- A [national manufacturer agreed to pay \\$35 million](#) to settle allegations related to its efforts to detect and inform DEA of controlled substances suspicious orders.
- A [national wholesaler paid \\$150 million](#) to resolve alleged violations of the Controlled Substance Act (CSA). The settlement also required the wholesaler to hire an Independent Monitor to assess their compliance and ensure the terms of the negotiated settlement.

At the federal level, the Department of Justice, DEA, FBI, Office of Inspector General Health and Human Services and other members of the U.S. Interagency are developing new initiatives to complement their already robust enforcement activities. More specifically, the DEA Diversion Control Division, the primary entity responsible for regulating DEA

Registrants by enforcing the CSA and implementing Code of Federal Regulations (CFR), will continue to focus its regulatory and investigative efforts on manufacturers, distributors, pharmacies, and practitioners. To support their efforts, over the next few years, the DEA plans on expanding the number of Tactical Diversion Squads; increasing the number of Diversion Investigators; [hiring Special Assistant United States Attorneys](#) dedicated to federal anti-diversion prosecutions and assigned to opioid “hotspots” around the country; hiring additional financial analysts who support investigations of DEA Registrants across the entire supply chain; and increasing the frequency of regulatory inspections.

In addition, this past summer, the Attorney General announced the formation of the [Opioid Fraud and Abuse Detection Unit](#) which will focus specifically on opioid-related healthcare fraud using data to identify and prosecute those that are contributing to the prescription opioid epidemic and hiring additional Assistant U.S. Attorneys to focus solely on investigating and prosecuting healthcare fraud related to proscription opioids.

Now, more than ever, DEA Registrants across the entire controlled substances supply chain must be proactive in their internal assessments and external engagement with government regulators. DEA registrants play a vital role in preventing diversion and maintaining a closed system of distribution. There are several concrete steps they can take now to help ensure compliance with the CSA and CFR, including but not limited to:

- Engaging an independent monitor/consultant to assess its diversion control program objectively and help ensure compliance with the CSA and CFR.
- Annually revisiting policies, procedures, processes and recalibrating them accordingly.
- Enlisting support from leadership across their organization to promote the goal of preventing and detecting the diversion of controlled substances.
- Maintaining the independence of DEA Regulatory Affairs and/or DEA Compliance units within their organization’s corporate structure.
- Mandating annual diversion compliance training for all employees tailored to their role and responsibility.
- Where appropriate, establishing a customer due diligence process mandated for all existing and any new customers.
- Mandating detailed due diligence documentation that is preserved for subsequent review.
- Developing a standardized due diligence checklist to establish consistency and minimum requirements for customer due diligence files.
- Leveraging organizational data associated with the CSA and diversion risks to monitor and alert management of potential violations.
- Conducting periodic mock DEA audits to focus on frequently cited DEA violations, for example:
 - Failure to set up a system to detect suspicious orders.
 - Failure to report to the Automation of Reports and Consolidated Reporting System (ARCOS).
 - Failure to report theft and loss.
 - Failure to maintain complete and accurate records.
 - Failure to document transfers between Registrants.
 - Failure to account for losses.
 - No Biennial Inventory.
 - Making security changes without notifying DEA.

It should be noted that the majority of DEA Registrants are law-abiding and have appropriate anti-diversion protocols in

place. However, there often is a discrepancy between delineated protocols and their actual implementation. Regular, robust anti-diversion assessment and appropriate improvement and the development of policies that ensure compliance with the CSA and CFR will help avoid the financial and reputational risk that can result from enforcement actions. Proactive external engagement with government regulators and investigators is also critical to enhance communication, receive clarity regarding nuanced regulatory requirements, and minimize the litigation risk associated with government investigations.



LOUIS MILIONE

Senior Managing Director