

DEA REGULATORY COMPLIANCE

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DEA registrants play a vital role in preventing diversion and maintaining a closed system of distribution. However, now, more than ever, DEA registrants throughout the controlled substances supply chain must be proactive in their internal assessments and external engagement with government regulators.

Our DEA Regulatory Compliance practice is made up of nationally respected, multi-disciplinary experts in the Controlled Substances Act (CSA) and the Code of Federal Regulations (CFR). The team includes former DEA attorneys and compliance experts, Diversion Investigators, and Special Agents. Our experts can outline the appropriate steps to ensure fulfillment of the regulatory requirements of a DEA registration and help avoid the financial and reputational risk that can result from noncompliance, including potential enforcement actions.

In both the public and private sector, our experience finds that the majority of DEA registrants are law-abiding and have appropriate anti-diversion protocols in place. However, there are times when a discrepancy occurs between delineated protocols and actual implementation. That's why we recommend a periodic review and assessment of any anti-diversion program, including its policies and procedures and personnel training practices. This can serve to enhance an already robust compliance program. Further, proactive external engagement with government regulators and investigators is also critical to improve communication, receive clarity regarding nuanced regulatory requirements, and minimize litigation risk associated with government investigations.

We can assist you in navigating the regulatory "waters" in any number of ways - from our variety of services offerings that can be tailored to meet the needs of your specific situation.

SERVICES INCLUDE:

• ANTI-DIVERSION PROGRAM COMPLIANCE REVIEW

- We will conduct a full assessment of your anti-diversion program in an objective manner to ensure compliance with the CSA and CFR.
- Assessments can be done in a proactive manner, in coordination with counsel (if litigation is ongoing or anticipated), or in anticipation of a potential investigation.
- The review will include an evaluation of Suspicious Order Monitoring System (SOMS), anti-diversion and due

diligence policies and procedures, and training protocols.

- Additionally, we can include suggestions for overall enhancements, program improvement, assistance with implementation, and monitoring support.

- **CREATION/ESTABLISHMENT OF ANTI-DIVERSION PROGRAM**

- Needed for new DEA registrants
- Possibly needed for DEA registrants whose compliance program needs a full overhaul
- Includes creation and implementation of anti-diversion and due diligence policies and procedures, Suspicious Order Monitoring System (SOMS) program, training protocols, staff/personnel hiring and support, and full program support until personnel are fully trained

- **DEA REGISTRATION APPLICATION ASSISTANCE FOR NEW DEA REGISTRANTS**

- Includes application assistance, creation of policies and procedures, compilation of DEA binders, preparation for DEA pre-registration inspection, including "mock inspection"

- **FULL COMPLEMENT OF DEA REGULATORY COMPLIANCE TRAININGS**

- Soon-to-be accredited
- Can be customized to meet your needs
- Live, virtual, or combination
- "Train-the-trainer" options available