

# DEA REGULATORY COMPLIANCE

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DEA registrants play a vital role in preventing diversion of controlled substances, protecting the closed system of distribution, and maintaining the integrity of the controlled substances supply chain. Now, more than ever, all DEA registrants must be proactive and effective in their internal assessments of anything and everything related to controlled substances as well as with their external engagements 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 compliance with the regulatory requirements of a DEA registration and help avoid the financial and reputational risk that can result from noncompliance, including potential enforcement actions. We have successfully worked with our clients to establish compliance programs that have withstood the scrutiny of DEA.

In both the public and private sector, our experience has been 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 is 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 and effective 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. The variety of services we offer can be tailored to meet your specific needs.

### **Services Include:**

#### **ANTI-DIVERSION COMPLIANCE PROGRAM**

- We will conduct a full assessment of your DEA regulatory compliance program to ensure compliance with the CSA and CFR.

- If you do not have an anti-diversion compliance program, we will work with you to create one customized for your business needs.
- Our assessments will include an evaluation of controlled substance policies and procedures, anti-diversion and due diligence measures and systems, training protocols, personnel hiring and support, and effective compliance controls.
- We can include suggestions for overall enhancements and program improvement, assist with implementation, and provide program and monitoring support.

#### **PREPARING FOR A DEA INSPECTION**

- We work with you and your team to ensure you are fully prepared for a DEA inspection.
- We will conduct a mock DEA inspection, consisting of an on-site review of policies and procedures and controlled substance records, the creation/review of DEA binders, completing an accountability audit, assessing effective controls, and conducting employee interviews.
- We will provide trainings related to controlled substances compliance and what to expect from DEA.

#### **DEA REGISTRANT ASSISTANCE - New and Existing Registrants**

- We will review all aspects of your DEA registration(s) to ensure compliance and provide recommendations as appropriate.
- We will collaborate with you to ensure understanding of the regulations and requirements.
- We will assist with the creation of policies and procedures, and compilation and review of DEA binders for each registration.
- For new DEA registrants, we offer 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 CME accredited
- Can be customized to meet the needs of your business
- Can be live, virtual, or a combination
- "Train-the-trainer" options available