



The following visual presentation is intended for use when accompanied by an oral presentation from the creator of the presentation. This presentation is not legal advice.



How to Keep (or Lose) Your DEA Registration

*“I’m a Government Lawyer and I’m
Here to Help!”*

Rules of the Road

Manufacturers and Distributors

- Don't falsify an application for registration
- Do maintain effective controls against the diversion of controlled substances into other than legitimate channels
- Do comply with applicable state and local law
- Don't do anything that makes your handling controlled substances inconsistent with the public health and safety



Effective Controls Against Diversion

- Good recordkeeping is essential
- Detect and report suspicious orders
 - Unusual size
 - Deviating substantially from a normal pattern
 - Unusual frequency
 - Anything else that makes it unusual to a registrant
- Theft and significant loss report

Key Questions

- What is my customer's practice area?
- How does this particular customer's orders compare with the orders of similarly situated customers that I service?
- How does this customer's recent orders compare with the customer's historical ordering patterns?
- Can the customer explain peculiarities or anomalies in its orders?
- Are there readily observable warning signs about certain localities?

Rules of the Road

Pharmacies

- Don't falsify an application for registration
- Do maintain appropriate state licenses
- Do comply with applicable federal, state and local law
- Don't do anything that makes your handling controlled substances inconsistent with the public health and safety



General and Corresponding Responsibility

- Good recordkeeping is essential
- Theft and significant loss report
- Ask questions when you become suspicious

Key Questions

- Is this prescription typical for this type of prescriber?
- Does this prescriber tailor his prescribing to needs of the patient?
- Does the prescriber possess the required state licenses to issue this prescription?
- Does the customer's history or behavior raise red flags about this prescription?
- Is the unusual explainable?

What Doesn't Work

(Or How to *Lose* Your DEA Registration)

- “They have (or had) a DEA registration and that’s good enough.”
- “It’s not my job to second guess the doctor.”
- “Our automated screening system works great, but it doesn’t catch that.”
- “Our volume of business is too great to screen each order/prescription.”
- “I’m not responsible for what my customer does with the drugs.”

Instructive Final Orders

Patrick W. Stodola, M.D., 74 Fed. Reg. 20727 (May 5, 2009)

Bob's Pharmacy and Diabetic Supplies, 74 Fed. Reg. 19599
(April 29, 2009)

George C. Aycock, M.D., 74 Fed. Reg. 17529 (April 15, 2009)

Lawrence T. McKinney, M.D., 73 Fed. Reg. 43260 (July 24, 2008)

Paul H. Volkman, M.D., 73 Fed. Reg. 30630 (May 28, 2008)

Southwood Pharmaceuticals, 72 Fed. Reg. 36487 (July 3, 2007)

United Prescription Svcs., 72 Fed. Reg. 50397 (Aug 31, 2007)

Emerging Issues

- Retail and wholesale distribution of scheduled listed chemical products can affect your DEA controlled substances registration
 - Distributors must report transactions in extraordinary quantities
 - Distributors must verify the apparent validity of its customers (self-certification under the CMEA)
 - Retailers must keep accurate and complete logbooks
 - Retailers must be self-certified
 - Retailers must adhere to daily sales limit of 3.6 grams per customer

Emerging Issues

- Dispensing by individual practitioners
- Compounding (it is manufacturing unless you meet both prongs of the exception)
- Modified Internet diversion schemes
 - Geographic distance between prescriber and “patient”
 - Frequently involves a narcotic and a depressant
- Traditional means of diversion are on the rise
 - Prescription mill/pill mill operation
 - Employee theft

How to Keep Your DEA Registration

- Master the obvious
 - Recordkeeping
 - Reporting
 - Does it quack like a (diverting) duck?
- Know your customer's, and where applicable, the prescriber's business or professional practice
- Know the statutory factors that lead to revocation
- Study DEA's Final Orders
- Act consistently with DEA's goal: protect the public health and safety from the harms caused by diversion