

Preparing for Increased DEA Office of Diversion Control Cyclical Inspections

Gates Healthcare Associates' Controlled Substance Division can assist you in meeting the requirements and challenges described below.

Headline: DEA to Increase Pharmacy Opioid Inspections (April 29, 2014)

Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA) noted: *16,000 people lost their lives in 2010 to overdoses involving prescription opioids:*

“The cycle of abuse between licit and illicit opioids requires us to recognize that what these individuals and communities are facing is not a heroin or a prescription drug problem. **It is an addiction problem.** Heroin use and prescription drug abuse are both addictions that begin with use and are sustained and promoted through increased trafficking. This serious public health problem can be addressed by education, appropriate screening and treatment, recovery support, and **enforcement.** These initiatives can be effective regardless of whether the problem is fed by heroin or prescription drugs. The DEA supports all of these initiatives to address both prescription drug misuse and abuse and heroin use.”

Further noting: DEA has **steadily increased the frequency of compliance inspections** of specific registrant categories, including pharmacies and stated that “this renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the Controlled Substances Act and its implementing regulations.”

CDC reports as of July 1, 2014:

- Forty-six individuals die every day in the US from prescription overdose;
- Healthcare providers wrote 259 million prescriptions for opioid painkillers in 2012

Let's take a step back and be vigilant in protecting against opioid losses through theft, diversion, improper dispensing, or fraud.

Gates Healthcare Associates, Inc.
One Central St. Suite 201
Middleton, MA 01949

(978) 646-0091 | www.gateshealthcareassociates.com

Controlled
Substance
Division

Gates Healthcare Associates believes that with the increased theft/diversion of controlled substances by impaired healthcare workers (i.e. pharmacists, nurses, physicians, pharmacy technicians, etc.) employed in DEA licensed facilities, it is very important to recognize that all registrants are responsible to ensure that security is adequate to prevent diversion and that failure to do so may result in significant civil fines.

Stronger risk management policies and procedures will assist registrant pharmacies in preparing for, and responding to increased DEA Diversion compliance inspections.

Gates Healthcare's Top Ten Suggestions:

1. Ensuring that registrant conducts biennial inventory every two years (21 CFR 1304.11) of all controlled substances (must be done any time within two years from previous inventory).
2. Ensure security is effective to prevent theft/diversion of controlled substances (21 CFR 1301.71)
3. Ensure all Form-222 Schedule Narcotic/Non-narcotic order forms for purchases of Schedule II controlled substances are compliant (21 CFR 1305.13)
4. Ensure all prescriptions written are for a legitimate medical purpose and issued by a practitioner acting in the usual course of professional practice (21 CFR 1306.04); this is called "Corresponding Responsibility".
5. Ensure all records to account for receipt of controlled substances are "readily retrievable" (on hand) for past two years (21 CFR 1304.21).
6. Conduct thorough background checks on each employee hired (best practice security provision).
7. Each registered premises should designate a primary employee to manage controlled substance security and policies/procedures.
8. Each registered premises should conduct a mock inspection, including a controlled substance audit. Random audits will assist in discovering early stage, reportable thefts or losses.
9. Each registered premises should randomly review a selected number of controlled substance hard copy purported prescriptions to ensure that they contain all information required and were issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice (verify the authenticity of each).
10. Each registered premises should develop and routinely review and update controlled substance policies and procedures.

Contact us for a free consultation on how to be ready for these changes!

Gates Healthcare Associates, Inc.
One Central St. Suite 201
Middleton, MA 01949

(978) 646-0091 | www.gateshealthcareassociates.com

Controlled
Substance
Division

