Guidepost

Eyes Wide Open: Mastering Suspicious Order Monitoring Under DEA Rules

By Sarah Pechnick
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Despite the absence of updated federal regulations on suspicious order monitoring, this area has garnered significant attention recently. There have been countless reports detailing the multi-district opioid litigation settlements, amounting to billions of dollars. Furthermore, the U.S. Department of Justice has filed more recent lawsuits (and forced settlements) against wholesale distributors alleging their failure to comply with federal regulations, specifically creating effective systems to detect and report suspicious orders. Given this heightened focus, Drug Enforcement Administration (DEA) Registrants are seeking answers surrounding these crucial compliance issues.

The Basics of SOMS for DEA Registrants

This guide aims to clarify the fundamentals, staring with: "what is a Suspicious Order Monitoring System (SOMS)?" A SOMS, which is often a compliance framework combined with software tools, is implemented by DEA registrants (mainly pharmaceutical manufacturers and distributors) to detect, evaluate, and report orders of controlled substances that could indicate diversion into illegal or non-legitimate channels.

Next, what exactly constitutes a suspicious order? A suspicious order includes orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. The more challenging aspect is how does a registrant effectively identify a potentially suspicious order, and when that happens, how do they determine whether or not it is suspicious. A potentially suspicious order is one that falls outside of a pre-determined baseline. For example, a customer ordering three times their normal order quantity or a customer suddenly placing weekly orders instead of once a month. These are the kinds of purchases that warrant questioning and proper follow-up.

This leads us to our next question: when should a DEA registrant report an order to the DEA? Per 21 Code of Federal Regulations C.F.R. § 1301.74(b), registrants are required to inform the local DEA office upon discovery of the suspicious order. Proposed changes to current DEA regulations, introduced in 2020, suggest that DEA registrants may have an option in the future to report suspicious orders immediately upon being flagged or subsequent to an investigation which cannot dispel all suspicious circumstances.

Reporting and Integrating Best Practices into Your SOMS

In order to establish baselines, instituting proper customer thresholds is a crucial component of an efficient suspicious ordering monitoring program. Consider these thresholds as your first alert system. They must be flexible enough to accommodate normal business fluctuations (like seasonal changes), yet tight enough to catch potentially problematic orders. And here's the thing – these thresholds aren't set-it-and-forget-it numbers. They require regular review and adjustment based on your ongoing business observations.

Having and following clear due diligence policies and procedures is crucial for DEA compliance. This means knowing exactly what steps to take when an order looks suspicious. Whether that step is as simple as calling the customer to verify the order or a more in-depth investigation, you need a clear process that everyone understands and consistently follows.

Technology and access to “good data” play a huge role in suspicious order monitoring programs. Most DEA-registered manufacturers and distributors utilize sophisticated software that can analyze patterns in real-time and flag potential issues before they become problems. But remember, technology is only as good as the people using it. This is why staff training is also absolutely crucial. Regular training updates help keep your team sharp and informed about new trends or patterns to watch for.

Documentation and Adapting to Evolving DEA Standards

Documentation is another critical aspect of robust suspicious order monitoring. Think of it as covering your bases – every flagged order, every investigation, every decision needs to be thoroughly documented. This isn't just about compliance; it's about building a system that can demonstrate your commitment to preventing drug diversion.

The industry standards for suspicious order monitoring are always evolving, making it essential to stay current. This involves regular program reviews, updates to procedures, and maintaining open lines of communication with regulators. It's a dynamic process that requires ongoing attention and adjustment.

Partner with Experts for DEA Compliance and Public Health Protection

By taking a proactive approach to establishing a robust suspicious order monitoring program, you're not just protecting your business but also contributing to the larger effort to maintain a safe and effective pharmaceutical supply chain. And in today's world, that's more important than ever.

Navigating the complexities of suspicious order monitoring and ensuring DEA compliance can be challenging, especially with progressing industry standards and the need for meticulous processes such as establishing proper customer thresholds, implementing clear due diligence policies, effectively leveraging technology, and providing crucial staff training. Partnering with experts, like Guidepost Solutions , who possess specific DEA training and extensive experience offers valuable benefits by providing the insight needed to master these areas. Our deep understanding of best practices for Suspicious Order Monitoring Systems (SOMS) can help your company develop, refine, and maintain highly effective systems for detecting, evaluating, and reporting potentially suspicious orders. This strategic partnership ensures your business not only meets current industry standards and addresses compliance requirements, but also stays ahead of future regulatory changes, proactively protecting public health and safeguarding your operations.

Sarah Pechnick

Managing Director, DEA Regulatory Compliance Practice

Sarah Osborne Pechnick is an expert in pharmaceutical controlled substance investigations and regulatory compliance. She proudly served with the Drug Enforcement Administration for more than 13 years