Suspicious Order Reporting and Prescription Opioid Medications

As the logistics experts of the pharmaceutical supply chain, distributors have developed advanced security and monitoring systems to make sure that the medications they handle and transport are authentic and legitimate; secured throughout delivery to avoid tampering or diversion; and received by licensed pharmacies and healthcare providers across the country.

The Drug Enforcement Administration (DEA) regulates the manufacture, distribution, prescribing and dispensing of controlled substances, including prescription opioid medications, along a closed supply chain. Each entity in that supply chain — from manufacturers to distributors to pharmacies to physicians — has distinct roles and responsibilities along the closed supply chain.

One obligation of a wholesale distributor is to design and operate a system to disclose “suspicious orders,” as that term is defined in the regulation, and to report those orders to DEA. But while “suspicious order” reports have been a focal point of numerous news stories and legal filings, there has been comparatively little focus on what that term means and whether or not such reports impact the diversion of opioid-based medications.

Fact: DEA has only provided vague guidance on what constitutes a suspicious order. In the absence of clear industry-wide guidance, then, distributors have each crafted their own programs to detect and report suspicious orders.

Distributors’ monitoring programs are designed to identify suspicious orders as defined by the federal government’s sparse definition in the Controlled Substances Act (CSA). Under the CSA, suspicious orders include “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” Currently, the CSA contains no definition for “unusual.” In an era where pharmacies place numerous orders every day, and may order from among thousands of different products, substantial variations in size, pattern and frequency are the norm.

Fact: Every order of Schedule II and III opioid-based medications, along with the quantity of the order and the identity of the receiving pharmacy, is reported to DEA and cataloged in a consolidated database.

Pharmaceutical distributors are required to report sales of Schedule II and III opioid-based medications to DEA. DEA then relies on its own consolidated database, Automation of Reports and Consolidated Orders System (ARCOS), to monitor the flow of opioid controlled substances from the point of manufacturing through commercial distribution to delivery to DEA- and state-licensed pharmacies, hospitals and other healthcare providers.

ARCOS data was available to be analyzed and could have been used by DEA to proactively identify pharmacies that the regulators believed had suspicious ordering patterns and thus required investigation. However, a recent report on the agency’s actions in West Virginia at the height of the opioid crisis found that the DEA “did not proactively use ARCOS data to investigate diversion trends.” Further, the report found that distributors were reporting suspicious orders “to local DEA offices that held varying regulatory interpretations, resulting in inconsistent handing of the reports” by DEA.
For years, HDA and its pharmaceutical distributor members have consistently asked for greater insight and transparency related to ARCOS data as a necessary step toward improving monitoring and coordination with DEA. Only recently has DEA, in step with the Department of Justice, outlined new guidelines to make ARCOS data more accessible and transparent to distributors and other entities in the supply chain.

**Fact: Distributors are not law enforcement entities and have limited legal ability to access information belonging to other entities in the supply chain, including DEA- and state-licensed pharmacies to which they distribute medications.**

DEA, as well as state regulatory entities (e.g., state boards of pharmacy), oversee and regulate the volume and supply of opioid controlled substances in the market. Each entity in the supply chain that handles these medicines, including prescribers, dispensers, manufacturers and distributors, is registered with DEA and licensed by state regulators. Putting the onus on distributors, which service pharmacies, to seek out potential diversion by those pharmacies’ customers asks distributors to overstep their role and puts the work of law enforcement in the hands of corporations, even as regulatory and law enforcement authorities already have access to ARCOS and other data.

Distributors have no law enforcement power. The DEA is also the only entity with authority to limit production of prescription opioids, as the agency sets an annual quota for their manufacturing. Until recently, the DEA continuously raised annual production quotas for opioids. Unlike the DEA, distributors have no power to stop physicians from writing prescriptions for medication, nor can they take unilateral action to halt pharmacies’ ability to dispense medication. In some instances, distributors have terminated shipments of controlled substances to pharmacies only to face judicial orders forcing the distributor to continue shipping.

**Fact: Distributors support improved coordination and monitoring across the supply chain.**

HDA and its pharmaceutical distributor members supported federal legislation to help strengthen and improve communication between the industry and DEA, as well as other state and federal regulators and law enforcement officials. This legislation, passed by Congress and enacted into law in 2018, is designed to enhance data sharing and increase coordination between distributors and DEA. The new data management system created by this legislation aims to expand distributors’ access to critical information within DEA’s ARCOS database, helping individual companies have a better understanding of the full scope of the distributions received by licensed pharmacies and other healthcare facilities across the country.

This legislation also called for the establishment of a centralized suspicious orders database, which will provide a more streamlined and uniform reporting mechanism for submitting suspicious order reports to DEA. A comprehensive data management system that is operated by DEA, along with the data DEA is required to share with state and local partners, will help federal and state entities identify trends that indicate that a pharmacy or other dispenser should no longer be permitted to handle controlled substances.

Our industry is eager to act on these new opportunities to collaborate with DEA and state regulators, so that we can be even more effective in supporting law enforcement efforts.

**Fact: Distributors are committed to working with the healthcare community as well as policymakers on solutions to address the prescription opioid abuse epidemic.**

HDA and its pharmaceutical distributor members are committed to stopping opioid abuse and misuse before it begins through investments in information technology and state-of-the-art monitoring tools to prevent diversion, initiatives to provide education and awareness to consumers, and practical policy solutions to address this public health crisis.