PART 1

A New Standard For Suspicious Order Monitoring

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As the opioid crisis continues to be a top public health priority, the "Suspicious Order Monitoring (SOM) requirement" has become an increasingly important enforcement tool for the U.S. Drug Enforcement Agency. In the past year alone, several significant settlements and court decisions have resulted from enforcement of this requirement, a regulatory clause that dates back to changes to the 1970 Controlled Substances Act (CSA) enacted in 1971. These recent developments point to enhanced DEA expectations for compliance and escalated penalties for noncompliance throughout the prescription opioid distribution chain. Two recent enforcement resolutions are the D.C. Court of Appeal's upholding of the DEA's decision to revoke Masters Pharmaceuticals controlled substance registration and the DOJ/DEA settlement with Mallinckrodt.

Under the SOM requirement, any DEA-registered entity distributing opioids or other controlled substances must "design and operate a system to disclose … suspicious orders of controlled substances." Suspicious orders are defined in the statute as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[1] To date, there has been little guidance provided by DEA beyond these words, but its position in recent cases involving wholesale distributors reveals that expectations are high for monitoring orders of controlled substances — particularly in terms of making use of available data.

In the Masters Pharmaceutical distributor case,[2] for example, the court found that DEA was within its rights to revoke Masters' controlled substance license — meaning it will be

prohibited from selling opioids or other controlled drugs — based on what were deemed to be failures to comply with the SOM requirement. The Masters decision follows several other high-profile settlements in this context (i.e., Cardinal — $44 million; McKesson — $150 million). Like many pharmaceutical distributors, Masters employed a statistical algorithm to screen pharmacy orders, with the output of the algorithm subject to manual review. One of the key points of contention in the case was whether the Masters' algorithm and review process appropriately made use of available data and analytics to determine which orders to report to DEA as suspicious.

In this article, we discuss several key takeaways from Masters that point to challenges for distributors in complying with DEA requirements.[3] In Part 2 of this series, we will discuss implications of the recent Mallinckrodt settlement for manufacturers' use of available data in managing risk associated with controlled substance diversion.

Evaluation Criteria and Data Requirements are Expansive, yet Ambiguous

Although the statute defines suspicious orders in terms of size, pattern and frequency, the Masters decision emphasizes that these are not an exhaustive list of criteria. Other red flags should be considered including, for example, the relative volume of controlled and noncontrolled substances as well as mismatches between ordering and actual dispensing/utilization at the pharmacy. However, a distributor's own ordering data would typically not contain sufficient information to analyze these retail-level indicators. One would also need to include attention to pharmacy dispensing and/or overall ordering activity, which are not generally available to distributors in the regular course of business.

Moreover, the DEA administrator's original decision, now upheld by the court, states that "a distributor is required to use the most accurate information available to it [emphasis added]."[4] What constitutes available, however, is not straightforward, and gives rise to the following types of questions about the DEA's application of the standard:

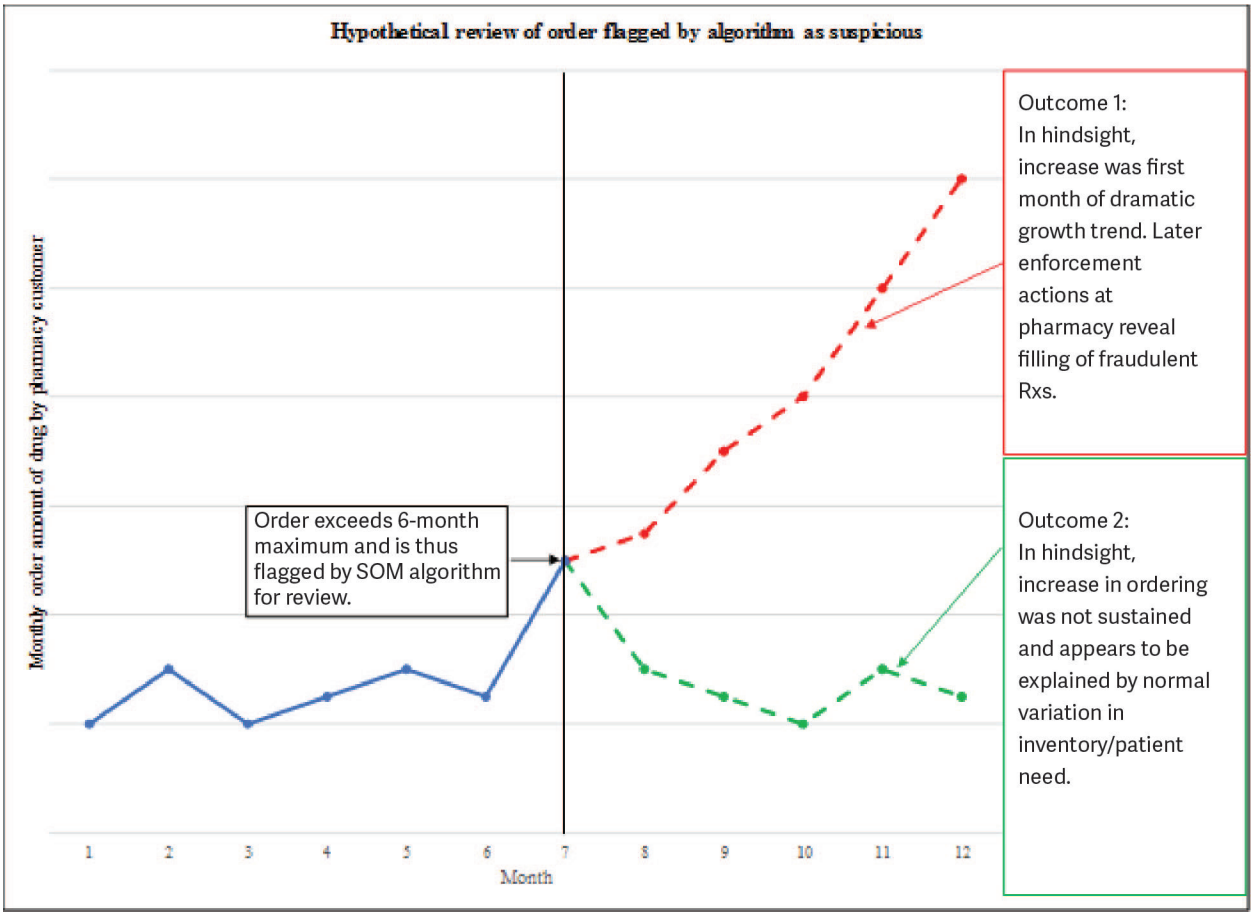
- Do distributors have a responsibility to obtain additional data beyond what is generated from their own business activity?
- Do distributors have to purchase data concerning regional trends or prescribers from third-party vendors?
- Do distributors have to negotiate contracts with pharmacies to obtain their dispensing data?

In the Masters case, the distributor had put in place a statistical algorithm to flag potentially suspicious orders based on its own ordering data. In some instances, the manual review process that followed for flagged orders involved obtaining additional pharmacy utilization data to assess the proportion of prescriptions attributable to controlled substances. However, in other instances, additional data of this type was not obtained. According to the Masters decision, this selective approach was inadequate in analyzing additional data beyond size, pattern and frequency.[5]

Prediction Accuracy is Critical but Involves Important Tradeoffs

The Masters decision underscores that the bar to dispel the possibility of suspicion for a flagged order is high. Masters viewed the orders initially flagged by its algorithm as potentially suspicious, i.e., worthy of further investigation to determine if the orders are in fact suspicious. The decision rejects this approach, indicating that any orders flagged by the algorithm should be considered suspicious unless otherwise dispelled. Given the derivative requirements to block and report suspicious orders, there is a gulf between "potentially suspicious" and "suspicious" that may be as wide as that between "innocent until proven guilty" (or indicted and awaiting trial) and "guilty until proven innocent" (or convicted, pending appeal). In each of these cases, the default setting can greatly affect the outcome.

There are high costs associated with both blocking legitimate orders that meet patient need and fulfilling orders to pharmacies later found to have illegitimate activity. However, no algorithm or review process is guaranteed to distinguish legitimate from illegitimate activity, and some improper dispensing can only be identified with certainty based on hindsight (e.g., when diversion is confirmed by DEA action taken against prescribers or pharmacists). The chart below provides an illustrative example of an order that might have been flagged by a statistical algorithm based on a customer's prior order history and only with the benefit of hindsight would the presence of any illegitimate dispensing have become clear.



While it may be possible to calibrate a particular statistical approach based on analysis of pharmacies known to have had illegitimate dispensing in the past, data on such pharmacies is often limited. Moreover, there is no *ex ante* guarantee that doing so will reliably identify the next issue, nor that the resulting algorithm will appropriately filter out legitimate activity. This point is made emphatically in the context of mortgage underwriting, where there is an abundance of data on past defaults, but as was discovered in the 2007-2008 financial crisis, an automated loan approval system calibrated to historical data proved myopic and insufficient to predict future results. Here, pharmaceutical distributors have no choice but to operate with incomplete information, as certain types of data, like incriminating video evidence captured by DEA at a doctor's office, may never be available to a distributor until well after the fact. Nonetheless, distributors should strive to make the best use of the data they have, keeping track with current trends to avoid an overly backward-looking approach.

Given the high cost of imprecision while acknowledging that perfection is not possible, distributors should carefully consider the balance between sensitivity and specificity in designing their statistical approaches.[6] The more sensitive a statistical algorithm, the more orders it will flag. A highly sensitive algorithm will cast a wide net and will be unlikely to miss any genuinely suspicious activity, but it will also flag many orders that are not especially unusual. With an overly sensitive system, a distributor that blocks and reports all orders could easily put legitimate patient need in jeopardy. A distributor that reviews and investigates orders identified by the initial algorithm, such as Masters did, will find it faces a task akin to finding a needle in a haystack. In this scenario, human reviewers may become ineffective as they review a multitude of orders that were unnecessarily flagged. Such a system may result in reporting a large number of orders to the authorities if a distributor decides it is safer not to rely on manual review at all. In turn, as one industry observer noted, this outcome could make "it more difficult for the [DEA] to use the data as a means of investigating potential bad actors within the system," subverting the goals of the regulation.[7]

Conversely, a highly specific algorithm will have a larger share of its flagged orders prove to be of genuine concern, but may miss others that are also of concern. In this scenario, review of flagged orders will be more efficient than under an overly sensitive system. But that could come at a high cost, as some pharmacies making illegitimate orders may not be identified.

Regardless of how sensitive or specific the calculations, there will generally be some orders unnecessarily identified as problematic on the one hand and/or some undetected orders that actually are problematic on the other.

Consistency Should be Maintained, but Improvements are Encouraged

The Masters decision stresses the importance of consistency in the review process. Absent explicit regulatory guidance on the SOM requirement, internal consistency may act as the most straightforward standard. The decision finds that Masters' review process was inconsistent across orders and conflicted with the approach laid out in its own

compliance documentation. At the simplest extreme, Masters could have achieved this objective by simply blocking and reporting every order flagged by its algorithm. The decision explicitly states that "it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them."[8] However, this approach would almost certainly have blocked many legitimate orders. For distributors who choose to "shoulder the burden of dispelling suspicion in the hopes of shipping any [orders found] to be non-suspicious," consistency appears to require an ongoing effort to monitor the review process itself.[9] This effort may require collaboration with retail customers to obtain additional data. Additionally, setting up standard reports with key data analytics pertaining to flagged orders can make the manual review process more systematic and less ad hoc. Perhaps counterintuitively, maintaining consistency may also require periodic modifications to the statistical algorithm to incorporate analyses that are repeatedly identified as part of manual review. The approach should adapt over time to take into account new information while seeking an appropriate balance between over- and under- flagging. Distributors who are not inclined to incorporate manual review into their SOM may still want to minimize risk by setting up efficient statistical tools to analyze available customer data retrospectively to comply with the Effective Controls Against Diversion requirement.

The Bottom Line for Distributors

With SOM being featured as a critical plank in DEA's approach to countering the opioid crisis, distributors will no doubt require increased efforts in attempting to meet these requirements. Yet, effort alone does not guarantee compliance. Limited guidance, the lack of sufficient data for calibration and incomplete information from customers present real challenges. Even with carefully thought-through statistics and well-trained reviewers, the decision of whether an individual order should be blocked and reported may come down to a "know-it-when-you-see-it" standard that is difficult to systematize. Nonetheless, the principles discussed above can help manage risk in this and other contexts that rely on a sound combination of statistics and judgment.

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Endnotes

1 Title 21 Code of Federal Regulations §1301.74 (b), available at https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm.

2 See Dani Kass, "DC Circ. Clears DEA To Block Opioid Supplier's Sales," *Law360*, June 30, 2017. Full decision available at https://www.cadc.uscourts.gov/internet/opinions.nsf/D83B55CAB08AC6698525814F00517D77/$file/15-1335-1682127.pdf.

3 While controlled substance order monitoring provides the backdrop here, these concepts may well apply in other venues where risks are managed using a combination of statistics and judgment (e.g., mortgage underwriting, credit card fraud detection).

4 Federal Register, Vol. 80, No. 179, September 15, 2015, 55420, available at https://www.gpo.gov/fdsys/pkg/FR-2015-09-15/pdf/2015-23038.pdf.

5 *Masters Pharmaceutical Inc., v. Drug Enforcement Administration*, United States Court of Appeals for the District of Columbia Circuit, June 30, 2017 decision No. 15-1335, p. 20.

6 Sensitivity is the proportion of true positives that are correctly identified, while specificity is the proportion of true negatives that are correctly identified.

7 Larry Cote, "DEA Prevails Over Masters Pharmaceutical, Inc.," *Quarles & Brady DEA Chronicles*, July 2, 2017, available at http://deachronicles.quarles.com/2017/07/dea-prevails-over-masters-pharmaceutical-inc/.

8 *Masters Pharmaceutical Inc., v. Drug Enforcement Administration,* United States Court of Appeals for the District of Columbia Circuit, June 30, 2017 decision No. 15-1335, pp. 23-24.

9 *Masters Pharmaceutical Inc., v. Drug Enforcement Administration*, United States Court of Appeals for the District of Columbia Circuit, June 30, 2017 decision No. 15-1335, p. 24.