Suspicious Order Monitoring

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Agenda

+ SOMS Regulations and Proposed NPRM
+ McKesson Settlement
+ Masters Decision
+ Mallinckrodt Settlement
+ Morris & Dickson ISO
Current Issues
Fall 2018 Unified Agenda of Regulatory and Deregulatory Actions

Issued on October 17, 2018

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<thead>
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<th>Agenda Stage of Rulemaking</th>
<th>Title</th>
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<tbody>
<tr>
<td>Proposed Rule</td>
<td>Revision of Hearing Procedures in Association With Show Cause Orders</td>
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<td>Proposed Rule</td>
<td>Emergency Medical Services (EMS)</td>
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<td>Proposed Rule</td>
<td>Special Registration to Engage in the Practice of Telemedicine</td>
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<td>Proposed Rule</td>
<td>Registration Requirements for Mobile Narcotic Treatment Programs</td>
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<td>Proposed Rule</td>
<td>New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)</td>
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<tr>
<td>Proposed Rule</td>
<td>Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Partial Filling of Prescriptions for Schedule II Controlled Substances</td>
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<td>Proposed Rule</td>
<td>Establishing Reporting Procedures for Purchasers and Suppliers to Follow in the Conduct of Double-Blind Studies</td>
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<td><strong>Proposed Rule</strong></td>
<td><strong>Suspicious Orders of Controlled Substances – New Date February 2019</strong></td>
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<tr>
<td>Proposed Rule</td>
<td>Controlled Substances Manufacturing Quotas: Inventory Allowance; Subcategories for Quotas; Certification of Procurement Quota for Controlled Substances</td>
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<tr>
<td>Final Rule</td>
<td>Retail Sales of Scheduled Listed Chemical Products; Chemical; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products</td>
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<tr>
<td>Final Rule</td>
<td>Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of Transfers Following Importation or Exportation</td>
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Enacted on October 24, 2018.

Addresses multiple issues regarding opioid use and abuse.

Places into the CSA a statutory requirement that DEA registered manufacturers and distributors must report to the DEA suspicious orders of controlled substances.

Uses same regulatory definition of a suspicious order.

Requires DEA to establish a centralized database of suspicious orders.

Share information with the states “within a reasonable period of time” after obtaining the information.

Increases civil monetary penalty up to $100,000 per violation.
SOMS Regulations
The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.
Registrants must provide effective controls to prevent theft and diversion

Title 21 CFR 1301.71(a)

“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances”
New DEA SOMS Regulations

The Drug Enforcement Administration is proposing to revise its regulations relating to suspicious orders of controlled substances. The proposed rule defines the term suspicious order and specifies the procedures a registrant must follow upon receiving such orders.

Estimated publication date as an NPRM is September 2018
McKesson Settlement MOA
Memorandum of Agreement and Compliance Addendum

“DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. 1301.74(b) or 21 USC 821(b)(1). DEA has taken no action during the negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations.”

January 17, 2017
Terms of Recent/Major MOU/Compliance Addendum

- Staged Suspension of DEA Registrations
- Must Maintain a Compliance Program with Specified Organization
- Monthly Report of all CS Transactions Sent to DEA
- SOMS Reports Sent to DEA HQs
Terms of Recent/Major MOU/Compliance Addendum

1. New Definitions of “Order” and “Threshold”
2. May Employ Independent Contractors
3. Independence of Regulatory Affairs Department
4. Compliance Reviews by IRO
Masters Decision
## Masters Pharmaceutical

*DEA Registered Distributor*

<table>
<thead>
<tr>
<th>Year</th>
<th>Action</th>
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<tbody>
<tr>
<td>2008</td>
<td>DEA issued an OTSC to revoke Masters DEA registration based on failure to report suspicious orders of hydrocodone placed by Internet pharmacies.</td>
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<td>2009</td>
<td>Settlement and $500,000 civil fine – MOA to implement a system to detect and report suspicious orders.</td>
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<tr>
<td>2013</td>
<td>DEA issues an OTSC to revoke Master’s DEA registration based on failure to detect and report suspicious orders of oxycodone. Orders to eight pharmacies in Florida and Nevada.</td>
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<tr>
<td>2014</td>
<td>Administrative Show Cause hearing and recommendation against revocation by ALJ.</td>
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<tr>
<td>2015</td>
<td>DEA acting administrator rejects ALJ recommendation and orders revocation of Master’s DEA registration.</td>
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<tr>
<td>2015</td>
<td>Masters appeals to DC Court of Appeals.</td>
</tr>
<tr>
<td>2017</td>
<td>Court of Appeals upholds DEA order to revoke.</td>
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</tbody>
</table>
Masters’ Court of Appeals Issues

All flagged orders are suspicious

- As held by the Computer Program within the meaning of 21 CFR 1301.74(b).

On hundreds of occasions Masters failed to report suspicious orders

- As held by the Computer Program nor implemented the Employee Protocol to dispel the suspicion surrounding held orders.

Overwhelming evidence that Masters’ employees failed to implement the Employee Protocol

- “[E]mployees frequently simply brushed suspicion under the rug…”
- The employees accepted “half-baked or implausible explanations…”
Mallinckrodt Settlement
Some Firsts

• First settlement of this magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances."

• Know your “customer’s customers” issue addressed.
Mallinckrodt Settlement Issues/Terms

MOA – Now public, not released with press statements by DEA or Mallinckrodt

$35 million civil penalty

Review of “chargeback” data included in settlement agreement.

July 11, 2017
Allegations

• Mallinckrodt offered “chargeback” (discount) program to distributors based on sales to downstream customers
• To obtain the discount, the distributor would provide Mallinckrodt with information about the downstream customers’ purchases
• Government alleged – Distributors provided suspicious quantities of controlled substances to downstream customers
• Mallinckrodt failed to report suspicious orders despite the information it had obtained from the chargeback program
• Mallinckrodt failed to design and operate an effective system to detect and report suspicious orders from 2008-2011
Morris & Dickson
Morris & Dickson – First ISO Since 2012

Immediate Suspension of DEA registration
• May 4, 2018, ISO issued based on alleged failure to identify and report suspicious orders of oxycodone and hydrocodone to DEA.

Temporary Restraining Order
• May 8, 2018, U.S. District Court (W. Dist. Of Louisiana) issues a TRO against DEA. Hearing scheduled for May 22.

ISO Withdrawn
• May 18, 2018, DEA withdraws ISO. No additional action to date.
Recommended SOMS Elements
## Successful SOM Program

*Five Key Elements to Respond to Regulation*

<table>
<thead>
<tr>
<th>Defensible SOM Model</th>
<th>Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Statistically based model – highly recommended</th>
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<tbody>
<tr>
<td>Appropriate Due Diligence and “Know Your Customer” Activities</td>
<td>Determine legitimacy of existing and potential new customers (customers and customer’s customers)</td>
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<td>Appropriate Review and/or Investigations of Pended Orders</td>
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<td>Clear, Comprehensive SOM SOPs</td>
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<td>Management Support and Employee Training</td>
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Thank You!