



"Mapes, Michael R."  
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v>

06/27/2007 08:30 AM

To <Dwayne.Pinon@walgreens.com>

cc

bcc

Subject RE: Suspicious Orders

History: This message has been forwarded.

Mr. Pinon,

The situations that I discussed with you at the meeting in Alexandria are situations where DEA has signed a MOU with companies due to issues with the suspicious order process at the companies. While the controlled substance suspicious order regulations does not provide detailed, specific guidance, we would welcome the opportunity to work with Walgreens to create a system that would provide the information required by the regulation, while narrowing the amount of information provided to DEA to sales that are confirmed as suspicious. If appropriate, we could draft a specific agreement with Walgreens.

Let me know if you are interested in pursuing this issue further,

Mike Mapes  
202-307-7438

-----Original Message-----

**From:** Dwayne.Pinon@walgreens.com [mailto:Dwayne.Pinon@walgreens.com]

**Sent:** Monday, June 25, 2007 6:18 PM

**To:** Mapes, Michael R.

**Subject:** Suspicious Orders

Mr. Mapes:

It was a pleasure meeting you and your colleagues last Wednesday at the NACDS meeting. As a follow up to our brief discussion, I would appreciate if you could clarify DEA's expectations with respect to reporting suspicious orders of controlled substances.

The following regulation is applicable.

21 CFR Sec. 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(b) 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.

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In addition, Appendix E-3 from the Chemical Handler's Manual is instructive.

### Appendix E-3

## Suspicious Order Reporting System for Use in Automated Tracking Systems

### Terms & Definitions

This voluntary formula is for use by distributors to wholesale and retail levels. The formula calculates the quantity which, if exceeded in one month, constitutes an order which **may** be considered excessive or suspicious and therefore require reporting to DEA.

- 1) Add purchase quantities for the last 12 months for all customers within same Distribution Center and for customer type (Hospital, Pharmacy or Other) for any List I chemical containing item stocked by the Distribution Center.
- 2) Add Customer months for every record used in above total. (Months within the last 12 that customer purchases of the item were not zero.)
- 3) Divide total quantity purchases by the total customer months.
- 4) Then multiply by the factor below to give the maximum amount that the customer can order per month before showing up on the suspicious order report.

Note: Factor equals 3 for C-II and C-III Controlled Substances Containing List I Chemicals and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products containing List I chemical items.

- 5) At the end of each month, a report will be transmitted to DEA (separate reports for List I Chemicals and Schedule II-V Controlled Substances) of all purchases of List I Chemicals and/or C-II-V Controlled Substances and List I containing OTC items by any customer whose purchase quantities exceed the parameters (above) any (2) consecutive months or in three (3) of any moving six (6) month period.

Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.

Walgreens produces a monthly report of suspicious orders and forwards the same to DEA in accordance with 21 CFR 1301.74(b) using the "voluntary" formula described in Appendix E-3. The term "voluntary" may be a misnomer because the Detroit DEA Office recently admonished Walgreens for not using this particular formula. As you may expect, these reports typically are quite voluminous.

During our conversation, you indicated that DEA does not expect to receive reports which identify all suspicious transactions, but instead, only those transactions that the registrant cannot classify as not suspicious after review. Unfortunately, the regulation does not distinguish suspicious orders identified to the registrant from those that are reportable to DEA. In other words, I am unable to read into the regulation that the registrant must utilize a system to identify *potentially*

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suspicious orders and that only orders *confirmed* as suspicious must be reported to DEA. I would appreciate if you could confirm that this, in fact, is DEA's expectation.

Thank you again for agreeing to open up the lines of communication between DEA and retail pharmacy. I look forward to your response.

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