

Department: Distribution Operations	SOP #:040
Title: Suspicious Order Monitoring	

1.0 SCOPE

The directives contained in this SOP apply to all Anda DEA Compliance Analysts who are involved in the review of a sales order deemed to be of “interest”. Orders of Interest are captured using historical sales information with a user defined time frame by looking at past averages of the following using a user defined multiplier:

- DEA Registrant’s average dosage units ordered per month of a specific chemical family
- DEA Registrant’s average dosage units per order of a specific chemical family
- The average dosage units per order by that class of trade for a specific chemical family
- Order frequency per rolling 30 day period

2.0 PURPOSE

To document the procedures involved in reviewing Held Orders of Interest/Suspicious Orders.

3.0 PROCEDURE

Investigating Pended Orders

1. When an order is pended in Anda’s SOM system, follow the following procedures as applicable:
 - a. Select the “Order Number” from the order review screen and review the “stress bars”
 - b. Review the customer’s historical order data, including:
 - i. Orders for the same active ingredient as the current pended order.
 - ii. Monthly averages of orders and purchases including the customer’s purchases of all controlled substance products for the last 30, 60 and 90 days.
 - c. Review if any system “rules” have been established for the customer.
 - d. Review system notes on previously pended orders.



- i. Navigate to the Journal entries screen to observe entries
 - ii. Review notes on the order screen
 - e. Review the customer maintenance license information.
 - i. Focus on the geographic locations and city/state of the customer.
 - f. Review system notes including:
 - i. Historical requests, trends, approvals or denials.
 - ii. Comments regarding changes to account, ownership, or licensure.
 - iii. Verification if Anda is a primary or secondary source for controlled substances.
 - iv. Review information regarding the customer's class of trade.
 - g. Review the Customer's Questionnaire
 - i. Determine pharmacy type
 - ii. Review location
 - iii. How long has pharmacy been operating
 - iv. Determine types of customers serviced by pharmacy
 - v. review identified physicians submitting controlled substance prescriptions,
 - vi. pharmacy proximity to healthcare facilities and physician practices
 - h. Pharmacy procedures for ensuring that products are being dispensed for legitimate medical purposes by physicians who are in good standing.
- Review summarized Dispensing Data.
 - i. Determine the prescribing/dispensing volume for time frame.
 - ii. Determine ratio of controlled substance product to non-controlled product.
 - iii. Identify and evaluate top products dispensed.
 - iv. Attempt to determine whether amounts ordered are consistent with amounts prescribed.
 - v. Determine particular products or NDC's dispensed most frequently.
 - vi. On an as needed basis, Compliance will call customer to gain clarification on any open questions.
2. Approving "pending" orders
 - a. Regulatory staff will analyze all information developed in conjunction with their SOM order entry procedures to determine whether the order can be cleared of suspicion.
 - b. Once a "pending" order has been investigated, all investigative activity will be documented in Anda's SOM cloud appliance and/or in TPS.
3. If the order is not deemed to be suspicious upon investigation, the order will be released and filled.

Reporting Suspicious Orders

1. If an order is deemed suspicious the order will be cancelled and the account will be suspended from ordering controls.



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STANDARD OPERATING PROCEDURE

2. Compliance Management will notify the local DEA offices (and any other applicable state agencies that require such notification) where Anda maintains DEA registrations of any suspicious order via an email within two business days.

4.0 REVISION HISTORY

SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
December 2011	040	Michael Cochrane	Original Issue
April 5, 2012	040.01	Michael Cochrane	Review
June 10, 2013	040.01	Emily Schultz	Review
June 2, 2014	040.01	Emily Schultz	Review
August 26, 2014	040.01	Emily Schultz	Review
February 1, 2015	040.02	Emily Schultz	Added Non Controlled review
February 26, 2016	040.02	Michael Cochrane	Review
March 4, 2017	040.03	Emily Schultz	Added new details for suspicious holds