

Department: Distribution Operations	SOP #:045
Title: Remedy Review Process	

1.0 Scope

The directives contained in this SOP apply to all Anda DEA Compliance Analysts who are involved in the review of Anda pharmacy customer's for control eligibility and control family increase allotments. This is to include:

- Corrective Adjustment for pending order
- New Account – Anda Control Eligibility
- Control Limit Increase (Over standard control family allocation of 1k)
- Oxycodone & Methadone Eligibility

2.0 Purpose

To define the analyses involved with reviewing Anda customers for control eligibility and/or control family limit increases.

3.0 Procedure

I. Determine Type of Remedy Request

- Corrective Adjustment for pending order
- New Account – Anda Control Eligibility
- Control Limit Increase (Over standard control family allocation of 1k)
- Oxycodone & Methadone Eligibility

II. Refer to TPS – Customer Maintenance License Info (TPS 2.2.4.1)

- Pay particular attention to Customer Type and affiliation
- Observe DEA license status of Active/Expired
- Determine if DEA schedule loaded includes all schedules
- Pay particular attention to City/State of request
- Determine if a Customer Questionnaire is on file (customer flagged “Y”)
- Determine if the customer is currently flagged “Y” for controls or new

III. Review Customer Compliance Notes (TPS 2.2.4.1/Shift+F4)

- Determine if customer had previously been reviewed or grandfathered in to control eligibility
- Review Compliance notes regarding: historical requests, trends, approvals or denials

IV. Review Customer Notes (TPS 2.2.4.1/F8)

- Determine if this customer had been previously cut off
- Review any comments regarding changes to account, ownership, licensure

V. Review Customer Questionnaire

- Save new Customer Questionnaire to O:Drive if necessary for record keeping
- Record date Customer Questionnaire is received in TPS (2.2.4.1) Flag “Y”
- Open Customer Questionnaire on shared drive if already saved. (O:\Florida\Anda\Warehouse\Compliance\Customer Questionnaire)
- Determine type of pharmacy reviewing: volume, location, age, etc.

VI. Conduct Necessary Research Online – DR’s, Location, Demographics

- If doctor names are provided, research: reviews, comments, or sanctions & citations
- Determine if doctors practice ethically
- Determine type of doctors which constitute majority of control business
- Determine if volume of control business coincides with local demographics
- Review location of pharmacy on Google maps: neighborhood, surroundings, proximity to local physicians, clinics, or hospitals

VII. Review Summarized Dispensing Data from Pharmacy

- Determine the way in which data is summarized: patient & script, descending pill quantity dispensed (by product or NDC), alphabetical, number of RX’s



Anda, Inc
Anda Pharmaceuticals, Inc

STANDARD OPERATING PROCEDURE

- Determine the level of control volume for time frame
- Determine ratio of controls versus non-controls
- Evaluate top products dispensed
- Determine particular products or NDC's dispensed most frequently
- For an increase request, determine if dispensed data indicates a need for an increase

VIII. Review TPS- Controlled Substance Inquiry (2.4.3.12)

- If customer is requesting new Anda control eligibility, research non-control business purchased through Anda historically
- If customer is requesting a control family limit increase: review current limits, review particular products purchased most regularly, and determine whether customer is in current need of an increase (maxing out)
- Determine customer needs for control eligibility through Anda (by product)
- Determine if Anda will be a primary source of controls, etc.
- Review purchasing trends on a monthly basis by product & product family
- Evaluate percentage of control business on a monthly basis (average)

IX. Determine Eligibility

- Approved
- Denied

4.0 Revision History

SOP will be reviewed annually by management

Effective Date	Version	Author	Change Description
April 5, 2012	045	Michael Cochrane	Original Issue
August 26, 2014	045.00	Emily Schultz	Review