Department: Distribution Operations	SOP #:028
Title: Customer Due Diligence	

1.0 Scope

The directives contained in this SOP apply to all Anda and Anda Pharmaceutical employees that have or may have contact or involvement in the activities associated with, Information Needed to Set up a New Account. This is to include, but not be limited to:

* Sales
* Customer Service
* Regulatory Compliance

2.0 Purpose

To provide the licensing requirements to establish pharmacy, physician and wholesaler/distributor ("Customer") accounts with Anda.

3.0 Procedure

1. All new accounts are identified via Anda's sales and marketing processes.
2. An account must be open for three months before the account may request to order controlled substances.
    a. Any active Anda pharmacy customer seeking to purchase controls from Anda must complete a Customer Questionnaire, either electronically or via fax, which is available on Andanet, Anda's website. A customer must attach to the completed Questionnaire the following items:
        I. Ninety (90) days prior dispense data listing the dispensed pill and tablet products and liquids and patches (controls and non-controls) in descending order by number of pills dispensed as well as the number of prescriptions for each product by GPID or NDC.
        II. The procedures that the customer utilizes to review and determine whether to fill controlled substance prescriptions.
        III. Photographs of the interior and exterior of the pharmacy.
    b. An Anda Sales Representative may also provide their customer with a copy of the Customer Questionnaire to be completed along with the attachments listed in section a. above.
3. Completed questionnaires will be assigned to the regulatory staff for review. In addition to the questionnaire, Anda staff will request three months of dispensing history for the controlled substance products, the number of prescriptions written, and any relevant procedures.

4. Before a new account is approved for controlled substance purchasing, Anda must receive copies of the following licenses and/or registrations:
    a. State licenses in order to ship non controlled substances. The address on the license must match exactly to the "Ship To" address for a pharmacy or wholesale/distributor. The address may differ in a situation where Anda services physicians who have a valid license at one place and practice in multiple locations. Anda's software system will track expiration dates and will prevent shipments from being processed accordingly.
    b. For Customers wishing to purchase controlled substances, the above information is needed, as well as a valid copy of the Customer's DEA certificate of registration. The "Ship to Address" must match exactly the address listed on the registration, including zip code. NO EXCEPTIONS. (Anda's software system tracks expiration dates and prevents shipments from being processed.)
    c. All new and reactivated customers that wish to purchase controlled substances are required to complete Anda's due diligence documents which include Anda's customer questionnaire. Authority to establish rules in the firm's SOM system is limited to the Compliance Management
    d. Oxycodone, Hydromorphone and Methadone products are initially excluded from availability. This is an Anda business rule. Oxycodone, Hydromorphone and Methadone may be purchased upon customer request after a period of 2-3 months of purchases of other controlled items from Anda and submission of updated dispense data. Any exceptions must be approved by the Regulatory Compliance department.
    e. Practitioners and wholesale distributor accounts are not eligible to purchase any controlled substances. This is an Anda business rule.
    f. Prior to state license expiration, the Licensing Team within Regulatory Compliance will request the customer to provide a copy of their updated registration.
    g. A daily file is received from NTIS (National Technical Information Service), this file contains all active DEA registrants. The file is uploaded directly into Anda's warehouse management system and updates all active and inactive registrants loaded at Anda. Any address exceptions are forced to a "hold bucket" and are managed manually.
    h. For chains of stores, Anda will accept a spreadsheet as long as it includes the store number, address, license number (both DEA registration number and state Pharmacy Permit number, including single state controlled substance licenses/registrations, if applicable) and the expiration date for the above registrations/licenses. It is then the responsibility of the Licensing Team to check the validity of the registrations/licenses.

i. For chains of greater than 50 stores, a spreadsheet containing the same information described in paragraph (g) will be sufficient under these two circumstances:
    1. The list is provided by the chain's legal department and/or regulatory department and the department(s) attest to Anda that the data is true and correct.
    2. The provided list is compared and matched, by DEA registration, to the "DEA Registration File" by the Licensing Team. This file resides on Anda's system and is updated every day sent by NTIS (National Technical Information Service via a flat file. This check is performed to ensure that the registrations are active and in good standing and that the addresses are correct. The Regulatory Compliance Team will utilize the DEA Inquiry Search Function in the Anda TPS system to verify the DEA license status when needed

ii. In addition to the regulatory documentation described in the preceding section, all chain locations requesting the ability to purchase controlled substances must provide a dispensing log that contains a list of all pharmaceutical products dispensed by the customer during the three months immediately preceding the date that the account is established which includes the quantities and number of prescriptions filled for each dispensed product. The dispensing log must be organized by the largest dispensed products in descending order. Additionally, each location may be required to provide additional information regarding the physicians who are prescribing controlled substances and the conditions of the patients for whom these prescriptions are written following review of the location's dispense data.

iii. Anda will permit a chain to provide a Corporate Customer Questionnaire that includes the procedures utilized by all locations to review and determine whether to dispense controlled substances for each controlled substance prescription.

iv. All information listed above shall be reviewed by the Compliance Team to determine whether an individual location shall be permitted to purchase controls and the quantities permitted to be purchased for each control family.

5. Action on New Accounts
    a. If the Anda due diligence activities have not discovered any concerns with respect to the control items and quantities being dispensed for the identified patient conditions as prescribed by appropriate physician practices or discipline actions involving prescribers or pharmacists or diversion issues associated with the prospective customer the account will be permitted to purchase controlled

substances in quantities consistent with the dispense data provided by the customer, the customer's class of trade and Anda's role as a secondary supplier.

b. If one or more of the following items are discovered during the due diligence procedure the account will not be eligible for controlled substance purchase:
   i. Not properly licensed/registered
   ii. Failure to submit renewed permits/registrations
   iii. Undesirable quantities and/or combinations of dispensed controlled substances
   iv. Suspicious controlled substance purchases
   v. Inconsistencies with respect to information provided on the Anda questionnaire and information developed during the onsite review.
c. Anda will provide a written report to appropriate federal agencies and any other applicable state agencies within two business days of denying an application, rescinding or reinstating the ability of a customer to receive controlled substances.
d. A hardcopy file will be maintained for each customer. Contents of the file will include all previous state and federal licensing.

4.0 Revision History

SOP will be reviewed annually, each February, by management

Effective Date	Version	Author	Change Description
August 20, 2004	028	Patrick Cochrane	Original Issue
March 9, 2007	028.01	Patrick Cochrane	Addition of 3.0-1.-(d)-(1)
September 26, 2008	028.02	Michael Cochrane	Change Management where Applicable
May 21,2010	028.02	Michael Cochrane	Review
February 2, 2011	028.02	Michael Cochrane	Review
August 2011	028.03	Michael Cochrane	Include CQ and DD requests
April 5, 2012	028.03	Michael Cochrane	Review
June 10, 2013	028.03	Emily Schultz	Review
June 2, 2014	028.03	Emily Schultz	Review
August 26, 2014	028.03	Emily Schultz	Review
January 5, 2015	028.04	Emily Schultz	Added additional licensure information
February 6, 2016	028.04	Michael Cochrane	SOP Name change
February 13, 2017	028.04	Emily Schultz	Review
February 26, 2018	028.05	Emily Schultz	Additional CS review details added