
From: Cochrane, Patrick <Patrick.Cochrane@Andanet.com>
Sent: Wednesday, July 14, 2010 3:20 PM
To: Spellman, Jay
Subject: Fw: Discussion Strategy document
Attachments: DEA Discussion Strategy Bullets.docx

From: Patrick Cochrane
To: Albert Paonessa
Sent: Wed Jul 14 00:00:20 2010
Subject: Discussion Strategy document

Let's start with these topics and add more Wednesday.

Confidential



Anda_Opioids_MDL_0000108116

P-18263 _ 00001

Account Setup

- There will be questions regarding how we find new accounts.
 - We need to discuss strategy here.
- There will be questions related to what information is obtained and what research is performed prior to opening an account.
 - We will submit our current SOP detailing what regulatory information is needed to create an account.
 - Patrick will work with Finance/Customer Maintenance on their SOP regarding account setup

Suspicious/Excessive & Limits

- We need to hold a firm stance supporting that we have not had suspicious or excessive orders since 2007 meeting with DEA in Washington, DC.
 - We created chemical families of products to ensure that limits could be enforced across multiple strengths of chemicals and multiple bottle /pack sizes.
 - All accounts are granted a baseline of 5000 dosage units per month per chemical family as long as a valid DEA license and applicable schedules are loaded for the account.
 - Our systems restrict orders from being entered if either a single order or cumulative orders for a given month exceed the customer's dosage unit limits.
 - A warning message is displayed to the sales rep stating that the line item attempting to be ordered exceeds the customer's monthly dosage unit limit.
 - If the order is attempted to be entered via one of the electronic methods, the order is rejected and not processed any further
 - Our systems do not record and track attempted orders, regardless of order entry method.
- In regards to increases of limits, we will submit the current SOP (OPS 035-Anda-SOP-Controlled Substance Monthly Override)
 - While brief, it does outline what is done in regards to reviewing data in order to consider and grant an increase
 - We can speak to the details of information that is looked at while considering an increase and the level of the increase – need to discuss the ranges below
 - 5001-15000 – Review sales history, gauge % of control volumes vs. non controls, review non-controlled volumes for internet type products(Viagra, Lyrica, Lipitor, etc)
 - 15001-50000 – Above plus report from customer detailing products dispensed products and customer questionnaire.
 - Greater than 50000 – All above plus site visit.
- We will submit the legacy report parameters for Suspicious and Excessive orders
 - These reports were submitted to DEA prior to 2007 meeting in Washington, DC.
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From: Cochrane, Patrick <Patrick.Cochrane@Andanet.com>
Sent: Wednesday, July 14, 2010 4:00 AM
To: Paonessa, Albert
Subject: Discussion Strategy document
Attachments: DEA Discussion Strategy Bullets.docx

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