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**From:** Cochrane, Michael <Michael.Cochrane@Andanet.com>  
**Sent:** Friday, April 12, 2013 3:16 PM  
**To:** Versosky, William; Brown, Robert (Andanet); Paonessa, Albert  
**Cc:** Harrington, Leslie  
**Subject:** RE: Rite Aid Presentation  
**Attachments:** Compliance Assistance Program.pptx; Compliance Analysis Program.pptx

There are a few things we should change in the presentation. For starters, we shouldn't call it a Compliance Assistance Program. We need to rename the document and pull out any references to CAP. We could call it a Compliance Analysis Program, and you could still keep CAP throughout or Compliance Data Review Program, or something along those lines. We also need to pull out some lines regarding Anda's man power. We are going to need to rely on them to get the questionnaires out to pharmacies and submit to us. I made some changes on the revised one attached. You can compare the two and lets regroup this afternoon.

Thanks  
Mike

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**From:** William F Versosky  
**Sent:** Tuesday, April 09, 2013 11:53 PM  
**To:** Robert Brown  
**Cc:** Michael Cochrane; Leslie A Harrington  
**Subject:** Rite Aid Presentation

Hi Robert,

Could you please review the attached presentation which is intended for Rite Aid and let me know if you have any concerns about the statements or information provided.

Leslie, once approved please save as a PDF before sending on. I think you should include the letter as well, once it's adjusted to add some statement on data to external parties. The letter has a lot of pertinent info that I didn't want to restate in the presentation...

Thanks,  
Bill Versosky  
VP, National Accounts  
Anda Inc.  
Phone: (954) 217-4635  
Cell: (954) 805-1939  
Email: [bill.versosky@andanet.com](mailto:bill.versosky@andanet.com)





CAP - Compliance Assistance Program

# Controlled Substance Compliance

*The risks of dispensing Controlled Substances have recently been highlighted as the DEA has focused more of it's attention on Chain Pharmacies.*

- Manufacturers and Distributors are required to “Know Your Customers” and maintain suspicious order monitoring systems
- Each pharmacy must be treated as an individual, regardless of group or chain affiliation
- Pharmacies have a **“corresponding responsibility”** along with physicians to ensure that Rx’s are for a legitimate medical purpose and in the normal course of professional practice



# Continuing Education

## Pharmacist CE LESSON

**CE**  
PHARMACIST

Pharmacist program number: 40100012012H03  
Activity type: Knowledge based  
Initial release date: Oct. 3, 2012  
Renewed expiration date: Oct. 3, 2015  
This program is worth two contact hours (2 CEUs).

**Target Audience**  
Pharmacists in community-based practice

**Program Goal**  
To provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing.

**Learning Objectives**  
Upon completion of this program, the pharmacist should be able to:

1. Explain the Drug Enforcement Administration's definition of "dispensing responsibility" to community pharmacists and pharmacists to ensure that controlled substance medications are only dispensed to patients based on prescriptions within the appropriate medical practice and the overall scope of professional practice, including the pharmacist's responsibilities regarding the program.
2. Describe control initiatives by the DEA, Food and Drug Administration, Office of National Drug Control Policy and general state policies to help monitor, assess and decrease all controlled substances and their relationship to pharmacy practice.
3. List control initiatives by regulatory agencies, the Advanced Part D program and state Medicaid programs to curb misuse, abuse and diversion of controlled substances.
4. Identify red flags, suspicious and warning signs that can be taken by the pharmacist and the pharmacy staff to reduce the likelihood of misuse, abuse and diversion of controlled substances.
5. Identify a checklist for the pharmacy staff to use in conducting the program, including identifying prescriptions and patients that may be involved in controlled substance dispensing.
6. Discuss available resources to develop effective, comprehensive controlled substance dispensing policies in pharmacies.

**To receive credit:** A minimum final score of 70% is needed to obtain a statement of credit. Student score remains online at [www.cedrugstorenews.com](http://www.cedrugstorenews.com) and remains your permanent record in your CE account unless removed.

Questions regarding statements of credit and other important course issues should be directed to 800-552-9886. This lesson is free of charge.

**TO LINK DIRECTLY TO THIS LESSON, VISIT:**  
[WWW.CEDRUGSTORENEWS.COM/40100012012H03](http://WWW.CEDRUGSTORENEWS.COM/40100012012H03)



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1 • NOVEMBER/DECEMBER 2012

This lesson is supported by an educational grant from **Anda**

### Pharmacists' responsibility in appropriate controlled substance dispensing

**INTRODUCTION**

Dispensing controlled substances in community pharmacies continues to increase as the number of opioid analgesic prescriptions has continued to grow steadily each year since 2000.<sup>1</sup> There was a slight reduction of these prescriptions reported in 2011 among teens, young adults ages 18 years to 25 years and "weekend" consumption claims.<sup>2</sup> This reduction may be related to more readily available consumer education and aggressive actions by federal, state

and local officials to curb prescription drug abuse, particularly for opioid analgesics. The same, however, is not completely positive; prescriptions containing hydrocodone and acetaminophen in combination remained the most prescribed medications in the United States between 2007 and 2011. Prescriptions for products containing oxycodone as a single agent also increased in 2011 (Figure 1).

Overight and authority of substance prescribing and dispensing is conduct-

**Figure 1**  
Total number of prescriptions dispensed for ER/LA and IR opioids from U.S. independent retail pharmacies, 2000-2009



Year	ER/LA Opioids	IR Opioids
2000	8.3	16.8
2001	11.8	171.9
2002	12.7	174.8
2003	14.7	173.9
2004	15.0	181.6
2005	17.2	186.9
2006	18.4	211.1
2007	21.3	227.9
2008	22.4	221.6
2009	25.4	224.0

Source: U.S. Food and Drug Administration

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In working with many of our chain partners, it became apparent that there is not much information available to pharmacists related to this topic.

As a result, Anda has recently sponsored a CE through Drug Store News promoting education of a pharmacist's role in the dispensing of controlled substances

- available online at [www.cedrugstorenews.com](http://www.cedrugstorenews.com)

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# Regulatory Compliance

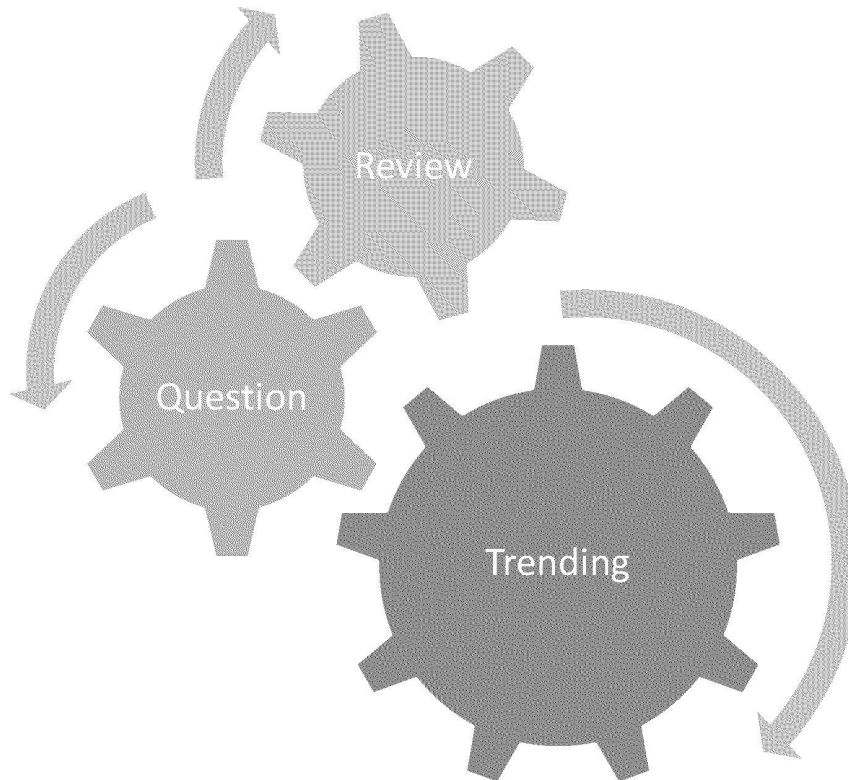
*Anda can be an integral partner in your responsible distribution of  
Controlled Substances*

- Anda's Regulatory Compliance Department has expert level knowledge and systems to be able to identify store level usage issues
- Anda's experience across 11,000 CII customers we sell to and in working with the DEA give us great experience in the requirements for responsible distribution
- To help our chain partners, we have developed a **Compliance Assistance Program** to utilize our resources to complement their compliance efforts



# Compliance Assistance Program

*Anda's CAP consists of three distinct concepts:*



*Anda can act as an analytical resource and **partner** to your regulatory compliance department, providing an **independent** view of your store level data, utilizing our experience in selling CII products to over 11,000 retail pharmacies.*



# CAP - Data

*Anda's Compliance Assistance Program requires that our customers provide dispensed data for each of their stores.*

- Because Anda is a secondary supplier, it does not have access to as much information as a primary wholesaler to determine the total products purchased and dispensed by its customers, thus requiring us to potentially ask for more detailed information.
- Any information provided is considered confidential within the Anda Regulatory Compliance Department and is not to be viewed or utilized by any other internal groups within the Anda organization.



# CAP - Review

*In the Review period, Anda performs a spot check on your store-level data through our business intelligence systems to identify any quantitative concerns.*

- Full chain review in 1-2 business days
- Store level concerns identified using a comprehensive checklist of criteria
- Stores are “flagged” for questions on each of the specific logical criteria failed

*Anda can return a complete store listing with identification of exactly which flags were hit for each store.*

*Example: If Hydrocodone, Carisoprodol, and Promethazine all rank in the top 20 products*





# CAP - Question

*In the Question period, Anda will work to obtain questionnaires from each store.*

- Specific Questionnaires based on the flags that were tripped at each store
- In conjunction with your Compliance and Store Operations teams
- Anda can provide tracking and review of the completed questionnaires
- Interactive dialogue with your compliance department related to concerns that arise from store answers

*Utilizing Anda's manpower and resources can dramatically improve the turnaround time to aggregate questionnaires for all stores.*



# CAP - Trending

*With consistent data, Anda has developed additional criteria to identify store-level concerns as dispensing trends change over time.*

- Helps to identify if a store's incremental controlled usage changes abnormally
- Specific criteria developed to identify abnormal changes from period to period
- May lead to additional questions for stores that have abnormal changes

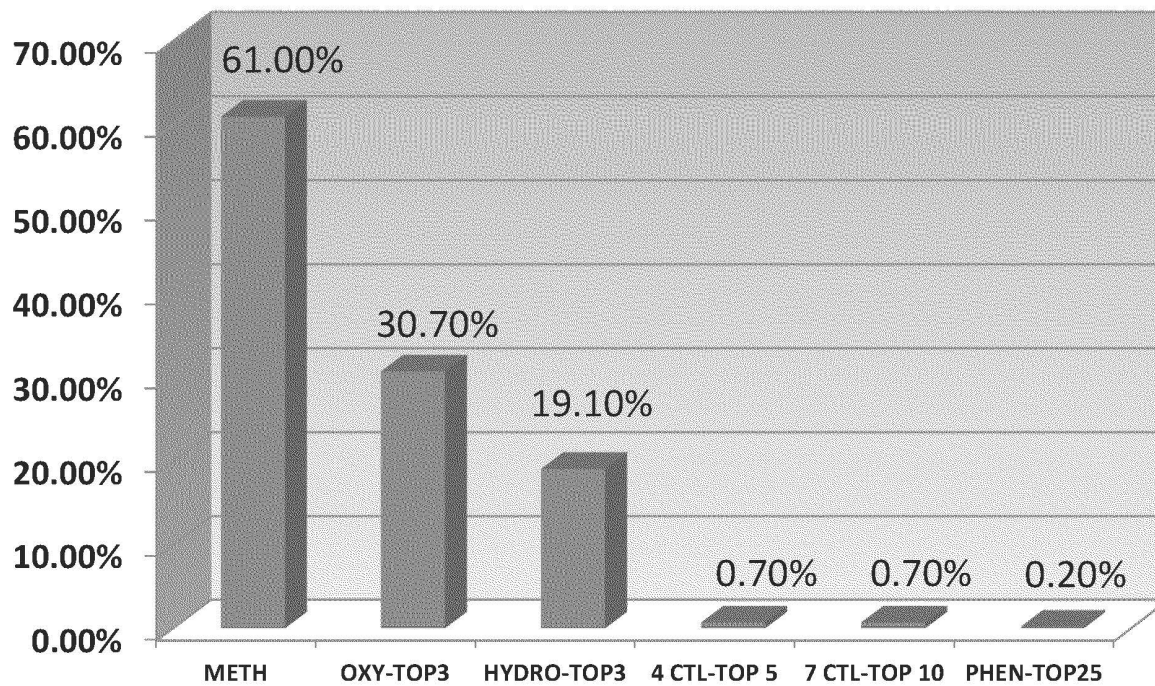
*The compliance process works best as an ongoing dialogue and partnership, with constant review, questioning, and trending.*

*Example: If Oxycodone Rx's are over 50 per month, did they grow by more than 1.5% month over month in units or Rx's*



# Rite Aid Sample Data

*As a sample, Anda ran the last data received from Rite Aid through our CAP flagging review.*



Comparing the data provided in February 2012 against our other chain partners, Rite Aid had:

- a similar % of stores where Oxycodone was in the top three product families
- an abnormally high amount of stores where Methadone exceeded 150 pills/Rx



**Produced in Native Format**



CAP - Compliance Analysis Program

# Controlled Substance Compliance

*The risks of dispensing Controlled Substances have recently been highlighted as the DEA has focused more of it's attention on Chain Pharmacies.*

- Manufacturers and Distributors are required to “Know Your Customers” and maintain suspicious order monitoring systems
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# Continuing Education

## Pharmacist CE LESSON

**CE**  
PHARMACIST

Author: Deborah Maly, D.C., PharmD, is a clinical pharmacist and continuing education staff at a large hospital system in the Midwest.

Pharmacist program number: 40100012012H03  
Initial release date: Oct. 3, 2012  
Renewal expiration date: Dec. 3, 2015  
This program is worth two contact hours (2 CEUs).

**Target Audience:**  
Pharmacists in community-based practice.

**Program Goal:**  
To provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing.

**Learning Objectives:**  
Upon completion of this program, the pharmacist should be able to:

1. Explain the Drug Enforcement Administration's definition of "unlawful dispensing responsibility" to community pharmacists and pharmacists to ensure that controlled substance medications are only dispensed to patients based on prescriptions within the appropriate medical process and in the correct course of professional practice, including the pharmacist's responsibilities regarding the regimen.
2. Describe current initiatives by the DEA, Food and Drug Administration, Office of National Drug Control Policy and general state policies to help monitor, assess and decrease all controlled substances and their relationship to pharmacy practice.
3. List current initiatives to help primary payers, the Medicare Part D program and state Medicaid programs to curb misuse, abuse and diversion of controlled substances.
4. Identify red flags, suspicious and warning signs that can be taken by the pharmacist and the pharmacy staff to reduce the likelihood of misuse, abuse and diversion of controlled substances.
5. Identify a checklist for the pharmacy staff to use in conducting the regimen, including verifying prescriptions, medications that may be received in alternate appropriate packaging.
6. Discuss available resources to develop effective, comprehensive controlled substance dispensing policies in pharmacies.

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2002	174.7	12.7
2003	178.8	14.7
2004	186.6	15.0
2005	198.9	17.2
2006	211.1	18.4
2007	227.9	21.3
2008	221.6	22.4
2009	204.0	20.6

Source: U.S. Food and Drug Administration.

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# Regulatory Compliance

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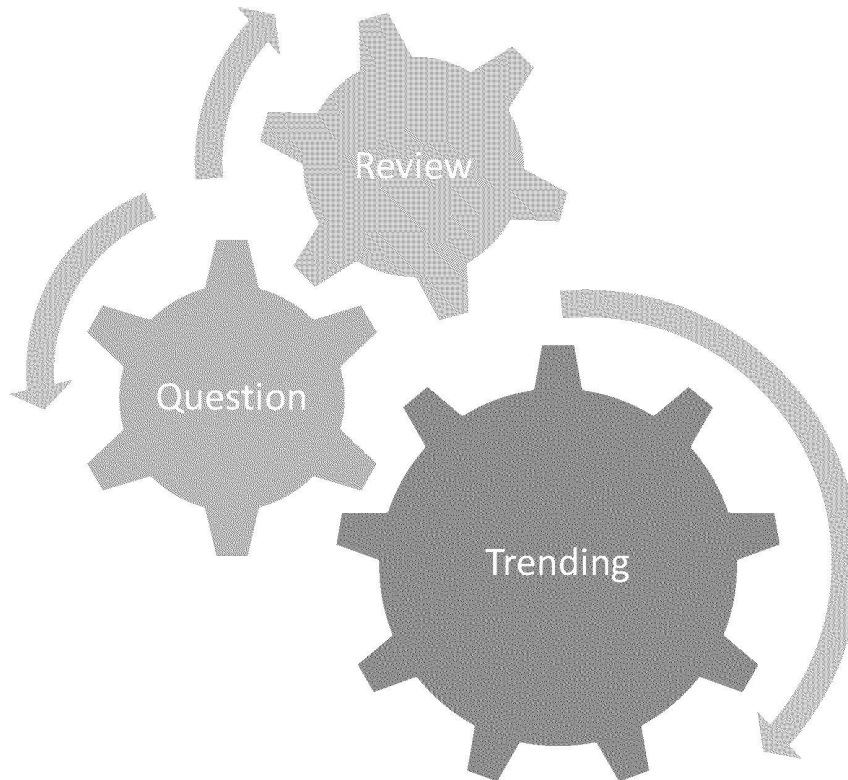
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*Example: If an Oxycodone product is in the top 3 products dispensed by pill count*



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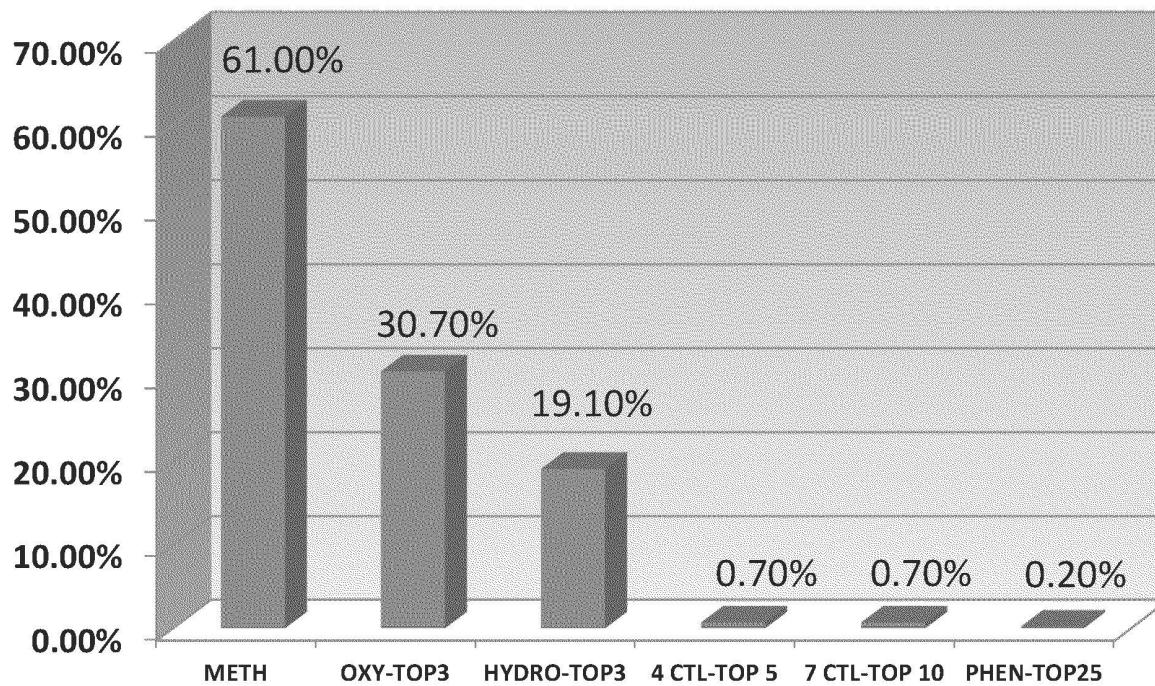
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