

Message

From: Dymon, Christopher [christopher.dymon@walgreens.com]
Sent: 1/10/2013 4:36:39 PM
To: Osullivan, Lauren [lauren.osullivan@walgreens.com]; Polster, Tasha [tasha.polster@walgreens.com]; Daugherty, Patricia [patricia.daugherty@walgreens.com]
Subject: DEA Update Presentation For Market Leadership
Attachments: DEA Market Leadership Scrubbed Version Jan 2013.pptx

Hi Lauren,

Please let me know if you are the contact in order to send this presentation out to the Market Leadership group.

Thanks!

Be Well,
Chris

Christopher Dymon, PharmD
200 Wilmot Road, MS 2194
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p. 847
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Every day I help people **get, stay and live well.**

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DEA Update Market Leadership Meeting

Tasha Polster

Director, Pharmaceutical Integrity

January 2012

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AT THE CORNER OF **HAPPY** & **HEALTHY**



The New HOT Topic



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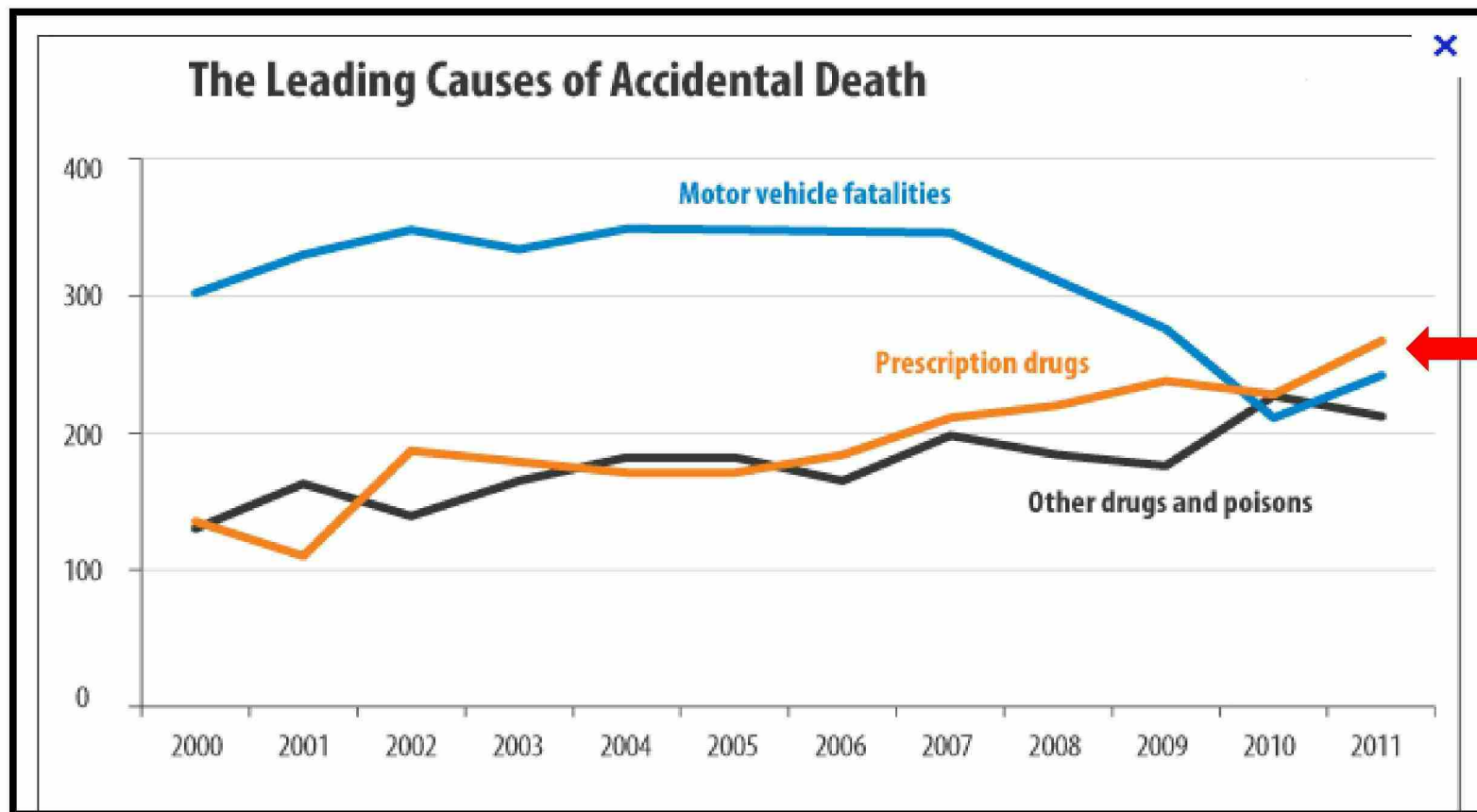
Florida Pill Mill Busts



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Leading Cause of Death - Prescription Drugs



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Title 21 Code of Federal Regulations

Section 1306.04 Purpose of issue of prescription.

*(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.*

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Timeline of Events

Pre-August
2010

- Steady increase in FL pill mills
- Prescribers dispensing medications

October
2010

- Change in Florida legislation restricts prescriber dispensing to only 72 hour supply of pain medications

October 10-
March 11

- Dramatic increase in the number of opioid pain medications prescriptions seen at retail stores

July 2011

- Florida law amended to prohibit practitioners from dispensing C2-3, except in very limited instances

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Timeline 2012

April 2012

- Administrative Inspection Warrants were served on 6 stores and the Jupiter DC

May –June
2012

- 8 stores voluntarily removed all C-II products, Xanax and Soma
- Re-launch of Good Faith Dispensing Policy

September
2012

- ISO was issued for the Jupiter DC

November
2012

- Order to Show Cause issued to 3 of the original Florida pharmacies

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Timeline

December
2012

- Target Drug GFD pilot begins in FL and Vegas

January
2013

- Sanction prescriber pilot begins NJ and PA

February
2013

- DEA administrative hearing begins



Operational Steps Taken

- In June, we re-launched our Good Faith Dispensing Policy across the Chain
- Pilots
 - Target Drug Good Faith Dispensing in FL and NV
 - Prescriber Sanctioning in NJ and PA
 - 8 prescribers total
- Invalid Prescriber DEA removal from IC+

Reporting Tools

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Expired DEA CAP Override

Rx #	Store	Sold Date	Campaign ID	DEA #	Prescriber First Name	Prescriber Last Name	Drug	RPH	Consult Completed Date	Comments	Sold?
1491441	Xxxx	12/28/2012	Doctor Suspension	XX1234567	First	Last	OXYCODONE 30MG IMMEDIATE REL TABS	EXW	12/28/12 7:20 PM	Consultation Completed:	YES
1900255	Xxxx	12/26/2012	Doctor Suspension	XX1234567	First	Last	CONTOUR TEST STRIPS 100'S	NAH	12/26/12 1:33 PM	Consultation Completed:	YES
3002349	Xxxx	12/26/2012	Doctor Suspension	XX1234567	First	Last	VIT D 50,000 IU D2 (ERGO) CAPS (RX)	ERL	12/26/12 12:01 PM	Consultation Completed:	YES
3017623	xxxx	12/26/2012	Doctor Suspension	XX1234567	First	Last	OMEPRazole 20MG CAPSULES	ERL	12/26/12 12:01 PM	Consultation Completed:	YES

- Each week RxIntegrity gets a report showing CAP overrides
- We need documentation back from the RXS that they discussed with the pharmacist
- We should not be dispensing any controls and for the example of Dr Pogue his medical license was revoked, so non-control rx's are not valid either

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Customer Service in Regard to GFD Policy

- Intentionally written with grey areas
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- Does not replace sound professional judgment

Suspicious Order Monitoring

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Suspicious Order Monitoring

How normal and expected transactions are identified:

- Accumulation of Receipts over time period - The system accumulates the amount of each controlled substance over the last six weeks.
- Ceiling Limit - Data mining is done across Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive in a rolling six week time period, based on statistical linear regression. The analysis compares like pharmacies across the country based on script volume and determines by drug what would represent unusual quantities.



SOM as it Applies to Cardinal

- Cardinal will limit the entire family of a drug based on monthly purchases
 - example: HC/APAP, Hydromet, Tussionex is all grouped into one
- Orders they flag (ie; your invoice says “Restricted Due to DEA Regulations”) are reported immediately to the DEA
- Cardinal has our sales history by store for the past year, so they can monitor any orders that deviate from the norm
- Anything they deem as suspicious gets cut



All Receipts Count Toward Rolling 6-weeks

- Warehouse
- Interstore – should not be doing this
- Vendor



Best Practices For Ordering

- Review all Controlled Substance receipts before posting
 - Adjust the shipped quantity to “0” if you did not receive
 - Post as short when appropriate
- On-hands
 - Do not falsely increase/decrease on-hands
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Industry Efforts

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Industry Work

- American Pharmaceutical Association (APhA)
- American Academy of Pain Medicine (AAPM)
- American Medical Association (AMA)
- National Association of Chain Drug Stores (NACDS)
- National Association of Boards of Pharmacy (NABP)



Task Forces and Committee Meetings

- If you or your Supervisors are asked to participate
 - Yes, we need your help!
- Contact us before agreeing to participate
 - Tasha Polster or Al Cater
 - We will ensure that you are fully versed or have additional corporate support
- This team work will ensure we continue to build relationships with state agencies and remain a leader in the industry



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The New HOT Topic



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2

The new hot topic in the news is the epidemic America has: Prescription Pain Drug Abuse



Florida Pill Mill Busts

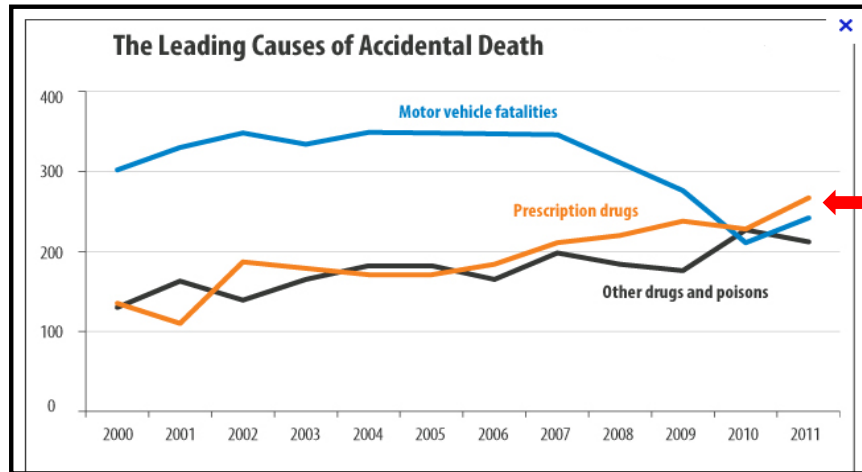


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3



Leading Cause of Death - Prescription Drugs



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This particular stat came out of California, but there were multiple examples across the country where the leading cause of accidental death is prescription pain medications (opioid use). This national problem has brought increased scrutiny to physicians, pharmacists and drugs wholesalers from regulators, policy makers and law enforcement.



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5

Pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are dispensed for a legitimate medical purpose. This legal responsibility is pursuant to Title 21 code of Federal regulations. The important point of this regulation is “the corresponding responsibility rests with the pharmacist who fills the prescription”



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6



The key to note is that this isn't just a Florida problem.



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8



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9

We had a COMPASS Communication last week announcing that we are removing Invalid DEAs

What is it?

A new IC+ enhancement is being released this week that will flag and remove Invalid DEA #'s

How will I know the DEA number was removed because it was invalid?

When the prescriber's DEA # is removed, a message will be put in the comment field of the Prescriber Inquiry window that says:

WARNING INVALID DEA #. DO NOT ADD DEA #. DO NOT FILL C2-5 Rx's FOR THIS PRESCRIBER.

What do I need to know?

Pharmacy staff must look in the prescriber inquiry window for the message above before adding a DEA #.

If the message above is in the profile, do not register the prescriber again and do not add the DEA # back into IC+.

Pharmacy staff must verify that the prescriber's DEA number is valid from the DEA website before registering any prescriber.

SNet -> RxOps-> Filling Prescriptions -> Good Faith Dispensing -> DEA Diversion Website -> Registration Validation or click link below

<https://www.deadiversion.usdoj.gov/webforms/validateLogin.jsp>

What do I do if this is a refill?

Speak with the patient to ask if they have a new prescriber they would like you to contact for a new prescription. If they do not have a new prescriber, they need to contact their existing prescriber for next steps, as Walgreens cannot fill this prescription under the current prescriber.

What if this is a new prescription?

Return the prescription to the patient and let them know they need to contact the prescriber for next steps.

Reporting Tools

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11



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Suspicious Order Monitoring

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Suspicious Order Monitoring

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14

DEA regulations require that distributors (i.e.; the Walgreen distribution centers) *must* take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify transactions that are suspicious in nature. Orders must be assessed to ensure that quantities for controlled substances at a specific location are reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served. In addition, Walgreens ***must report*** to the DEA any order that is deemed suspicious.

So the system takes into account normal accumulation for the store over the last 6 weeks and the maximum (a.k.a. ceiling) they should have over a rolling 6 weeks.



SOM as it Applies to Cardinal

- Cardinal will limit the entire family of a drug based on monthly purchases
 - example: HC/APAP, Hydromet, Tussionex is all grouped into one
- Orders they flag (ie; your invoice says "Restricted Due to DEA Regulations") are reported immediately to the DEA
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15



All Receipts Count Toward Rolling 6-weeks

- Warehouse
- Interstore – should not be doing this
- Vendor

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All receipts count toward the store's rolling six week volume.



Best Practices For Ordering

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- On-hands
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19

This is not just a Walgreen issue, this is an industry wide issue. We have been working with or are in conversations with various organizations

Talk to some of the meetings/conversations.....

As we further advance our pharmacy practices to meet these new challenges, we continue to believe that addressing prescription drug abuse will require all parties – including leaders in the community, physicians, pharmacies, distributors and regulators – to play a role in finding practical solutions to combatting abuse while balancing patient access to critical medication

Our goal is to lead the industry to a solution for this problem that affects all areas of healthcare.



Task Forces and Committee Meetings

- If you or your Supervisors are asked to participate
 - Yes, we need your help!
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20

Many state regulators or agencies will ask for your participation in different task forces or committees because of the national presence Walgreens brings. We do need your help, but we also want to make sure that the person participating is fully versed on the national issue and not just seeing it from a district, state, or local level. Contact me or Al Carter and we will ensure that you have what you need from corporate before agreeing to participate.

This is an opportunity to make sure that laws and regulations that are created don't hinder us from continuing in expanding our pharmacy practice to the highest level.