

Ohio State Board of Pharmacy Law and Compliance Updates OPA Annual Meeting 4/13/13

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Today's Topics

- ▶ Case review of Pill Mill: Understand basis for HB 93 and SB 301
- ▶ Understand pharmacy delegate process
- ▶ Analyze effects of HB 93 from 2012 OARRS data
- ▶ CE update
- ▶ Compliance "lessons learned" via actual OSBP case study review

Why HB 93? Case study on Professional Pain Management of Ohio New Philadelphia, Ohio



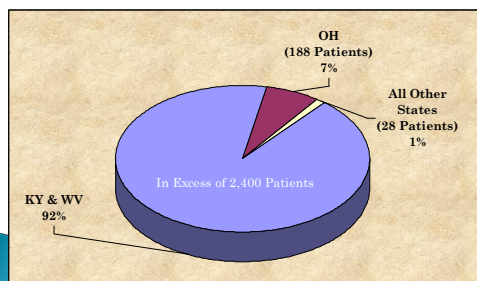
▶ In less than **11 months** two PPMO prescribers were responsible for the illegal distribution of **over 1.5 million** doses of **hydrocodone 10mg** and over **600,000** **carisoprodol 350mg**. This enterprise profited **over \$2.1 million** from the more than **2,600** Kentucky and West Virginia patients seen in the rural north central Ohio town of New Philadelphia. These patients drove over ten hours (round trip) each month in order to get these drugs. The street value of these drugs **exceeded \$15 million**.

During a 10 Day Surveillance

- In excess of 600 vehicles arrived at PPMO
- 28 vehicles were from West Virginia.
- 73 vehicles were from Ohio (Of these, only 28 were from the New Philadelphia area).
- **499 vehicles were from Kentucky.**
- In excess of **1,400** individuals arrived at PPMO.

Total Number of PPMO Patients by Selected States

State	# of PPMO Patients	# of PPMO Cities
KY	2322	272
WV	145	41
OH	188	62
AOS	28	n/a

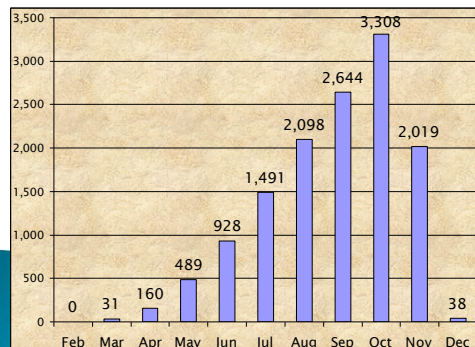


Round Trip Distances & Travel Time

State	City	Round Trip Distance
KY	Louisa	500
KY	Grayson	496
KY	Inez	548
KY	Paintsville	558
KY	Tomahawk	546
KY	Winchester	652
KY	Prestonsburg	582
KY	Hagerhill	562
KY	Mt. Sterling	680
KY	Van Lear	568
WV	Huntington	440
WV	Ft. Gay	498
WV	Lenore	482
WV	Naugatuck	494
WV	Kermit	554
WV	Crum	540
OH	Columbus	236
OH	Grove City	250
OH	Proctorville	436

Out-of-State Patients
Averaged 537 Miles Each Trip with 10.6 Hours of Travel Time

PPMO 2003 Prescription Growth at Ohio Pharmacy # 1



SB 301 a.k.a. HB 93– Version 2

Finally passed –effective May 13th!

- Allows delegates for pharmacists to query OARRS
- Excludes nursing homes and clinical research facilities from definition of pain management clinic
- Excludes buprenorphine (for purpose of substance abuse treatment) and drugs in clinical research trials from 72 hour limitation on personally furnished.

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OARRS Delegates-SB 301

Pharmacists

- ▶ Get an account (needed in order to allow delegates to run them for you)! If you do not have an account yet, send your application as soon as possible; do not get caught in the flood of delegate applications the Board is expecting.
- ▶ Be sure your account is current and correct. Log in and click on “My Account.” The e-mail address is where OARRS will send information or questions to you.
- ▶ Do not allow anyone to use your username and password. Every person needs his or her own account to access OARRS.
- ▶ The responsible person on a TDDD license should be the supervisor of each technician or support staff person in that pharmacy who will have OARRS access.

OARRS Delegates-SB 301

Pharmacists

- ▶ You are responsible for all OARRS activity linked to your account. To help you monitor the activity, you will receive bi-weekly e-mails that summarize all requests linked to your account.
- ▶ When an OARRS delegate is no longer under your supervision, fax an “Add/Remove Delegate” form (available on the OARRS Web site) to OARRS. The fax number, 614/644-8556, is also listed on the form.
- ▶ A delegate’s only responsibility is to obtain the OARRS report. **A pharmacist is still responsible for interpretation of the data.**

OARRS Delegates-SB 301

Pharmacy Technicians/Support Staff

- ▶ OARRS delegate accounts are available now! Send your application early to receive a username and password as soon as the law becomes effective.
- ▶ Be sure your supervising pharmacist already has an OARRS account. This pharmacist may be the responsible pharmacist on the pharmacy’s TDDD license.
- ▶ Do not use anyone else’s username and password to access OARRS.

OARRS Delegates-SB 301

Pharmacy Students – Interns and Externs

- ▶ A student on rotation does not need an OARRS account. The preceptor should obtain the OARRS report for use as a teaching tool.
- ▶ A student working in a pharmacy (not part of a pharmacy school rotation) may register as a pharmacist delegate, supervised by a pharmacist at that pharmacy.



Other Legislation to note:

SB 83-APN's

- ▶ Expanded scope to include prescribing of:
 - C2 Opiates
 - C2 Sedatives/Hypnotics
 - C2 Amphetamines/Stimulants
 - Script must have CTP# and DEA#
- ▶ Went into affect June 9th, 2012

HB 284- PA's

- ▶ PA prescribe C2's
 - Mirrors SB 83
 - Script must have CTP# and DEA#
- ▶ **Effective May 22nd!**

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OARRS Statistics-what's happened since HB 93?

- ▶ Ohio Population
 - 11.5 million
- ▶ Number of Prescriptions in OARRS (2011-2012)
 - 47.5 million↑ (3.6% over 2010-2011)
- ▶ Number of Patients in OARRS (2011-2012)
 - 5.8 million↑ (10% over 2010-2011)

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Average number of direct requests* (per weekday)

January 2013:	25,700
(5,000 next closest state)	
January 2012:	7,749
January 2011:	3,852
January 2010:	2,485
January 2009:	1,401
January 2008:	975
January 2007:	264

*Includes Interstate and hospitals

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Top Ten Drugs in OARRS 2012

Drug Class	Number of Solid Doses	% Change Since 2011
Hydrocodone & Comb.	288,916,417	-1.4%
Oxycodone & Comb.	259,859,420	5.2%
Tramadol	163,532,246	10.7%
Alprazolam	128,018,592	1.2%
Lorazepam	73,281,529	2.9%
Pregabalin	71,352,325	48.6%
Clonazepam	64,176,546	5.5%
Amphetamine & Comb.	55,462,943	32.6%
Zolpidem	48,588,443	3.4%
Methylphenidate	44,778,675	30.5%

Source: Ohio Automated Rx Reporting System

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Top Ten Drugs in OARRS 2012

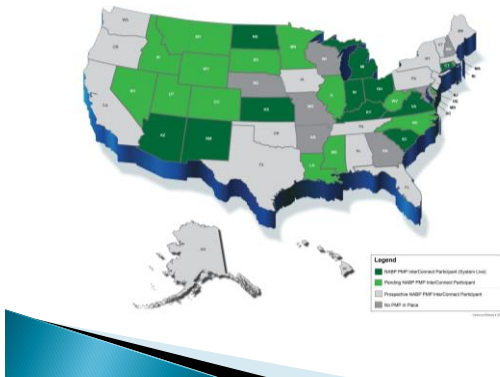
Drug Class	Number of Patients	% Change Since 2011
Hydrocodone & Comb.	1,790,174	-0.4%
Oxycodone & Comb.	953,125	1.7%
Tramadol	670,517	8.7%
Alprazolam	385,050	-0.4%
Lorazepam	343,368	4.0%
Codeine & Comb.	330,596	-7.5%
Zolpidem	308,751	-1.5%
Diazepam	206,603	2.2%
Amphetamine & Comb.	186,398	17.8%
Clonazepam	183,935	3.3%

Source: Ohio Automated Rx Reporting System

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NABP PMP InterConnect

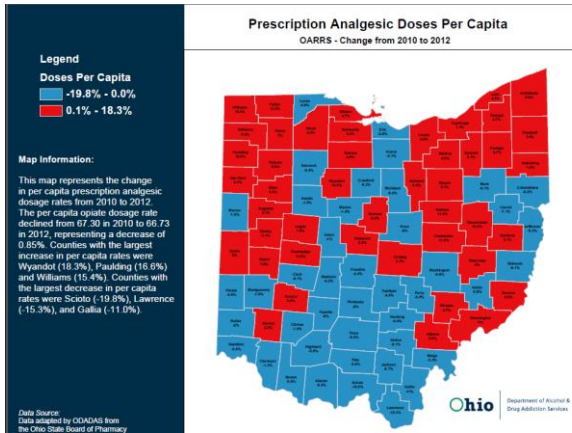


OARRS updates

- ▶ Compliance of usage now being enforced
- ▶ Daily submission to OARRS coming
 - Instead of real time!
- ▶ Improvement/Research projects
 - NARxCHECK (NABP) project
 - Integration project/SAMHSA
- ▶ Garbage in/Garbage out

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Prescription Analgesic Doses Per Capita OARRS - Change from 2010 to 2012



Effects of HB 93

- ▶ What's the data saying?
- ▶ Good news:
 - Major "Pill Mills" out of business
 - Licensure (250 apps)
 - Indictments
 - Collaboration btw agencies like never before
 - Opiate task forces
 - Forcing a multifaceted approach
 - OARRS compliance/enhancements
 - Better informed clinicians/prescribers

Effects of HB 93

- ▶ Challenges:
 - Chilling effect for pain Tx?
 - Whack a mole effect
 - Heroin up
 - Illicit Suboxone clinics-Phase 2 pill mills?
 - Robberies up
- ▶ Decrease in OD's ?

What's all this mean?

Ohio is Using a Multi-faceted approach:

- Legislation
- Licensing/Regulatory/OARRS
- Law enforcement
- Payment-Medicaid/BWC
- Education
 - Prescribers, pharmacists and public
- Treatment/ODADAS

No Silver Bullet for a complex problem

- HB 93 working, but will take time for metrics to show
- Any unintended consequences?

Last note: CE Update

- ▶ CE Time frame/range still the same (5/15)
- ▶ Reporting/attestment now done simultaneously with R.Ph. license renewal in late summer (by 9/15)
- ▶ Letters sent out and info on web

Compliance: Lessons Learned Case No. 1

Three Pharmacists all working together at the same smaller, independent pharmacy.

What did the three pharmacists do?

- ▶ Sold controlled substances to various patients after they all presented prescriptions from the same doctor.
- ▶ Evidence collected showed sixteen separate patients receiving prescriptions over the course of twelve months.

Samples of dispensing during a single visit

- ▶ Patient 1
 - Hydromorphone 8mg #900
 - oxycodone 30mg #120
 - methadone 10mg #960
 - Adderall XR 30mg #60
 - amphetamine 10mg #60
- ▶ Patient 2
 - methadone 10mg #120
 - oxycodone 30mg #120
 - Fentanyl 25mcg #56 patches
- ▶ Patient 3
 - OxyContin 40mg #60
 - methadone 10mg #90
 - oxycodone 30mg #60
 - Suboxone 2mg #30
- ▶ Patient 4
 - morphine sulfate ER 200mg #125
 - methadose 40mg #240
 - Duragesic 75mcg/h #30 patches
 - oxycodone 30mg #120
 - Duragesic 100mcg/h #10 patches

- ▶ Patient 5
 - OxyContin 40mg #120
 - oxycodone 30mg #120
- ▶ Patient 6
 - oxycodone 30mg #120
 - methadose 40mg #240
 - Opana ER 40mg #60
- ▶ Patient 7
 - OxyContin 80mg #180
 - methadose 40mg #120
 - hydromorphone 8mg #120
 - Adderall XR 30mg #60
- ▶ Patient 8
 - OxyContin 80mg #150
 - Methadose 40mg #90
 - oxycodone 30mg #150

Were these prescriptions for a legitimate medical purpose?

- ▶ Can a pharmacist decide if a prescription is for a "legitimate medical purpose"?
- ▶ How would a pharmacist make such a decision?
- ▶ What factors can or should be looked at when evaluating a prescription?

What laws or rules were violated?

- A. ORC 2925.03 Drug Trafficking
- B. ORC 2925.22 Deception to Obtain a Dangerous Drug
- C. ORC 2925.02 Corrupting Another With Drugs
- D. OAC 4729-5-20 Prospective Drug Utilization Review
- E. OAC 4729-5-21 Manner of Processing a Prescription

What should the punishment be?

- A. License suspensions of 5 years each
- B. Fines of \$25K, \$37K and \$50K
- C. Probation of 10 years with restriction that cannot be responsible pharmacists
- D. Continuing Education & Reprimand
- E. Revocation of Pharmacy License

Case No. 2

Independent Pharmacy seeks to increase revenue through expansion

What did this pharmacist do?

- ▶ Sold dangerous drugs (non-controlled) to patients in and out of the state through a mail order system. 15,380 prescriptions written for 1,491,171 doses of dangerous drugs
- ▶ Prescriptions were presented electronically by out-of-state doctors.
- ▶ Doctors rarely resided in the same state as the patient. Doctors did not physically see patients.

- ▶ Pharmacist printed and filed the orders for dangerous drugs received electronically and maintained these orders separate from his "front-end" prescription files.
- ▶ Pharmacist did not report any of the dispensings resulting from the electronic system to the OARRS program despite dispensing Soma*, Ultram and Tramadol.

*Soma was not a scheduled drug at the time

Were these prescriptions for a legitimate medical purpose?

- ▶ How would a pharmacist make such a decision in this situation?
- ▶ What inquiries could/should have been made to verify legitimacy?
- ▶ Is this type of prescribing legal in Ohio?
- ▶ What can/should a pharmacist do when confronted with an order for drugs that fits this model?

What rules or laws were violated?

- A. ORC 2925.22 Deception to Obtain a Dangerous Drug
- B. ORC 2925.03 Drug Trafficking
- C. ORC 4729.51 Possession and Sale of Dangerous Drugs
- D. ORC 4729.77 Submission of Prescription Information
- E. OAC 4729-5-21 Manner of Processing a Prescription

What should the punishment be?

- A. Revocation of Pharmacy License
- B. \$75K fine, 10 years probation with restriction preventing pharmacist from being RP
- C. Continuing Education, Reprimand, \$5K fine
- D. \$20K fine
- E. Suspension of Pharmacy License for 3 years with 3 years of probation upon reinstatement restricting pharmacist from acting as RP

Case No. 3

Family owned retail and infusion pharmacies run by a family pharmacist

What happened in these pharmacies?

- ▶ For a period of two years and 9 months, instead of dispensing the commercially available single-dose vials of Kineret with instructions for use, single-dose vials were emptied into a beaker and drawn up into syringes for the exact amount necessary for daily administration to a child patient. One month supplies of the exact-dose syringes were dispensed to the child's care-taker.

- ▶ For a period of approximately one year, when a prescription for Lioresal was received, pharmacist compounded the product from baclofen powder or tablets and labeled it as "Lioresal" before dispensing it to patients. The prescriptions did not require the addition of any other drug or solution.

- ▶ Laminar and vertical flow hood out of certification

- ▶ Failure to keep a controlled substance inventory
- ▶ Maintained DEA 222 forms at pharmacist's residence
- ▶ Sale of drugs without keeping a manual or electronic record
- ▶ Failure to maintain separate files for C2's

What laws or rules were violated?

- A. OAC 4729-5-21 Manner of Processing a Prescription
- B. ORC 2925.03 Drug Trafficking
- C. ORC 3715.52 Adulteration
- D. OAC 4729-9-09 Security of DEA Order Forms
- E. 21 CFR 1304.11(c) Inventory Requirements
- F. OAC 4729-5-09 Prescription Filing

What should the punishment be?

- A. License suspension of 3 years + \$20K fine
- B. \$47K fine + 5 years probation with restriction on compounding
- C. Continuing Education, Reprimand and Probation with restriction on compounding
- D. \$5K fine, Continuing Education in compounding, quarterly reports from agents
- E. Revocation of Pharmacy License

Case No. 4

New pharmacist with drug addiction

What did this pharmacist do?

- ▶ Pharmacist was licensed October 2009, acted as intern while in pharmacy school and worked at a doctor's office.
- ▶ Prior to licensure as a pharmacist, stole prescription blanks from the doctor.
- ▶ Wrote prescriptions for controlled substances on the blanks for herself, her family and her friends.
- ▶ Summarily Suspended December 2009.

What laws or rules were violated?

- A. ORC 2925.03 Drug Trafficking
- B. ORC 2925.22 Deception to Obtain a Dangerous Drug
- C. ORC 2925.02 Corrupting Another With Drugs
- D. ORC 2925.23 Illegal processing of a drug document
- E. ORC 4729.28 Unlawful selling of drugs or practice of pharmacy

What should the punishment be?

- A. Public Reprimand, Continuing Education, \$1000 fine
- B. Revocation of Pharmacy License
- C. 5 years of Probation, Requirement to seek drug treatment, \$2500 fine and Continuing Education
- D. 3 Year Suspension of Pharmacy License, Requirement to obtain drug treatment and Continuing Education.