Opiates:
Transforming Prescribing Protocols at the Practice Level

October 9, 2014

ProMedica Toledo Hospital
Donald V. Kellermeyer Medical Education Center
Auditorium

Faculty Disclosures:

- Dr. Buoni and Becky Wilkins have no financial interests or other relationships with any manufacturer of commercial products or services to disclose.

Committee Disclosures:

- Hy Kisin, Dr. Dee Ann Bialecki-Haase and Debbie Marinik have no financial interests or other relationships with any manufacturer of commercial products or services to disclose.

Transforming Prescribing Protocols at the Practice Level

Becky Wilkins, BS
William Buoni, MD

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Improving People's Lives Through Innovations in Personalized Health Care

Transforming Prescribing Protocols at the Practice Level

William Buoni, MD
Becky Wilkins
Associate Director Ambulatory Services

OSU Rardin Family Practice

The Ohio State University
Wexner Medical Center

Our Goal

- To allow an understanding of:
  - Why change is difficult within our office
  - The reason we decided we had to change our prescribing practices
  - Many of the actual steps we took to make those changes
  - The lessons we learned along the way
  - What changes in our office have occurred as result of the changes
  - Legislation requiring action by prescribers

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Office Demographic

- 10 Attending Providers
- 2 Nurse Practitioners
- 1 Pharmacist
- 1 Dietician
- 1 Psychologist
- 5 Psychology Practicum Trainees
- 1 Psychiatrist
- 22 Residents
- 1 RN
- 1 Social Worker
- 11 Medical Assistants
- 10 Front Office Staff
- 1 Office Manager
- Various other supervising Faculty that practice in other offices
- It's Complicated

A 10 Year Journey

Reputation on the street as an easy mark

Residency non-continuity perfect storm for drug seekers
RN – "You're a pain clinic whether you admit it or not"
Patients were blatant in their abuse and diversion

Very Poor Employee Satisfaction

Staff were abused by our patients
Very high turnover and due to complexity very long training period
Staff were very aware of diversion
People go into health care to feel good about their day

Very Poor Provider Satisfaction

Turnover reduced provider efficiency and resulted in poor quality of care
Providers were developing sub optimal patient panels inconsistent with RRC requirements

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Made multiple attempts with the
providers
to change this with no lasting results

Children began attending funerals
This is the new normal
Don't Get Me Started

And then one patient came and provided some feedback that could not be ignored

Addiction is not a moral choice……

- ……but working in an atmosphere you know is contributing to the problem became one
- I could not go to work anymore and live with myself so I opened a dialog with my Director.

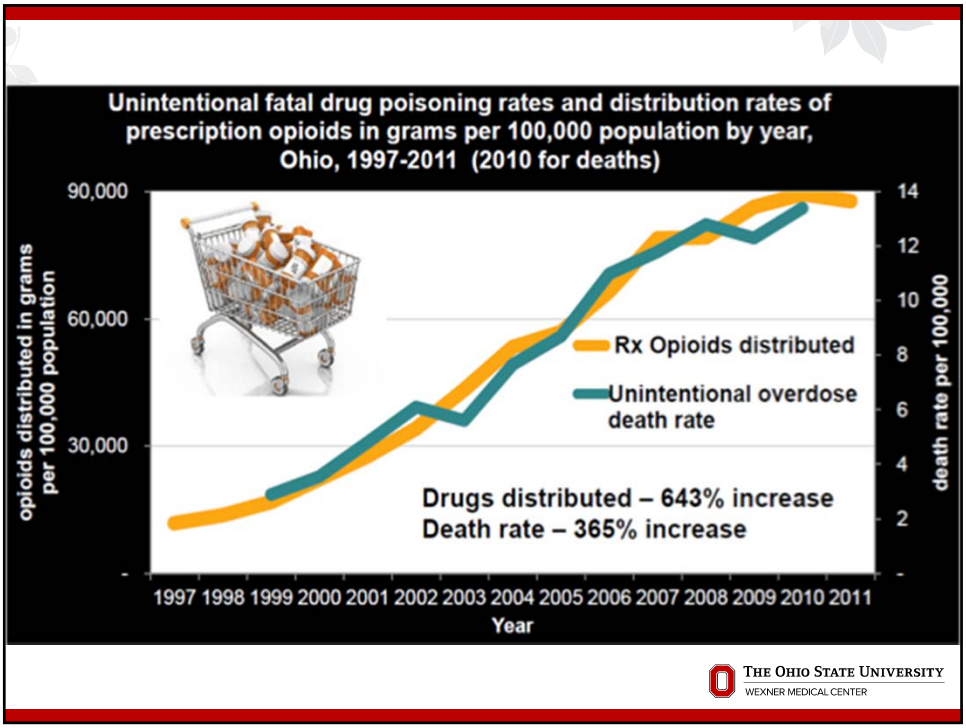
Addiction is a Disease

- *"At its core, addiction isn't just a social problem or a moral problem or a criminal problem. It's a brain problem whose behaviors manifest in all these other areas. Many behaviors driven by addiction are real problems and sometimes criminal acts. But the disease is about brains, not drugs. It's about underlying neurology, not outward actions."*
- The new definition also describes addiction as a primary disease, meaning that it's not the result of other causes, such as emotional or psychiatric problems. And like cardiovascular disease and diabetes, addiction is recognized as a chronic disease; so it must be treated, managed and monitored over a person's lifetime…..

Dr. Michael Mioller former president of ASAM

WHY IS THIS SO IMPORTANT?

Unintentional Drug Overdose continues to be the leading cause of injury-related death in Ohio, ahead of motor vehicle traffic crashes, suicide, and falls. This trend began in 2007 and continues through 2012.



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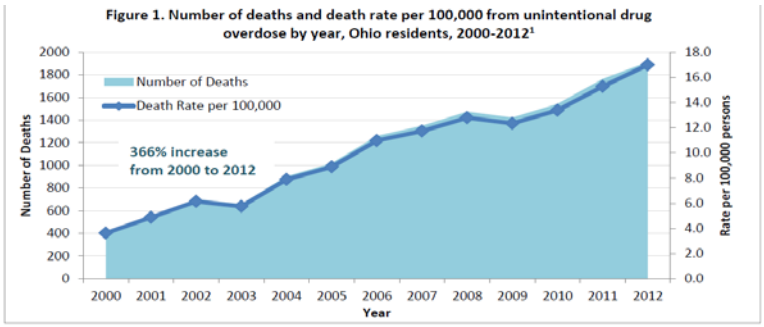
2012 Ohio Drug Overdose Data

- An Ohioan dies every 5 hours from accidental overdose
  (3 of which are overdoses of prescription medications)
- Largest contributors: opioids and multiple drug use
- In 2012, there was an average of 67 doses of opioids dispensed for every Ohio resident. *(Source: Ohio Board of Pharmacy, OARRS*



[1] Source: Ohio Department of Health; Office of Vital Statistics, Analysis Conducted by Injury Prevention Program

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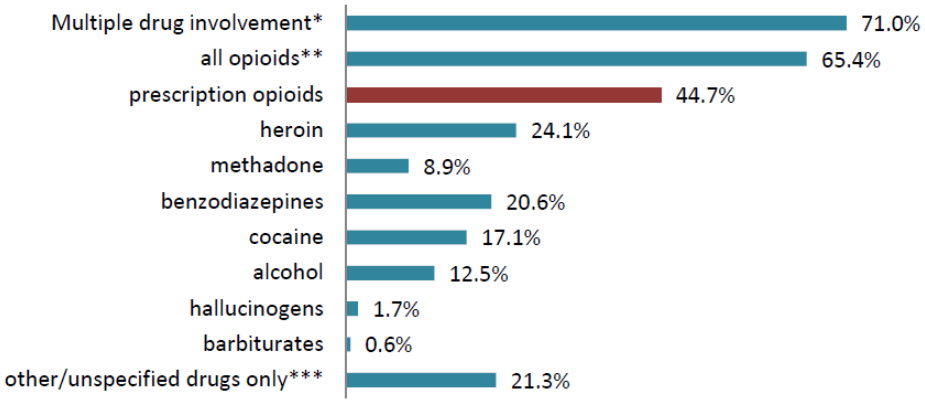
Figure 2. Proportion of drug overdoses among Ohio residents involving selected drugs, 2011[1,2]



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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 2013 OH State Board of Pharmacy

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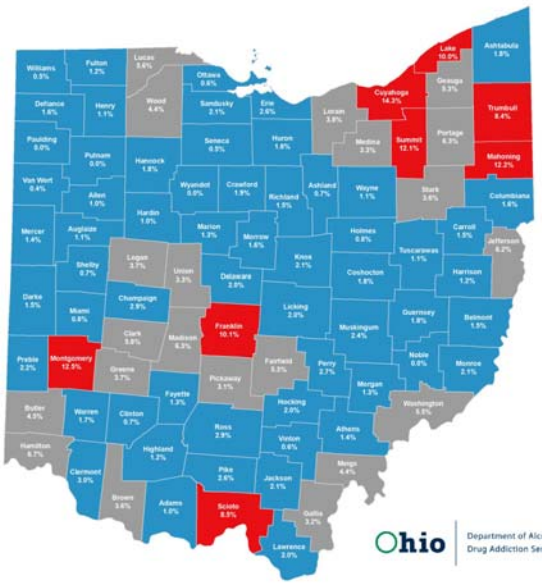
Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2001

Legend

Opiate Addicts (%)

- 0.0% - 3.0%
- 3.1% - 6.7%
- 6.8% - 14.3%



Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations of opiate admissions are in Cuyahoga (14.3%), Montgomery (12.5%), Mahoning (12.2%), Summit (12.1%) and Franklin (10.1%) counites. Noble, Paulding, Putnam and Wyandot did not have any opiate-related admissions.

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

Ohio Department of Alcohol & Drug Addiction Services

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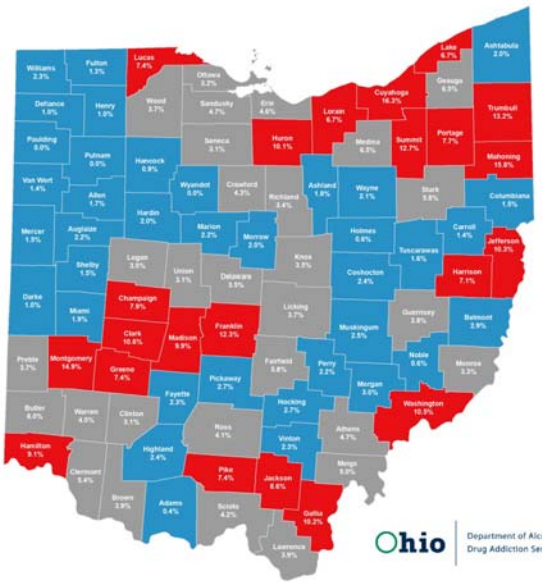
Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2003

Legend

Opiate Addicts (%)

- 0.0% - 3.0%
- 3.1% - 6.7%
- 6.8% - 16.3%



Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations for opiate admissions are in Cuyahoga (16.3%), Mahoning (15.8%) and Montgomery (14.9%) counties. Paulding, Putnam and Wyandot did not have any opiate-related admissions.

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

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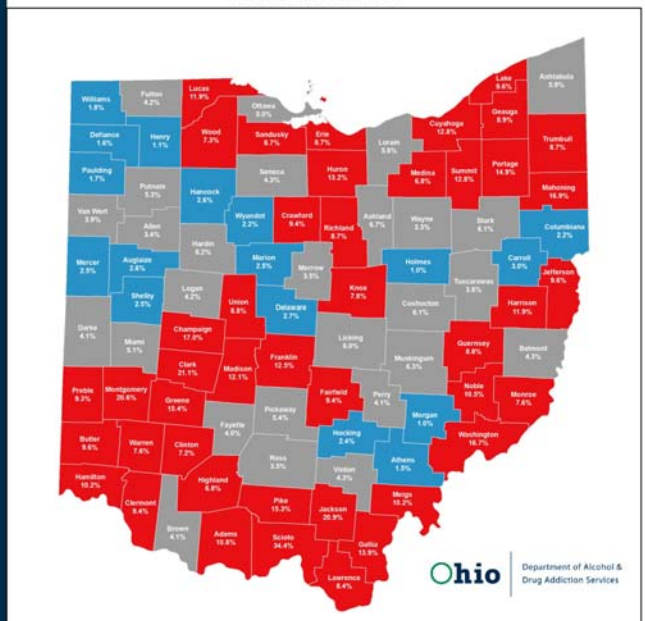
Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2005



Legend

Opiate Addicts (%)

- 1.0% - 3.0%
- 3.1% - 6.7%
- 6.8% - 34.4%

Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations for opiate admissions are in Scioto (34.4%), Clark (21.1%) and Jackson (20.9%) counties. The counties with the lowest concentrations of an opiate-related diagnosis are Holmes (1.0%), Morgan (1.0%) and Henry (1.1%).

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

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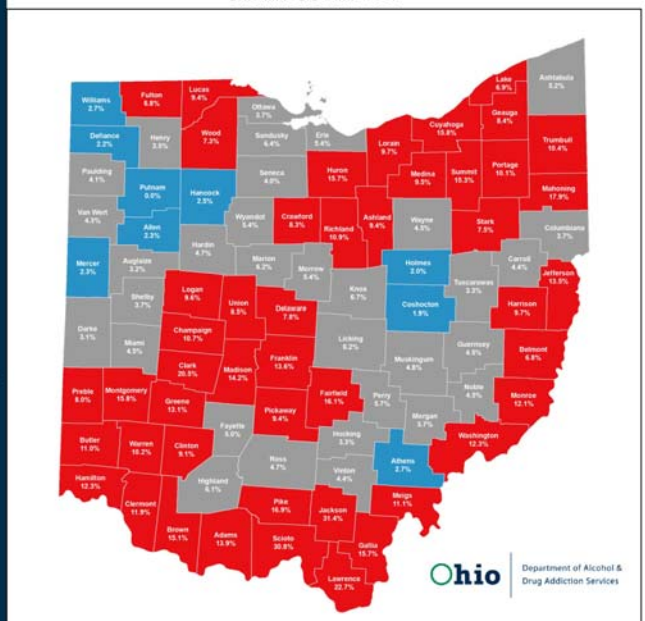
Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2007



Legend

Opiate Addicts (%)

- 0.0% - 3.0%
- 3.1% - 6.7%
- 6.8% - 31.4%

Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations for opiate admissions are in Jackson (31.4%), Scioto (30.8%) and Lawrence (22.7%) counties. The counties with the lowest concentrations of an opiate-related diagnosis are Putnam (0.0%), Coshocton (1.9%) and Holmes (2.0%).

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

TY

Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2009

Legend

Opiate Addicts (%)

- 2.3% - 3.0%
- 3.1% - 6.7%
- 6.8% - 64.1%

Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations for opiate admissions are in Scioto (64.1%), Lawrence (49.5%) and Jackson (35.7%) counties. The counties with the lowest concentrations of an opiate-related diagnosis are Allen (2.3%), Coshocton (2.4%) and Carroll (3.5%).

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

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Client Admissions for Opiate Abuse and Dependence

Ohio MACSIS Data - 2011

Legend

Opiate Addicts (%)

- 3.1% - 6.7%
- 6.8% - 70.2%

Map Information:

This map represents the percentage of clients in treatment with an opiate-related diagnosis (heroin and prescription opioid). The highest concentrations for opiate admissions are in Scioto (70.2%), Lawrence (56.2%) and Athens (41.9%) counties. The counties with the lowest concentrations of an opiate-related diagnosis are Tuscarawas (5.5%), Holmes (4.4%) and Morgan (3.1%).

Data Source:
Data from Multi Agency Community Information Systems (MACSIS)
Map produced April 2013

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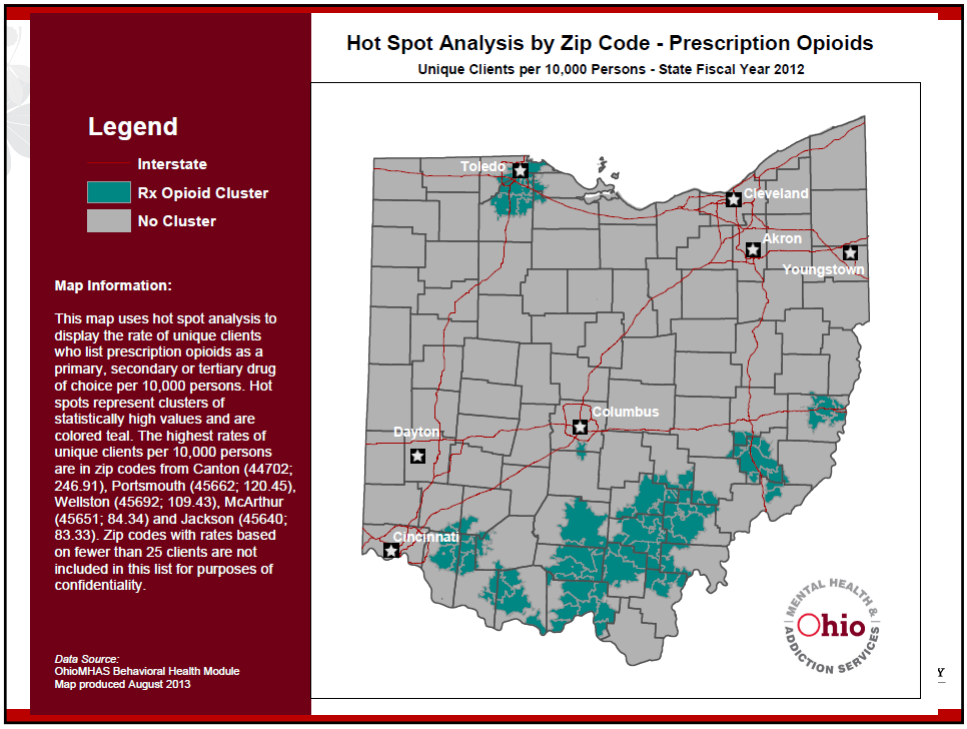

Other Ohio facts…

- *Only* 16% of 2008 unintentional poisoning decedents had a history of "doctor shopping"
- With prescription opioid listed on death certificate – 25% obtained through diversion
- In 2007, 26.5% of high school students reported using a prescription drug without a doctor's prescription one or more times

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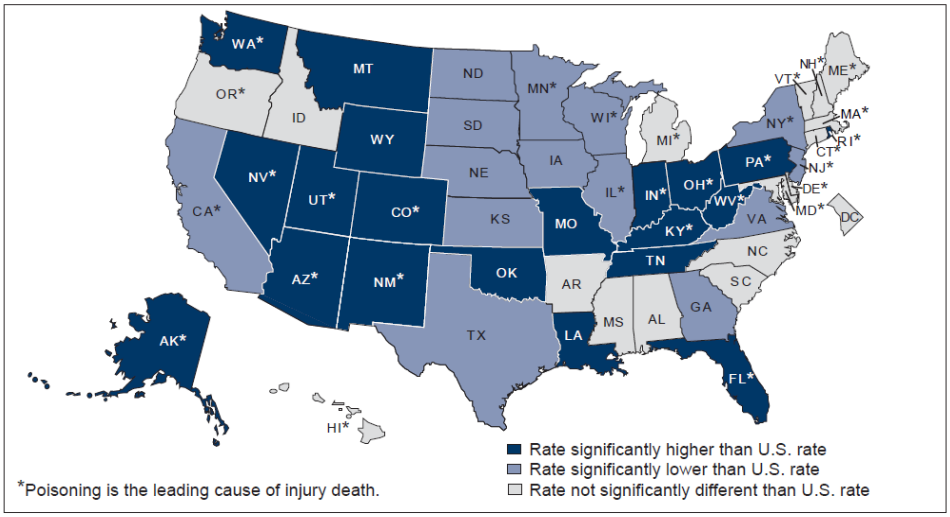
IT ISN'T JUST OHIO

- America represents less than 5% of the world's population
- Americans take 99% of the world's production of hydrocodone
- Americans take ~82% of the world's production of oxycodone
- An American dies every 19 minutes of a prescription overdose.

Figure 2. Age-adjusted poisoning death rates: Comparison of state and U.S. rates: United States, 2008



NOTES: The poisoning death rate for Georgia may not be based on the final numbers of poisoning deaths. See "Data source and methods" for details. Figure 2 at http://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#2.
SOURCE: CDC/NCHS, National Vital Statistics System.

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The Path To This Madness
Pain – The 5th Vital Sign

- Late 1990's brought and increased focus on effective pain management
- And enter OPIATES

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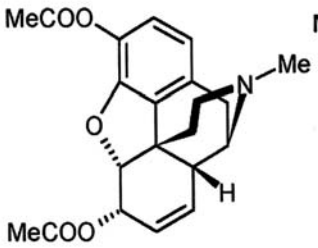
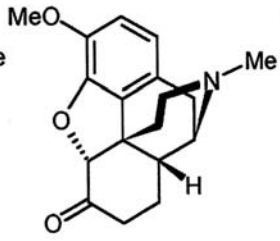
CONTRIBUTING FACTORS:

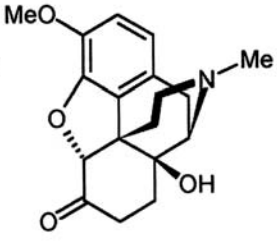
OPIOID CHEMICAL STRUCTURES



HEROIN



HYDROCODONE
(e.g., VICODIN®)



OXYCODONE
(e.g., OXYCONTIN®)

Laid Out Proposed Changes

- Took changes to the staff first.
  - Overwhelmed with their response
  - **This change was a key to our success**
- Only after staff fully engaged, went to providers
- Had one provider agree to pilot this.
  - He was instrumental as well

Dr. Buoni

- Agreed to pilot this but wanted a phased in approach that started with the patients he "knew"

"If I could track every pill I prescribed I might not need to evaluate my prescribing practices, but I can't"

A Model to Screen and Manage Patients

- Define and document your role to the patient
- Create an electronic medical record report to identify patients
- Inform patient – it is different
- Medication Management Agreement
- Urine Toxicology Screening
- OARRS Report
- Discontinue treatment if patient no longer meets the standards.

Myths and Fallacies

- It ain't what you don't know that gets into trouble. It's what you know for sure that just ain't so.

Mark Twain

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You might need to……..

- If not me then who
- I know my patients
- Quick visits
- Fear of conflict in the exam room
- Chronic Pain Specialists won't prescribe
- Patients don't want to substitute opioid treatment

A Model to Screen and Manage Patients

- Define and document your role to the patient
- Create an electronic medical record report to identify patients
- Inform patient – it is different
- Medication Management Agreement
- Urine Toxicology Screening
- OARRS Report
- Discontinue treatment if patient no longer meets the standards.

But it wasn't all peaches and cream

- Some of the providers had serious difficulty accepting the potential of their patients' deception
- Those providers required some good old fashioned nagging.

(but nagging supported by data)

Specific Steps for Change

Dual Process
Stop Incoming Patients
Manage Current Patients

"Discouraged" Taking New Patients with Chronic Controlled

- Schedulers owned this piece
  - Scripted education to every new patient
  - Marked the visit notes because providers were getting pushback from patients that they were not told
  - ER referrals proved challenging due to our demographic
- On very rare occasion if there was a highly acute need for a reason other than pain (i.e. transplant) we would accept the patient with very strict guidelines.

Developed Strong Partnerships

- Legal Department
- Pharmacist
- Dr. Hale – Generation Rx
- CNP that provides support to our residents
- My inner nag

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Managed Current Patients

- Developed fully downloadable patient education material, talking points, and bulletin board. Theme “Respect the Rx” and “I Wish Someone Would Have Told Me”

  http://pharmacy.osu.edu/outreach/patients-toolkit
- All providers **and** support staff have OARRS access
  - OARRS access is required for credentialing
- Ran report by zip code and reviewed all patients outside immediate area

Managed Current Patients (cont)

- **Developed new more comprehensive Medication Management Agreement (MMA)**
  - Ensure all patients have one on file
  - Built EMR filters in record to easily locate MMA
- **Absolutely NO phone refill requests filled**
- **Patient must see PCP**

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Managed Current Patients (cont)

- **Strengthen common documentation practices**
  - FYI Flag (available to all)
    - Track OARRS, MMA signature, Non-Compliance
    - Add this field to clinic schedule
  - Specialty Comments (available to all)
  - Problem List (provider intensive)
  - Medication Comments (provider's field to write prescriptions)

Managed Current Patients (cont)

- **Sought guidance from appropriate specialists**
  - Quality care does not consist of indefinitely just masking the pain
- **Providers listened to staff**
  - Urine cold or clear
  - Carrying walker across the parking lot
  - On phone with diversion activity
  - Insistence on being treated by intern

Managed Current Patients (cont)

- **All non-compliance with MMA was documented and addressed**
- Some patients dismissed others continued care for everything except controlled medication condition
  - Iron clad letter outlining care restrictions.
    - Pt could not call and ask for medication
    - Staff member checked the list every month

Managed Current Patients (cont)

- Develop packet of resources for patients including
  - Chemical Dependency/Addiction education
  - Drug rehabilitation facilities
  - AA meetings
  - Conducted non-judgmental conversations with patients about our concerns

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First 90 Days were Tough

- Staff were diligent
  - This was not a witch hunt
- Commit Manager's time to assist with intervention
  - Especially with residents
  - Investment return multi-fold
- Need at least one…
  - Zealot with the flag
  - Physician Champion
- Team commitment is critical

Education for new interns

- **Three to four hour intern orientation**
  - Office Manager, Pharmacist, Resident CNP
  - Epidemic
  - Residents are targets
  - Rules and expectations
- Received intern feedback this issue is their #1 fear as a new provider.
- Also oriented new faculty

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Patient Satisfaction vs. Quality

- We did take a slight hit at first but long term it has been good due to reduced chaos
- Satisfaction scores do not equate to quality care
- Must decide to commit to quality care
- Evidence of improved satisfaction by writing prescriptions.
- Positive feedback from patients about the risk education
- Presented to Patient Experience Council so they could be prepared.
  - They **scripted** responses similar to requests for abx
- Correlations with staff satisfaction and patient satisfaction

Patient Satisfaction (cont)

- **Conclusion:** In a nationally representative sample, higher patient satisfaction was associated with less emergency department use but with greater inpatient use, higher overall health care and prescription drug expenditures, and increased mortality.

Fenton JJ, Jerant AF, et al. The Cost of Satisfaction – Ach Intern Med 2012; 172(5); 405-411

Copies Available

STATE MEDICAL BOARD OF OHIO

Guidelines for Prescribing Opiates….

May 9, 2013

Health care providers are **not** obligated to use opioids when a favorable risk-benefit balance cannot be documented.

Providers must be vigilant to the wide range of potential adverse effects associated with long-term opioid therapy and misuse of extended-release formulations. That vigilance and detailed attention has to be present from the **outset** of prescribing and continue for the duration of treatment. Providers should avoid starting a patient on long-term opioid therapy when treating chronic pain. Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects.

ttp://www.med.ohio.gov/pdf/NEWS/Prescribing%20Opioids%20Guidlines.pdf

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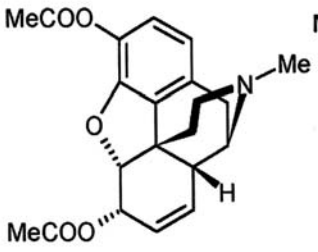
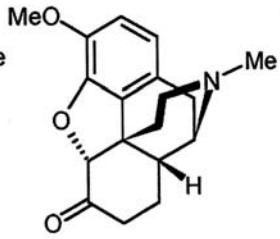


HEROIN



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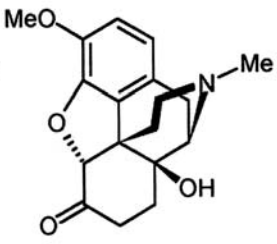
(e.g., VICODIN®)



OXYCODONE
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To further minimize risk a “time out” is recommended

Once a non-terminal pain patient reaches a threshold of 80 mg or more morphine equivalent daily dose (MED) as determined by OARRS the prescriber should “strongly consider” utilizing the following best practices:

(OARRS calculates the MED for you now)

- Re-establish informed consent including providing written information on the adverse effects of long term opioid therapy.
- Review the patient’s functional status including the 4A’s
- Review the patient’s progress toward treatment objectives during the duration.
- Utilize OARRS
- Reconsider having the patient evaluated by one or more other providers that specialize in the treatment of the area, system, or organ perceived as the source of pain.

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- Consider a pain treatment agreement which might include:
  - More frequent office visits
  - Different treatment options
  - Drug screens
  - Use of one pharmacy
  - Use of one provider for pain medications
  - Consequences for non-compliance

Morphine	80 mg
Codeine	533 mg 18 tabs/day Tylenol #3)
Hydrocodone	80 mg (16 tabs/day Vicodin/Lortab/Norco 5mg)
Mepridine	800 mg (16 tabs /day Demerol 50 mg)
Oxymorphone	27 mg (6tabs/day Opana 5mg)
Oxycodone	53 mg (11 tabs/day of Percocet 5mg)
Oxycodone extended release	53 mg (3 tabs per day Oxycontin 20 mg)
Fentanyl Patch	50 mcg/hour (Duragesic)
Hydromorphone	20 mg (5 tabs/day of Dilaudid 4 mg)
Or any combination thereof	Oxycodone HCL 5 mg every 6 hours PRN Oxycontin 20 mg TID

HB 93

- Law strengthens OSBP and Medical Boards ability to **summarily** suspend if there is clear and convincing evidence that the licensee presents a danger of immediate and serious harm to others. Terminal Distributors (TD)
- Wholesale Distributors (WD)
- Physician
- Law allows fines imposed to each day's violation: $5,000/day by the OSBP
- $20,000/day by the Medical Board

OARRS

- Is available 24/7
- Turnaround time from click on submit request until report is ready
- 99% ~ 3 seconds
- 1%~ 5 minutes
- Lag time (from Rx is dispensed until Rx appears in OARRS) 1-10 days
- https://www.ohiopmp.gov/Portal/Default.aspx

Restrictions on Prescribing Opioids for Minors HB 314

- New form required prior to prescribing opioids to minors
- The form will be known as the
  "Start Talking Consent Form"
- Begin using as of September 17

When the Requirement Applies

A "Start Talking Consent Form" is Required with:

- Opioid medications administered to a minor in a physician office/ office procedure area.
- Prescriptions for opioids given to a minor in an outpatient office setting following a procedure.
- All prescriptions for an opioid given to a minor in a physician office.
- No exemption for terminal illnesses.

Exemptions continued

- Medications given to a minor in conjunction with the treatment of an emergency: where there is an immediate threat or serious risk to the life or health of the minor.
- If the prescriber believes using the form would present a detriment to the minor's health or safety
- The minor is married, in the armed forces, can establish they are employed and self-sustaining or otherwise independent from the control of a parent or guardian

The Form

- Must be signed by the prescriber
- Must be signed by the parent or guardian
- Must be kept in the patient's medical record
- If a babysitter or relative has written authorization allowing us to treat the patient the prescription cannot be for more than a 72 hour supply

What the form does

The form is a certification from the physician that that physician has:

1. Assessed the minors history and risk of addiction, including a mental health assessment; and
2. Discussed with the minor and parent:
   - the risk of addiction,
   - any increased risk based on the patient's addiction and mental health risk assessment,
   - the increased risks with benzodiazepines, alcohol, and central nervous system depressants; and
   - any information in the patient counseling section of the medication labeling.

Pharmacy Board Guidance

- **What is the role of the pharmacist in enforcing this new law? (UPDATED 9.9.2014)**
- Pharmacists have a corresponding responsibility to ensure that a prescription issued by a prescriber is compliant with all state and federal laws. If the minor meets any of the exemptions listed in this document, then the pharmacist can safely assume, using professional judgment, that no consent form is required. If, however, they receive a prescription for a minor that does not meet the exemptions under the law (using professional judgment) and no consent is indicated on the prescription (or no copy of the signed consent is included), then the pharmacist should verify with the doctor that a consent form was completed (or was not required) prior to dispensing. It is recommended that the pharmacist document the informed consent or the reason why it is not required in the patient record. **Please note: The pharmacist must ultimately decide what is in the best interest of the patient and the lack of informed consent does not preclude a pharmacist from dispensing an opioid prescription to a minor.**

Other Opioid Legislation

By April 1, 2015 must follow this procedure:

- Before initially furnishing or prescribing an opioid, analgesic or benzodiazepine the practitioner must:
- Check OARRS for the prior 12 months
- If the course of treatment lasts more than 90 days from the initial report, the physician shall make periodic checks of OARRS at least every 90 days
- Assess the information on the report, and document the report was received and assessed

  (Do NOT copy OARRS into Medical Record)

Exceptions

This does not apply if:

- The OARRS system is down
- The prescription is for less than 7 days
- The medication or prescription is given to a hospice patient in a hospice program
- The medication is for the treatment of cancer
- The medication is administered in a hospital
- The medication is prescribed to treat *acute* pain from a surgery, invasive procedure or delivery

DEA Rules Changing

- Rescheduling of hydrocodone combination products- vicodin, lortab, cough suppressants such as tussionex and hycodan
- Moving to Schedule II security requirements on October 6
- No refills (prescriptions with refills written prior to October 6th can have refills dispensed if done before April 8, 2015)
- Cannot fax

Opportunities and Motivations

- PCMH certification requires a mental health or risky behavior be addressed
- The "University up North" has an opiate council that meets every month.
- Governor, The Attorney General, and the Medical Board are serious
- Patients are going to start bringing legal action
  - There is too much information out there to defend poor prescribing practices
  - I wish someone would have told me
- It's the right thing to do

We do, and you can, utilize a more systematic approach to prescribing controlled medications that incorporates objective data and alternative treatment therapies and does not rely exclusively on a subjective judgment of the provider.

Fifteen out of sixteen staff members indicated they were more satisfied with their jobs. They felt they were empowered to be a part of the solution and not an unwitting part of the problem

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

- ASAM American Society of Addiction Medicine
- CASA The National Center on Addiction and Substance Abuse at Columbia University
- OARRS Ohio Automated Rx Reporting System
- OBP Ohio Board of Pharmacy
- ODADAS Ohio Department of Alcohol and Drug Addiction Services
- http://www.oacbha.org/ohios_2013_opiate_conference.php
- http://www.oacbha.org/opiate_summit_2012.php
- http://www.medicalnewstoday.com/articles/232841.php

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Tip Sheet

PRESCRIBERS
OARRS WebCenter Application Instructions

If you have any problems, please contact OARRS support by email at support@ohiopmp.gov or by phone at 614-466-4143.

Before you start, make a copy of your Driver's license, professional license card, and DEA registration certificate.

Step 1 – Go to www.ohiopmp.gov. Click on the link below the login which says "*Click here to register*".

Step 2 – Choose "*Healthcare Professional/Law Enforcement.*" Click "*Next.*"

Step 3 – Enter your Driver's License number. Click "*Submit.*"

Step 4 – Select your Account type – Choose *"Prescriber (includes Physician Assistant with prescriptive authority and Nurse Practitioner with prescriptive authority)"*

Step 5 – Read and Approve the Acceptable Use Policy – ***Note: you may not share your user name and password with anyone else, include office staff.***
Click "*Approve*" at the bottom of the page to continue.

Step 6 – Complete the application
A. Enter your personal and professional information
Provide the e-mail address that you want OARRS to use when communicating with you. You must answer three security questions. For each security question, there are five options. Click on the down arrow to view alternate questions.

B. Click "*Submit*" to proceed.

C. Before printing your application, you must verify your e-mail address by retrieving a 6-digit verification code. The verification code will be in an email from Support@ohiopmp.gov. If you don't see the e-mail within 30 minutes of submitting your application, check your spam or junk mail folder.

Step 7 – Edit or Retrieve your Application
A. If you are not already at the page requesting your verification code, go to www.ohiopmp.gov and choose "*Click here to register" again.* Select "*Healthcare Professional /Law Enforcement"* and enter your driver's license number.

B. Enter Verification Code: Enter the 6-digit verification code and click "*Submit.*"

C. Edit Application if necessary.

D. Print Application. If you get a "File Damaged" error, try another computer with up-to-date Adobe PDF software.

Step 8 – Sign, notarize, and mail.

A. Sign your application in the presence of a public notary.

B. Mail your notarized application and the photocopy of your driver's license, professional license card, and DEA registration to the address on the application.

If your application is approved, you will receive a user name by e-mail and password by postal mail to your home. If you do not receive both within 10 business days of mailing your application, please email OARRS at support@ohiopmp.gov or call 614-466-4143.

ATTACHMENT D

PRESCRIBERS' Delegates
OARRS WebCenter Application Instructions

If you have any problems, please contact OARRS support by email at support@ohiopmp.gov or by phone at 614-466-4143 (Option 1).

Before you start, make a copy of your Driver's license and professional license card, if you have one.

Step 1 – Go to www.ohiopmp.gov. Click on the link below the login which says "*Click here to register.*"

Step 2 – Choose "*Healthcare Professional/Law Enforcement.*" Click "*Next.*"

Step 3 – Enter your Driver's License number. Click "*Submit.*"

Step 4 – Select your Account type – Choose "*Other Medical Facility Staff.*" Select the appropriate answer for "*Do you have a professional license? (RN, LPN, RDH, etc)*" Note: Medical Assistants do NOT have a professional license. Click "*Submit.*"

Step 5 – Read and Approve the Acceptable Use Policy – ***Note: you may not share your user name and password with anyone else, including other office staff.*** Click "*Accept*" at the bottom of the page to continue.

Step 6 – Complete the application
A. Enter your personal and professional information; then choose all applicable supervisors.
Provide a **personal** e-mail address that you want OARRS to use when communicating with you.
You must answer three security questions. For each security question, there are five options.
Click on the down arrow to view alternate questions. Provide answers that are known only to you.

B. Click "*Submit*" to proceed.

C. Before printing your application, you must verify your personal e-mail address by retrieving a 6-digit verification code. The verification code will be in an email from Support@ohiopmp.gov. Delegates with a professional license will receive this e-mail shortly after clicking "Submit". Delegates without a professional license must wait for a supervising prescriber to log in and approve the registration before the e-mail will be sent. If you don't see the e-mail within 30 minutes of submitting your application (or your supervisor approving your application), check your spam or junk mail folder.

Step 7 – Edit or Retrieve your Application
A. If you are not already at the page requesting your verification code, go to www.ohiopmp.gov and choose "*Click here to register" again.* Select "*Healthcare Professional /Law Enforcement*" and enter your driver's license number.

B. Enter Verification Code: Enter the 6-digit verification code and click "*Submit.*"

C. Edit Application if necessary.

D. Print Application. If you get a "File Damaged" error, try another computer with up-to-date Adobe PDF software or download the latest version of Adobe Reader from www.adobe.com .

Step 8 – Sign, notarize, and mail.
A. Sign your application in the presence of a public notary.

B. Mail your notarized application and the photocopy of your driver's license and professional license card, if you have one.

If your application is approved, you will receive a user name by e-mail and password by postal mail to your home. If you do not receive both within 10 business days of mailing your application, please email OARRS at support@ohiopmp.gov or call 614-466-4143.

ATTACHMENT A

Controlled Medicine Management Form

Name: _____ **Medical Record #** _____

Good communication with your doctor or advanced practice nurse is important to help manage your health problem and to build a trusting relationship.

Controlled Substance Medicine

Your care may require different types of treatment that could include medicines, changes to your diet, exercise, or care by other health care providers or counselors. You are to be treated with certain medicines, known as **controlled substances**. These medicines may be used to treat pain, anxiety, depression or other symptoms. As part of your treatment, the medicines can improve your symptoms and your quality of life. You need to understand that:

- The medicines can become less effective over time. Your doctor may need to change them to help your symptoms. Higher doses can increase the chance of side effects.
- Symptoms you have, such as pain or anxiety may be worse after the medicine wears off.
- The medicine may cause severe constipation. You may need to take a laxative or stool softener to prevent bowel problems while taking this medicine.
- The medicine may cause high blood pressure, fast or an irregular heartbeat.
- Medicines can cause problems with your thinking which can make it unsafe to drive a car, or do other activities where you need to be alert.
- Medicines can cause addictive behavior. If you or anyone in your family has had drug or alcohol problems, you have a higher chance of getting addicted to this medicine.
- If you are involved in a car or other accident, medicines can put you at increased liability if they are found in your system.
- If you need to stop taking these medicines, you need to stop them slowly. Stopping them slowly will help keep you from feeling sick from withdrawal symptoms.
- Mixing medicines, or mixing medicines with alcohol or illegal substances can cause:

• Dizziness	Overdose
• Depression	Trouble breathing
• Memory problems	Death

*Form effective Date: December 5, 2012

High Priority Scan

Name: _____ **Medical Record #** _____

Please read and initial each line below. Ask questions if there is anything you do not understand.

I know and agree that:

___ I will not accept prescriptions for controlled substance medicines from any other provider while I am on medicines from my OSU provider. If I need emergency care, I will be seen and will report my care and any medicines I received to my OSU provider immediately.

___ I will be seen by my OSU provider or designee every month or as directed to check my symptoms and medicine use. My provider will only change doses or refill prescriptions during regular hours. I know that other doctors in this office will not give me refills.

___ No controlled substance medicine prescriptions will be refilled by phone, on weekends or during evening hours, or during any unscheduled visit to the office. No early or after hour refills will be given. If I make repeated requests without an appointment, I know that I may not be able to continue care at this office.

___ I will take my medicines as they are prescribed. I will only use the following pharmacy (_____) for filling my controlled medication prescription.

___ Any changes in my prescription must be authorized by my provider in advance.

___ I will protect my medicine from being lost or stolen. Lost or stolen medicine may not be replaced.

___ I will not share, trade or sell my medicines. I know that these actions are against the law and will stop my care from being provided at this office.

___ I agree to random drug testing when asked by my health care team. If I do not give a sample, or the test results do not match the medicines I am currently taking, or the results show use of illegal drugs, I know that my care at this office can be stopped.

___ I will not use alcohol and this medicine at the same time.

___ I know medicines are just part of my care. My health care team may recommend other treatments as part of my care that may be outside the OSU Ambulatory Care clinics. If I do not seek care as my provider orders, I know that the prescriptions for the controlled substance medicine may stop.

___ I know I am expected to be respectful of the office staff.

___ I agree that my doctor or advanced practice nurse can share my health care information with my other current providers and pharmacies. I will have only one pharmacy (listed below) that I will use for my controlled substance refills.

High Priority Scan

Name: _____ **Medical Record #** _____

___ I understand and agree that my medicines may be changed or stopped at any point during my treatment per my provider's discretion.

___ I understand these medications can potentially lead to addiction/substance abuse problems in all persons.

___ I understand that a personal or family history of substance abuse can lead to increased personal struggles with substance abuse. I agree to tell my health care team any personal or family history of substance abuse, so that they are aware and can closely monitor my care and progress.

___ I will keep scheduled appointments with all of my health care providers.

___ To get the best treatment I know that my doctor can and will review how often and where I get my medicines refilled.

___ I may withdraw from this agreement at any time, but if I do, I understand any prescribed controlled substance medicines will be stopped.

___ I understand this agreement is specific to me and my provider. Another provider who takes over my care may decide to change or stop my medicine.

___ *(For Women)* I understand that if I become pregnant while taking this medication, my baby may be born dependent on the medication and other risks to the child may exist. I will contact my doctor immediately if I become pregnant while taking this medication.

___ I understand this agreement is valid for the entire time I am seeking care at this specific office, regardless of which provider is providing the services. I am aware that violation of any part of this agreement may result in termination of the provision of this drug, or termination of my care from this practice.

My signature below means that I have read, or someone has read and explained this form to me so that I understand it and I agree.

Patient Signature _____
Print Name: _____
Date: _____ Time: _____

Doctor/Advanced Practice Nurse: _____
Date: _____ Time: _____

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

(614) 466-3934

med.ohio.gov

Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point"

May 9, 2013

*These guidelines address the use of opioids for the treatment of **chronic, non-terminal pain**. "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. The guidelines are intended to help health care providers review and assess their approach in the prescribing of opioids. The guidelines are points of reference intended to supplement and not replace the individual prescriber's clinical judgment. The 80 mg MED is the maximum daily dose at which point the prescriber's actions are triggered; however, this 80 mg MED trigger point is not an endorsement by any regulatory body or medical professional to utilize that dose or greater.*

Recent analysis by the Centers for Disease Control and Prevention (CDC) shows that "patients with mental health and substance use disorders are at increased risk for nonmedical use and overdose from prescription painkillers as well as being prescribed high doses of these drugs." Drug overdose deaths increased for the 11th consecutive year in 2010. Nearly 60% of the deaths involved pharmaceuticals, and opioids were involved in nearly 75%. Researchers also found that drugs prescribed for mental health conditions were involved in over half. These findings appear consistent with research previously published in the *Annals of Internal Medicine* that concluded that "patients receiving higher doses of prescribed opioids are at an increased risk for overdose, which underscores the need for close supervision of these patients" (Dunn, et al., 2010).

Health care providers are not obligated to use opioids when a favorable risk-benefit balance cannot be documented. Providers should first consider non-pharmacologic and non-opioid therapies. Providers should exercise the same caution with tramadol as with opioids and must take into account the medication's potential for abuse, the possibility the patient will obtain the medication for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the medication.

Providers must be vigilant to the wide range of potential adverse effects associated with long-term opioid therapy and misuse of extended-release formulations. That vigilance and detailed attention has to be present from the outset of prescribing and continue for the duration of treatment. Providers should avoid starting a patient on long-term opioid therapy when treating chronic pain. Providers should also avoid prescribing benzodiazepines with opioids as it may increase opioid toxicity, add to sleep apnea risk, and increase risk of overdose deaths and other potential adverse effects.

Providers can further minimize the potential for prescription drug abuse/misuse and help reduce the number of unintentional overdose deaths associated with pain medications by recognizing times to "press pause" in response to certain "trigger points." This pause allows providers to reassess their compliance with accepted and prevailing standards of care. The 80 mg Morphine Equivalent Daily Dose (MED) "trigger point" is one such time.

Providers treating chronic, non-terminal pain patients who have received opioids equal to or greater than 80 mg MED for longer than three continuous months should strongly consider doing the following to optimize therapy and help ensure patient safety:

- ✓ Reestablish informed consent, including providing the patient with written information on the potential adverse effects of long-term opioid therapy.
- ✓ Review the patient's functional status and documentation, including the 4A's of chronic pain treatment:
  - Activities of daily living;
  - Adverse effects;
  - Analgesia; and
  - Aberrant behavior.
- ✓ Review the patient's progress toward treatment objectives for the duration of treatment.
- ✓ Utilize OARRS as an additional check on patient compliance.
- ✓ Consider a patient pain treatment agreement that may include: more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of pain medications, and consequences for non-compliance with terms of the agreement.
- ✓ Reconsider having the patient evaluated by one or more other providers who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.

The 80 MED "trigger point" is an opportunity to review the plan of treatment, the patient's response to treatment, and any modification to the plan of treatment that is necessary to achieve a favorable risk-benefit balance for the patient's care. If opioid therapy is continued, further reassessment will be guided by clinical judgment and decision-making consistent with accepted and prevailing standards of care. The "trigger point" also provides an opportunity to further assess addiction risk or mental health concerns, possibly using Screening, Brief Intervention, and Referral to Treatment (SBIRT) tools, including referral to an addiction medicine specialist when appropriate.

For providers treating acute exacerbation of chronic, non-terminal pain, clinical judgment may not trigger the need for using the full array of reassessment tools.

Providers treating patients with acute care conditions in the emergency department or urgent care center should refer to the *Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances Prescribing Guidelines* at http://www.healthyohioprogram.org/ed/guidelines.

Approved by Medical Board: May 9, 2013

OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: **614-466-4143** *E-MAIL:* **exec@bop.ohio.gov** *FAX:* **614-752-4836**

TTY/TDD: Use the Ohio Relay Service: 1-800-750-0750 *URL:* http://www.pharmacy.ohio.gov

Ohio House Bill 314: Prescribing Opioids to Minors Effective September 17, 2014

Effective September 17, 2014, HB 314 requires all prescribers (physicians, PAs, APRNs, optometrists, dentists and podiatrists) to obtain explicit informed consent, in the absence of a medical emergency or other specified circumstances (see below), if they intend to prescribe to minors controlled substances containing opioids.

The informed consent requirement has three components: assessing the minor's mental health and substance abuse history; discussing with the minor and the minor's parent, guardian, or another authorized adult certain risks and dangers associated with taking controlled substances containing opioids; and obtaining the signature of the parent, guardian, or authorized adult on a consent form. Additionally, the new law limits to not more than a 72-hour supply the quantity of a controlled substance containing an opioid that a prescriber may prescribe to a minor when another adult authorized by the minor's parent or guardian gives the required consent.

Please note: HB 314 requires written documentation of informed consent when prescribing opioids to a minor. A signed "Start Talking" consent form must be maintained in the minor's medical record and the form must be separate from any other document the prescriber uses to obtain informed consent for other treatment provided to the minor.

To assist prescribers with this requirement, the State Medical Board of Ohio has developed a "Start Talking" Consent Form, which can be accessed here: http://www.med.ohio.gov/pdf/NEWS/Start%20Talking!%20Model%20Consent%20Form%20-%20Med%20Bd%20August%202014.pdf

To assist with the processing of the prescription at the pharmacy, prescribers are strongly encouraged to either include a signed copy of the informed consent document with the prescription or document on the prescription itself that consent was obtained. If informed consent was not obtained, prescribers are further requested to document on the prescription which of the statutory exemptions applies (see below).

Exemptions

The law specifies that the informed consent requirement does not apply when any of the following is the case:

(1) The minor's treatment is associated with or incident to a medical emergency;

(2) The minor's treatment is associated with or incident to surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis;

(3) In the prescriber's professional judgment, fulfilling the bill's informed consent requirement would be a detriment to the minor's health or safety;

(4) The minor's treatment is rendered in a hospital, ambulatory surgical facility, nursing home, pediatric respite care program, residential care facility, freestanding rehabilitation facility, or similar institutional facility. This exemption does not apply, however, when the treatment is rendered in a prescriber's office that is located on the premises of or adjacent to any of the foregoing facilities or locations; OR

(5) The prescription is for a compound that is a controlled substance containing an opioid that a prescriber issues to a minor at the time of discharge from a facility or other location described in (4), above.

Definitions

"Another adult authorized to consent to the minor's medical treatment" means an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment.

A **"medical emergency"** is a situation that in the prescriber's good faith medical judgment creates an immediate threat of serious risk to the life or physical health of a minor.

A **"minor"** is a person under 18 years of age who is not emancipated. (For purposes of the law's informed consent requirement only, the law specifies that a person under 18 years of age is to be considered emancipated only if the person has married, entered the armed services of the United States, became employed and self-sustaining, or has otherwise become independent from the care and control of the person's parent, guardian, or custodian.)

What is the role of the pharmacist in enforcing this new law? (UPDATED 9.9.2014)

Pharmacists have a corresponding responsibility to ensure that a prescription issued by a prescriber is compliant with all state and federal laws. If the minor meets any of the exemptions listed in this document, then the pharmacist can safely assume, using professional judgment, that no consent form is required. If, however, they receive a prescription for a minor that does not meet the exemptions under the law (using professional judgment) and no consent is indicated on the prescription (or no copy of the signed consent is included), then the pharmacist should verify with the doctor that a consent form was completed (or was not required) prior to dispensing. It is recommended that the pharmacist document the informed consent or the reason why it is not required in the patient record. **Please note: The pharmacist must ultimately decide what is in the best interest of the patient and the lack of informed consent does not preclude a pharmacist from dispensing an opioid prescription to a minor.**

What is an Opioid?

The Ohio State Board of Pharmacy considers an opioid (analgesic) as a drug derived from or related to opium used in the management of pain through the activation of the mu receptor. It may also be utilized for its antitussive effects.[1] Opioid analgesics include, but are not limited to, the following drugs:

Generic Name	Brand Name	Schedule
Buprenorphine	BUTRANS, BUPRENEX	Schedule III
Butorphanol	BUTORPHANOL NS	Schedule IV
Codeine (acetaminophen and other combination products)	TYLENOL W. CODEINE #3, TYLENOL W. CODEINE #4	Schedule III
Dihydrocodeine/ASA/caffeine	SYNALGOS-DC	Schedule III

[1] Used to prevent or relieve a cough.

Fentanyl	DURAGESIC, ACTIQ, ABSTRAL, LAZANDA, FENTORA, SUBSYS, SUBLIMAZE, ONSOLIS, IONSYS	Schedule II
Hydrocodone	ZOHYDRO ER	Schedule II
Hydrocodone (acetaminophen combination products)	XODOL, MAXIDONE, ZYDONE, LORCET, HYCET, ZAMICET, CO-GESIC, ZOLVIT, STAGESIC, LIQUICET, LORTAB, VICODIN, NORCO	Schedule II *(Effective October 6, 2014)*
Hydrocodone (ibuprofen combination products)	IBUDONE, REPREXAIN, VICOPROFEN	Schedule II
Hydromorphone	DILAUDID, EXALGO	Schedule II
Meperidine	DEMEROL	Schedule II
Methadone	DOLOPHINE, METHADOSE	Schedule II
Morphine Sulfate	MS CONTIN, AVINZA, DURAMORPH, KADIAN, DEPODUR, ASTRAMORPH, IMFUMORPH	Schedule II
Oxycodone	OXECTA, ROXICODONE, OXYCONTIN	Schedule II
Oxycodone (acetaminophen, aspirin and other combination products)	PERCODAN, PERCOCET, ROXICET, ENDOCET, XOLOX, TYLOX, PRIMLEV, MAGNACET, XARTEMIS XR	Schedule II
Oxymorphone	OPANA, NUMORPHAN	Schedule II
Tapentadol	NUCYNTA	Schedule II
Tramadol	ULTRAM, ULTRACET, RYZOLT, CONZIP, RYBIX	Schedule IV

More Information

For more information on the law, see the following links:

Law Text: http://www.legislature.state.oh.us/bills.cfm?ID=130_HB_314

Legislative Service Commission Bill Analysis: http://www.lsc.state.oh.us/analyses130/h0314-rs-130.pdf

Questions

If you are a pharmacist, pharmacy intern or location licensed as a terminal distributor of dangerous drugs, please contact the Ohio State Board of Pharmacy at 614-466-4143. If you are a prescriber, please contact your respective regulatory board using the information below.

State Medical Board of Ohio: (614) 466-3934

Ohio Board of Nursing: (614) 728-2504

Ohio State Dental Board: (614) 466-2580

Ohio State Optometry Board: (614) 466-5115

Updated 9.9.2014

"Start Talking!" for Prescribing Opioids to Minors – New Law Effective Sept. 17, 2014

SUMMARY:

A "Start Talking Consent Form" is Required with:

- Opioid medications administered to a minor in a physician office/ office procedure area.
- Prescriptions for opioids given to a minor in an outpatient office setting following a procedure.
- All prescriptions for an opioid given to a minor in a physician office.
- No exemption for terminal illnesses

The form is not required with:

- Medications given to a minor in the hospital or an ambulatory surgical center.
- Medication given to a minor in conjunction with surgery in a hospital or ambulatory surgical center.
- A prescription given to a minor at the time of discharge from the hospital or an ambulatory surgical center.
- Medications given to a minor in conjunction with the treatment of an emergency: where there is an immediate threat or serious risk to the life or health of the minor.
- If the prescriber believes using the form would present a detriment to the minor's health or safety
- The minor is married, in the armed forces, can establish they are employed and self-sustaining or otherwise independent from the control of a parent or guardian

Limitations on amount prescribed:
If the adult signing the form has authorization to give consent for treatment, but is not a parent or guardian, no more than a 72 hour supply of opioids may be prescribed.

The form is a certification from the physician that that physician has:

1. Assessed the minors history and risk of addiction, including a mental health assessment; and
2. Discussed with the minor and parent:
   - the risk of addiction,
   - any increased risk based on the patient's addiction and mental health risk assessment,
   - the increased risks with benzodiazepines, alcohol, and central nervous system depressants; and
   - any information in the patient counseling section of the medication labeling

STATUTE:

Ohio Revised Code 3719.061 states in part:

(B) Except as provided in division (C) of this section, before issuing for a minor the first prescription in a single course of treatment for a particular compound that is a controlled substance containing an opioid, regardless of whether the dosage is modified during that course of treatment, a prescriber shall do all of the following:

(1) As part of the prescriber's examination of the minor, assess whether the minor has ever suffered, or is currently suffering, from mental health or substance abuse disorders and whether the minor has taken or is currently taking prescription drugs for treatment of those disorders;

(2) Discuss with the minor and the minor's parent, guardian, or another adult authorized to consent to the minor's medical treatment all of the following:

(a) The risks of addiction and overdose associated with the compound;

(b) The increased risk of addiction to controlled substances of individuals suffering from both mental and substance abuse disorders;

(c) The dangers of taking controlled substances containing opioids with benzodiazepines, alcohol, or other central nervous system depressants;

(d) Any other information in the patient counseling information section of the labeling for the compound required under 21 C.F.R. 201.57(c)(18).

(3) Obtain written consent for the prescription from the minor's parent, guardian, or, subject to division (E) of this section, another adult authorized to consent to the minor's medical treatment.

The prescriber shall record the consent on a form, which shall be known as the "Start Talking!" consent form. The form shall be separate from any other document the prescriber uses to obtain informed consent for other treatment provided to the minor. The form shall contain all of the following:

(a) The name and quantity of the compound being prescribed and the amount of the initial dose;

(b) A statement indicating that a controlled substance is a drug or other substance that the United States drug enforcement administration has identified as having a potential for abuse;

(c) A statement certifying that the prescriber discussed with the minor and the minor's parent, guardian, or another adult authorized to consent to the minor's medical treatment the matters described in division (B)(2) of this section;

(d) The number of refills, if any, authorized by the prescription;

(e) The signature of the minor's parent, guardian, or another adult authorized to consent to the minor's medical treatment and the date of signing.

(C)

(1) The requirements in division (B) of this section do not apply if the minor's treatment with a compound that is a controlled substance containing an opioid meets any of the following criteria:

(a) The treatment is associated with or incident to a medical emergency.

(b) The treatment is associated with or incident to surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(c) In the prescriber's professional judgment, fulfilling the requirements of division (B) of this section with respect to the minor's treatment would be a detriment to the minor's health or safety.

(d) Except as provided in division (D) of this section, the treatment is rendered in a hospital, ambulatory surgical facility, nursing home, pediatric respite care program, residential care facility, freestanding rehabilitation facility, or similar institutional facility.

(2) The requirements in division (B) of this section do not apply to a prescription for a compound that is a controlled substance containing an opioid that a prescriber issues to a minor at the time of discharge from a facility or other location described in division (C)(1)(d) of this section.

(D) The exemption in division (C)(1)(d) of this section does not apply to treatment rendered in a prescriber's office that is located on the premises of or adjacent to a facility or other location described in that division.

(E) If the individual who signs the consent form required by division (B)(3) of this section is another adult authorized to consent to the minor's medical treatment, the prescriber shall prescribe not more than a single, seventy-two-hour supply and indicate on the prescription the quantity that is to be dispensed pursuant to the prescription.

(F) A signed "Start Talking!" consent form obtained under this section shall be maintained in the minor's medical record.

History. Added by 130th General Assembly File No. TBD, HB 314, §1, eff. 9/17/2014.

Start Talking!

Consent Form

for Prescribing Opioids to Minors

Patient Name:
Date of birth:

Prescription name & quantity:
Number of refills:

The prescribed drug is a controlled substance containing an opioid. This means the medication has been identified by the United States Drug Enforcement Administration as having a potential for abuse, dependence or misuse.

I certify that I have discussed the following with the minor patient and the patient's parent, guardian or authorized adult:

(a) The risks of addiction and overdose associated with a controlled substance containing an opioid;

(b) The increased risk of addiction to controlled substances of individuals suffering from both mental and substance abuse disorders;

(c) The dangers of taking controlled substances containing opioids with benzodiazepines, alcohol or other central nervous system depressants;

(d) Any other information in the patient counseling information section of the labeling for the medication required by Federal law.

_____ Date

Signature of prescriber

_____ Date

Parent/Guardian

_____ Date

Adult Authorized to Consent to Minor's Treatment*

*An adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment. The prescription must be limited to not more than a single 72-hour supply if the person consenting to treatment is an adult authorized to consent to a minor's treatment. See, Section 3719.061, Ohio Revised Code.

See the Start Talking! website for tips on talking to kids about drugs
StartTalking.ohio.gov

Patient Name
Date of Birth or
Medical Record Number

OHIO STATE BOARD OF PHARMACY

77 South High Street, Room 1702; Columbus, OH 43215-6126

-Equal Opportunity Employer and Service Provider-

TEL: 614-466-4143 *E-MAIL:* exec@bop.ohio.gov *FAX:* 614-752-4836

TTY/TDD: Use the Ohio Relay Service: 1-800-750-0750 *URL:* http://www.pharmacy.ohio.gov

RESCHEDULING OF HYDROCODONE COMBINATION PRODUCTS EFFECTIVE OCTOBER 6, 2014

Effective October 6, 2014, all hydrocodone combination products (HCPs) will be classified as schedule II controlled substances pursuant to a rule adopted by the United States Drug Enforcement Administration (D.E.A.) on August 22, 2014.

In order to ensure compliance with state and federal controlled substance requirements, the Ohio State Board of Pharmacy advises that all pharmacists and prescribing practitioners adhere to the following requirements for schedule II drugs:

- ***Security:*** HCPs are subject to schedule II security requirements and must be handled and stored pursuant to **21 U.S.C. 821** and **823**, and in accordance with **21 CFR 1301.71-1301.93** as of October 6, 2014.

- ***Prescriptions:*** No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with **21 CFR 1306.22-1306.23**, **1306.25**, and **1306.27**, if such dispensing occurs before April 8, 2015. After April 8, 2015, no refills on HCPs issued prior to October 6, 2014 are permitted.

- ***Inventory:*** For any substance listed in schedule II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents. An exact count inventory of all HCPs should be conducted on or before October 6, 2014 (Ohio Administrative Code 4729-9-14). ***Please note: Effective January 1, 2015, OAC 4729-9-14 will require a terminal distributor of dangerous drugs or prescriber to conduct annual controlled substance drug inventories. For more information, please see:*** **www.pharmacy.ohio.gov/inventory**.

- ***Wholesalers and Manufacturers:*** An official written order for any schedule II controlled substances shall be signed in triplicate by the person giving the order or by their authorized agent. The original shall be presented to the person who sells or dispenses the schedule II controlled substances named in the order and, if that person accepts the order, each party to the transaction shall preserve their copy of the order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of Chapter 3719. of the Revised Code. Compliance with the federal drug abuse control laws, respecting the requirements governing the use of a special official written order constitutes compliance with this division (Ohio Revised Code 3719.04).

- ***Personally Furnishing Drugs:*** No schedule II controlled substances (HCPs) shall be personally furnished to any patient by a clinical nurse specialist, certified nurse-midwife,

certified nurse practitioner or physician assistant (Ohio Revised Code 3719.06). "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting (Ohio Administrative Code 4729-5-01).

- ***Prescription Filing:*** Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions (Ohio Administrative Code 4729-5-09). Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, should be filed in the prescription file for schedules III, IV, and V prescriptions. Any new prescriptions for HCPs issued on or after October 6, 2014 mush be filed in the prescription file for schedule II prescriptions.

- ***Hospice Patients:*** Preprinted prescription forms for hospice patients may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber. Verbal drug orders for schedule II controlled substances cannot be transmitted to the pharmacy by the hospice nurse at the direction of the prescriber. (Ohio Administrative Code 4729-5-14).

- ***Partial Dispensing:*** HCPs prescriptions must adhere to partial dispensing procedures for schedule II drugs listed in Ohio Administrative Code 4729-5-26. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be partially dispensed in accordance with **21 CFR 1306.23** if such dispensing occurs before April 8, 2015.

- ***Faxed Prescriptions:*** Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:
  - A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.
  - A narcotic substance issued for a patient enrolled in hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.
  - A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code. (Ohio Administrative Code 4729-5-30).

In order to ensure compliance with state and federal controlled substance requirements, the Ohio State Board of Pharmacy encourages all pharmacists and prescribing practitioners to read and follow the D.E.A. requirements for controlled substances before processing prescriptions or prescribing HCPs.

The Ohio State Board of Pharmacy is committed to ensuring your compliance with this rule change. If you have any questions or need additional assistance, please call 614-466-4143 or email by visiting: http://www.pharmacy.ohio.gov/Contact.aspx.

For more information, including additional federal restrictions, on the DEA's HCP rule please visit: http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm.

New Opioid, Analgesic and Benzodiazepine Furnishing/Prescribing Requirements:

By January 1, 2015 all prescribers of opioids, analgesics and benzodipines must be registered with the State Pharmacy database, OARRS.

- Certification of registration will be required by the licensing boards with renewal applications

By April 1, 2015 must follow this procedure:

Before initially furnishing or prescribing an opioid, analgesic or benzodiazepine the practitioner must:

- Check OARRS for the prior 12 months
- If the course of treatment lasts more than 90 days from the initial report, the physician shall make periodic checks of OARRS at least every 90 days
- Assess the information on the report, and document the report was received and assessed

This does not apply if:

- The OARRS system is down
- The prescription is for less than 7 days
- The medication or prescription is given to a hospice patient in a hospice program
- The medication is for the treatment of cancer
- The medication is administered in a hospital
- The medication is prescribed to treat *acute* pain from a surgery, invasive procedure or delivery

Ohio Revised Code Section 4731.055, Amended Sub HB 341, Effective 9/14/14

Screening Tools

NIDA Drug Use Screening Tool (NIDA QuickScreen and NM-ASSIST)
Electronic version
http://www.drugabuse.gov/nmassist/
Pdf version
http://www.drugabuse.gov/sites/default/files/pdf/nmassist.pdf
Resource Guide -- This guide is designed to assist clinicians serving adult patients in screening for drug use
http://www.drugabuse.gov/publications/resource-guide/preface

Opioid Risk Tool (ORT) This survey enables the clinician to determine a patient's potential risk for developing aberrant behaviors when prescribed opioids for chronic pain.
http://www.agencymeddirectors.wa.gov/Files/opioidrisktool.pdf

Current Opioid Misuse Measure (COMM) Assessment helps clinicians identify whether a patient currently on long-term opioid therapy may be exhibiting aberrant behaviors associated with misuse of opioid medications. *Copyrights apply
http://nationalpaincentre.mcmaster.ca/documents/comm_sample_watermarked.pdf

Pain Assessment and Documentation Tool (PADT) Clinician-directed interview that assesses pain relief, side effects, and aspects of functioning as well as potential aberrant drug- related behavior
http://healthinsight.org/Internal/assets/SMART/PADT.pdf

SAFE score: Social function, Analgesia, physical Functioning and Emotional functioning The SAFE tool offers a mechanism for the clinician to measure the patient's functioning across multiple domains and to document the rationale for continuation, modification, or cessation of opioid therapy. A summary of SAFE and other tools can be found here.
http://www.med.nyu.edu/pmr/residency/resources/general%20MSK%20and%20Pain/clinics%20anes_documentation%20and%20tools%20long%20term%20opioid%20rx.pdf

Are you signed up for OARRS?

If you prescribe controlled substances including tramadol the Board strongly encourages you to sign up for OARRS, the Ohio Rx Reporting System.

https://www.ohiopmp.gov/Portal/Default.aspx

Ohio Medical Board Newsletters
http://www.med.ohio.gov/professionals-newsletters.htm

DO YOU PRACTICE HIGH QUALITY PAIN MANAGEMENT?

There are characteristics that are associated with pill mill operations that are not typically found within a high quality pain management practice. It is best to avoid becoming a practice with some of the following characteristics:

- The physician has minimal to no training in pain management.
- A cursory or no patient exam performed and documented .
- Large volume of patients seen daily (100+).
- Patients drive long distances, often from other states. In many cases patients carpool.
- Clinics place advertisements for pain management physicians in small papers or craigslist.com Employer is a non-physician owned staffing company and work is part time. Clinic owners are not healthcare providers, have no medical training, may be from out of state, and attempt to convince the physician the clinic is operating legally.
- Clinic is run on a cash only basis.
- Similar prescription "cocktail" for each patient.
- Drugs are dispensed onsite (patient pays for office visit then pays for the drugs).
- Security guards are employed by the clinic.
- All patients receive an identical diagnostic work-up or are referred to the same MRI imaging facility.

SPOTTING "DRUG SEEKERS" AND MISUSE

While the presence of "red flags" does not necessarily mean that the patient is "drug seeking" the presence of some or all of the following circumstances should raise the prescribers index of suspicion:

- The patient is from out of state.
- The patient requests a specific drug and states that alternative medications do not work.
- The patient says his or her previous physician closed their practice.
- Prior treatment records cannot be obtained.
- The patient claims he or she cannot afford indicated or appropriate diagnostic testing.
- The patient presents to the appointment with an MRI.
- The patient presents to the appointment with his or her pharmacy profile showing specific drugs they want prescribed.
- Several patients arrive by carpool.
- The patient tests positive for illegal drugs.
- Drug screen reveals no prescribed medication in the patient's system.
- The patient recites textbook symptoms.
- The patient pays in cash only and has no insurance.
- The patient calls for early refills and prescriptions or regularly reports that medications are lost or stolen.
- The patient's pain level remains the same over several subsequent visits.
- The patient is noncompliant with the physician's treatment plan.

Quality medical care includes the appropriate, effective treatment of chronic pain. Prescribing controlled substances over the long term may be an essential part of an appropriate treatment program. Those who inappropriately or excessively prescribe opioids and other controlled substances remain an ongoing problem.

Adapted from the Georgia Medical Board's newsletter