Appropriate Prescribing

MODULE III: GUIDELINES AND REGULATIONS

Learning Objectives

•Review the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain

- •Discuss the Arkansas State Medical Board Regulation 2 concerning the prescribing of controlled substances.
- •Describe the various reports that can be accessed from the Prescription Drug Monitoring Program.
- •List resources available for education and consultation regarding opioid prescribing, monitoring and addiction.

CDC Guideline

•CDC Guideline for Prescribing Opioids for Chronic Pain were published in March 2016.

- •Developed for primary care providers for patients at least 18 years old with chronic pain, outside of palliative and end-of-life care
- •Uses the Grading of Recommendations Assessment Development and Evaluation method (GRADE) framework and recommendations are based on:
 - Quality of evidence
 - Balance between benefits and harms
 - Values and preferences
 - Cost

GRADE Recommendations and Evidence Types

Evidence Types

- Type 1: Randomized controlled trials (RCTs); overwhelming observational studies
- Type 2: RCTs (limitations); strong observational
- Type 3: RCTs (notable limitations); observational
- Type 4: RCTs (major limitations); observational (notable limitations) clinical experience

Recommendation categories:

- Category A: applies to all patients; most patients should receive recommended course of action
- Category B: individual decision making required; providers help patients arrive at decision consistent with values/preferences and clinical situation

www.cdc.gov

CDC Guideline Topic Areas

- •The guideline addresses 3 topic areas:
 - •When to initiate or continue opioids for chronic pain
 - Opioid selection, dosage, duration, follow-up and discontinuation
 - •Assessing risk and harms of opioid use.

Determine When to Initiate or Continue Opioids for Chronic Pain

•Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.

•Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.

•If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.

(Recommendation category A: Evidence type: 3)

Opioids are Not First-Line or Routine Therapy for Chronic Pain

•Use non-pharmacologic therapy such as exercise or cognitive behavioral therapy (CBT) to reduce pain and improve function.

•Use non-opioid pharmacologic therapy (nonsteroidal anti-inflammatory drugs, acetaminophen, anticonvulsants, certain antidepressants) when benefits outweigh risks, combined with non-pharmacologic therapy.

•When opioids used, combine with non-pharmacologic therapy and non-opioid pharmacologic therapy to provide greater benefits.

•Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.

•Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

• (Recommendation category A: Evidence type: 4)

Establish and Measure Progress Toward Goals

•Before initiating opioid therapy for chronic pain

- Determine how effectiveness will be evaluated.
- Establish treatment goals with patients.
 - Pain relief
 - Function
- •Assess progress using 3-item PEG Assessment Scale*
 - <u>P</u>ain average (0-10)
 - Interference with <u>Enjoyment</u> of life (0-10)
 - Interference with <u>General activity</u> (0-10)
- *30% = clinically meaningful improvement

•Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

•(Recommendation category A: Evidence type: 3)

Ensure Patients are Aware of Potential Benefits, Harms and Alternatives to Opioids

•Be explicit and realistic about expected benefits.

•Emphasize goal of improvement in pain and function.

Discuss

- Serious and common adverse effects
- Increased risks of overdose
 - Especially at higher dosages
 - Or when opioids are taken with other drugs or alcohol
- Periodic reassessment, PDMP and urine checks
- Risks to family members and individuals in the community.

Opioid Selection, Dosage, Duration, Follow-up and Discontinuation

•When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

(Recommendation category A: Evidence type: 4)

Choose Predictable Pharmacokinetics and Pharmacodynamics to Minimize Risk

•In general, avoid the use of immediate-release opioids combined with ER/LA opioids.

•Methadone should not be the first choice for an ER/LA opioid.

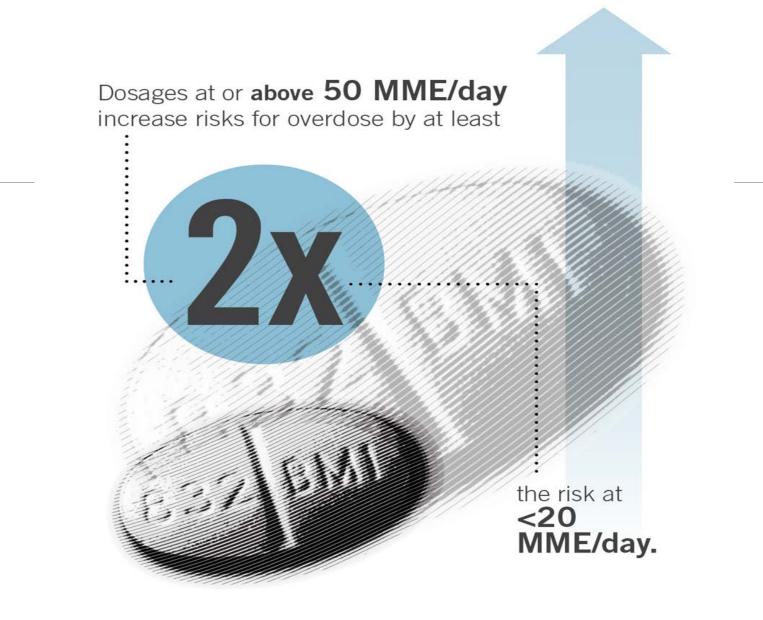
• Only providers familiar with methadone's unique risk and who are prepared to educate and closely monitor their patients should consider prescribing it for pain.

•Only consider prescribing transdermal fentanyl if familiar with the dosing and absorption properties and be prepared to educate patients about its use.

•When opioids are started, clinicians should prescribe the lowest effective dosage.

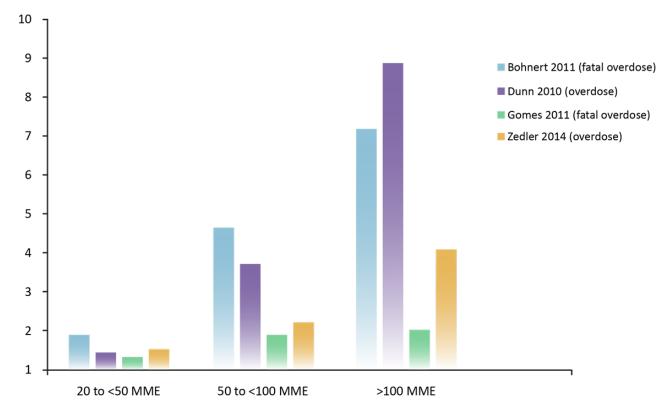
 Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

(Recommendation category A: Evidence type: 3)



Relationship of Prescribed Opioid Dose (MME) and Overdose

Odds Ratio or Hazard Ratio for Overdose Relative to 1 to <20 MME



Start Low and Go Slow

•Start with lowest effective dosage and increase by the smallest practical amount.

- •If total opioid dosage <u>></u>50 MME/day
 - Reassess pain, function, and treatment
 - Increase frequency of follow-up
 - Consider offering naloxone.

•Avoid increasing opioid dosages to <a>>90 MME/day.

- •If escalating dosage requirements
 - Discuss other pain therapies with the patient
 - Consider working with the patient to taper opioids down or off
 - Consider consulting a pain specialist.

For Patients Receiving Higher Doses of Opioids...

 Offer established patients already taking >90 MME/day the opportunity to re-evaluate their continued use of high opioid dosages

• Discuss recent evidence regarding the association of opioid dosage and overdose risk.

•For patients who agree to taper opioids to lower dosages, collaborate with the patient on a tapering plan.

•Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.

•3 days or less will often be sufficient; more than 7 days will rarely be needed.

(Recommendation category A: Evidence type: 4)

When Opioids are Needed for Acute Pain

•Prescribe the lowest effective dose.

- •Prescribe amount to match the expected duration of pain severe enough to require opioids.
- •Often < 3 days and rarely more than 7 days needed.
- •Do not prescribe additional opioids "just in case".
- •Re-evaluate patients with severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly.

•Do not prescribe ER/LA opioids for acute pain treatment.

•Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.

•Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.

•If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category A: Evidence type: 4)

Follow-up Schedule

•Re-evaluate patients:

- Within 1-4 weeks of starting long-term therapy or of dosage increase
- At least every 3 months
- •At follow up, determine if:
 - Opioids continue to meet treatment goals
 - There are common or serious adverse events or early warning signs
 - Benefits of opioids continue to outweigh risks
 - Opioid dosage can be reduced or opioids can be discontinued.

Tapering Opioids

•Work with patients to taper opioids down or off when:

- There is no sustained clinically meaningful improvement in pain and function
- Concurrent benzodiazepines that can't be tapered off
- Patients request dosage reduction or discontinuation
- Patients experience overdose, other serious adverse events, warning signs.
- •Taper slowly enough to minimize opioid withdrawal
 - A decrease of 10% per week is a reasonable starting point
- Access appropriate expertise for tapering during pregnancy
- •Optimize non-opioid pain management and psychosocial support

Assessing Risk and Addressing Harms of Opioid Use

•Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms.

•Clinicians should incorporate into the management plan strategies to mitigate risk including considering offering naloxone when factors that increase risk for opioid overdose are present:

- History of overdose
- History of substance use disorder
- Higher opioid dosages (<u>></u>50 MME/day)
- Concurrent benzodiazepine use

(Recommendation category A: Evidence type: 4)

Factors that Increase Risks for Opioid Associated Harms

- Avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing when possible.
- •During pregnancy, carefully weigh risks and benefits with patients.
- •Use additional caution with renal or hepatic insufficiency, aged <u>>65</u> years.
- •Ensure treatment for depression is optimized.
- •Consider offering naloxone with patients who:
 - Have a history of overdose
 - Have a history of substance use disorder
 - Taking central nervous system depressants with opioids
 - On higher dosages of opioids (> 50 MME/day)

•Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/her at high risk for overdose.

•Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

(Recommendation category A: Evidence type: 4)

Prescriptions from Multiple Sources, High Dosages or Dangerous Combinations

•Discuss safety concerns with patient (and any other prescribers they may have), including increased risk for overdose.

- •For patients receiving high total opioid dosages, consider tapering to a safer dosage, consider offering naloxone.
- •Consider opioid use disorder and discuss concerns with your patient.
- •If you suspect your patient might be sharing or selling opioids and not taking them, consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal.
- •Do not dismiss patients from care—use the opportunity to provide potentially lifesaving information and interventions.

•When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

(Recommendation category B: Evidence type: 4)

Urine Drug Testing to Assess for Opioids and Other Drugs that Increase Risk

•Be familiar with urine drug testing panels and how to interpret results.

•Don't test for substances that wouldn't affect patient management.

- •Before ordering urine drug testing
 - Explain to patients that testing is intended to improve their safety
 - Explain expected results
 - Ask patients whether there might be unexpected results.

•Discuss unexpected results with local lab and patients.

- •Verify unexpected, unexplained results using specific test.
- •Do not dismiss patients from care based on a urine drug test result.

•Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

(Recommendation category A: Evidence type: 3)

Avoid Concurrent Opioids and Benzodiazepines Whenever Possible

• Taper benzodiazepines gradually.

- •Offer evidence-based psychotherapies for anxiety:
 - Cognitive behavioral therapy
 - Specific anti-depressants approved for anxiety
 - Other non-benzodiazepine medications approved for anxiety

•Coordinate care with mental health professionals.

•Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

(Recommendation category A: Evidence type: 2)

If Opioid Use Disorder (OUD) is Suspected

•Discuss with your patient and provide an opportunity to disclose concerns.

•Assess for OUD using DSM-5 criteria. If the criteria is met, offer or arrange Medication Assisted Treatment (MAT).

- Buprenorphine through an office-based buprenorphine treatment provider or an opioid treatment program specialist
- Methadone maintenance therapy from an opioid treatment program specialist
- Oral or long-acting injectable formulations of naltrexone (for highly motivated nonpregnant adults)

•Consider obtaining a waiver to prescribe buprenorphine for OUD

•Information for buprenorphine waiver management can be found at <u>http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management</u>

Arkansas State Medical Board Regulations for Opioid Prescribing

•In Regulation number 2, a description of acts that authorized the Arkansas State Medical Board to revoke or suspend a license. Recent additions to this regulation were adopted August 8, 2018 to address prescription drug abuse.

- The prescribing of excessive amounts of controlled substances is described with specific practice recommendations to follow.
- The Board defines "excessive" as the writing of any prescription in any amount without a detailed medical justification for the prescription in the patient record.
- The regulation changes focus on the physician responsibilities when treating patients with
 - Chronic Pain
 - Chronic Non-Malignant Pain
 - Acute Pain

www.armedicalboard.org

Arkansas State Medical Board: Chronic Pain

•The definition of "excessive" refers to the CDC guideline for prescribing opioids for chronic pain at a level exceeding 50 MME (Morphine Milligram Equivalents) per day, unless each of the following is documented by the provider:

- Objective findings including, but not limited to, imaging studies, lab tests, nerve conduction studies, biopsy, or any other test that would establish the pathology of the pain.
- Specific reasons to prescribe more than 50 MME (Morphine Milligram Equivalents) per day
- Document other therapies trialed, failed or planned prior to considering chronic opioid therapy
- Document assessment of the potential for abuse and/or diversion of the prescribed drug
- Document checking the PDMP (Prescription Drug Monitoring Program) prior to issuing the prescription
- Document a detailed clinical rationale for the prescribing
- Patient must be seen for an in-person examination every 3 months or 90 days.

www.armedicalboard.org

Arkansas State Medical Board: Chronic Pain

•Regular urine drug screens should be done to insure the patient is taking the drugs as prescribed. CDC guideline will be used to relate to baseline and at least annual follow up.

- •A pain treatment agreement must be signed and reviewed by the patient when initiating chronic pain therapy. It should discuss the following points:
 - Informed risk of the addictive nature of the prescribed medications
 - Specific expectations between the patient and provider
 - Informed consent for periodic urine drug testing and random pill counts
 - Provisions to terminate opioid therapy

Arkansas State Medical Board-Chronic, Non-Malignant Pain

•Chronic Non-Malignant Pain is described as *pain requiring more that 3 consecutive months of prescriptions for:*

- Opioid prescription written for more than 90 tablets, each containing 5mg or more of hydrocodone
- A MME (Morphine Milligram Equivalent) of more than 15 mg per day
- Tramadol 50mg per dose with a quantity of 120 tablets

•Providers must check the PDMP for the patients' prescriptive history with each prescription

•Patients shall be evaluated at least once per 6 months

Arkansas State Medical Board-Acute Pain

•For the treatment of Acute Pain, the description of "excessive" is changed to further define it as:

- •An initial prescription written for more than 7 days, without detailed, documented medical justification in the patient record.
 - If the patient requires further prescriptions, they must be evaluated in regular increments with documented medical justification for continued treatment.

Arkansas State Medical Board-Opioid Dosing

•Providers should prescribe the lowest effective dosage, but use caution at any dose.

- •Reassess evidence of individual benefits and risks when increasing doses to more than 50 MME per day.
- •Avoid increasing the dosage to more than 90 MME per day.
- •Doses titrated above 90 MME per day must be carefully justified in the medical record.

An Exception to the Definition of Excessive

•The definition of "excessive" as contained in the regulation, shall not apply to the following prescriptions:

- Those written for a patient in hospice care, in active cancer treatment, palliative care or end-of-life care.
- Patients in nursing homes
- Patients in assisted living
- Inpatient settings
- Emergency situations

AR-PDMP

•The Arkansas Prescription Monitoring Program (AR PMP) was established by Act 304 of 2011 to do the following:

- Enhance patient care
- Help curtail the misuse and abuse of controlled substances
- Assist in combating illegal trade and diversion of controlled substances
- Enable access to prescription information by authorized individuals

https://cji.edu/site/assets/files/1011/arkansas_prescription_drug_monitoring_program.pdf

AR-PDMP

•Dispensers of controlled substances are required to submit data. These include:

- In-state pharmacies
- Out-of-state pharmacies
- Practitioners dispensing controlled substances
- •PDMP information may be accessed by:
 - Prescribers and pharmacists
 - Licensing boards (as a part of an investigation)
 - Law enforcement (with a search warrant)
 - Certified Law Enforcement Prescription Drug Diversion Investigator (no warrant required)
 - Other state PDMP
 - Researches and educators (information must be de-identified)

 $https://cji.edu/site/assets/files/1011/arkansas_prescription_drug_monitoring_program.pdf$

AR-PDMP: Patient Reports

•Patient History reports allow the practitioner to check for:

- Previous use of a controlled substance
- Misuse via multiple prescribers or pharmacies
- Medication duplication
- Drug interactions
- Compliance with pain contracts

https://cji.edu/site/assets/files/1011/arkansas_prescription_drug_monitoring_program.pdf

AR-PDMP Prescriber Feedback Reports

- •Per Act 820, the AR PDMP is required to issue regular reports to individual prescribers
- •Provide valuable information pertaining to your own opioid and benzodiazepine prescribing, and that of others within your healthcare specialty and role
- •All prescribers registered with the AR PDMP that have prescribed at least one opioid within the reporting period will receive a Prescriber Comparison Report

www.healthy.arkansas.gov/programs-services/topics/prescription-monitoring-program

Accessing the Prescriber Comparison Report

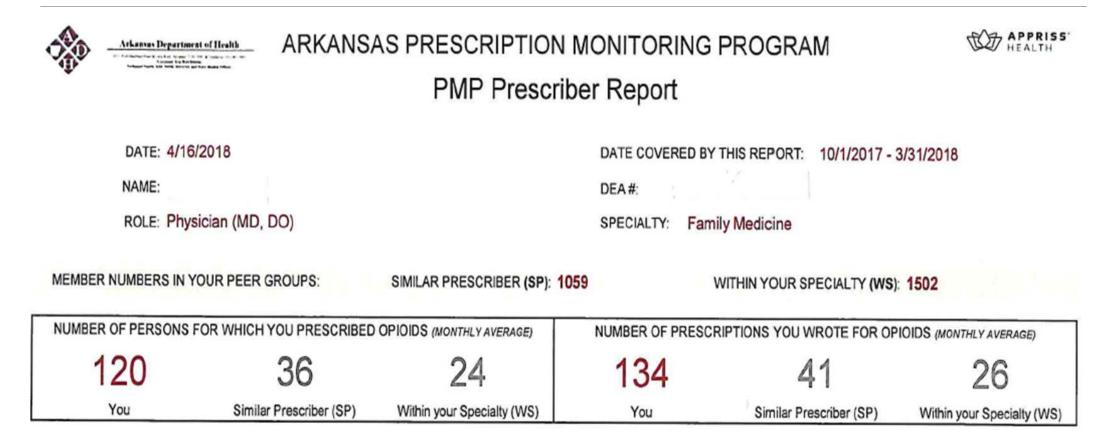
•Go to AR PDMP website: https://arkansas.pmpaware.net/login

•Login

- •Click RxSearch, then click MyRx
- •Next, enter the date range (10/1/17-3/31/18)
- •Select the DEA number associated with your Prescriber Comparison Report
- •Alternatively, the report will be sent via email to the address associated with the PDMP account on a quarterly basis.

www.healthy.arkansas.gov/programs-services/topics/prescription-monitoring-program

Sample Report: Number of Patients and Prescriptions



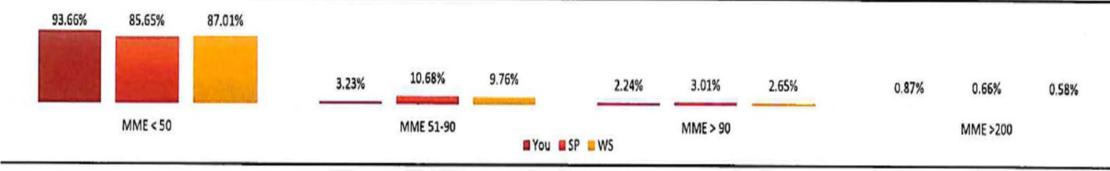
Sample Report: Top Controlled Medications Prescribed

TOP MEDICATIONS PRESCRIBED (FULL REPORT PERIOD)

HYDROCODONE BITARTRATE/ACETAMINOPHEN	ALPRAZOLAM	ZOLPIDEM TARTRATE
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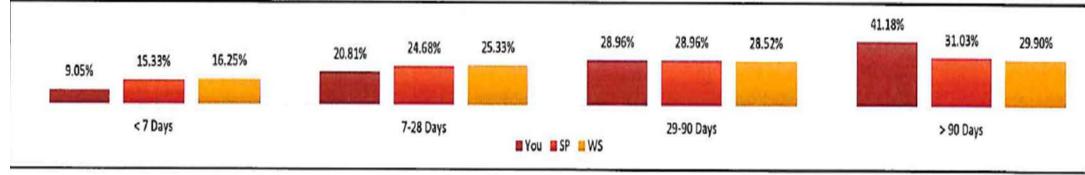
Sample Reports: Percentage of Prescriptions by MME

PRESCRIPTIONS BY DAILY MME (MORPHINE MILLIGRAM EQUIVALENT) (FULL REPORT PERIOD)



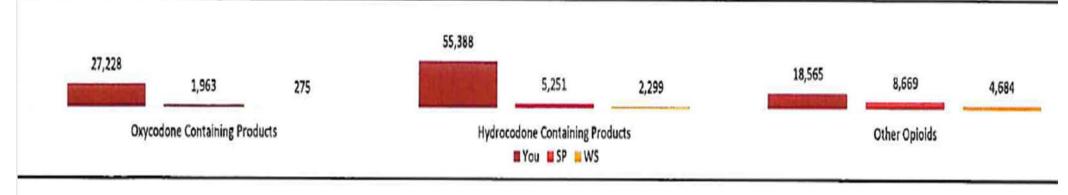
Sample Report: Duration of Opioid Treatment

OPIOID TREATMENT DURATION (% OF PATIENTS) (FULL REPORT PERIOD)

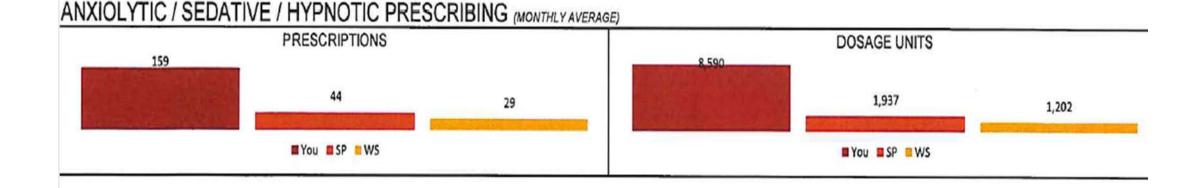


Sample Report: Total of Various Opioid Products

PRESCRIPTION VOLUMES (TOTAL MME) (MONTHLY AVERAGE)



Sample Report: Number of Prescriptions and Doses of Anxiolytics/Sedatives/Hypnotics



Sample Report: Number of PDMP Queries

PDMP USAGE (MONTHLY AVERAGE)				
PDMP REQUESTS BY YOU	PDMP REQUESTS BY YOUR DELEGATE(S)	SIMILAR PRESCRIBER AVERAGE	SPECIALTY FIELD AVERAGE	
129	0	27	20	

Sample Report: Number of Patients Receiving Problematic Combinations

DANGEROUS COMBINATION THERAPY					
PRESCRIPTIONS FOR OPIOID + BENZO IN SAME MONTH		PRESCRIPTIONS FOR OPIOID + BENZO + CARISPORODOL IN SAME MONTH			
95	139	0	1		
BY YOU	BY YOU + OTHER PRESCRIBERS	BYYOU	BY YOU + OTHER PRESCRIBERS		

Arkansas Naloxone Protocol

- •Naloxone hydrochloride is an opioid antagonist that reverses or blocks the effects of opioid analgesics.
- •In 2017 the Arkansas Legislature passed Act 284 into law, allowing pharmacists to initiate therapy, administer or dispense Naloxone when following a statewide protocol and physicians to distribute Naloxone without a dispensing permit.

www.arkleg.state.ar.us/assembly/2017/2017R/Acts/Act284.pdf

Arkansas Naloxone Protocol

The Statute states that a "healthcare professional acting on good faith may directly or by standing order prescribe and dispense an opioid antagonist" to:

- Persons at risk of experiencing an opioid-related drug overdose
- Pain management clinics
- Harm reduction organizations
- Emergency Medical Technicians
- First Responders
- Law Enforcement Officers or Agencies
- Family members or friends of persons at risk

The following individuals are immune from civil or criminal liability or professional sanctions for administering, prescribing or dispensing an opioid antagonist under the statute:

A healthcare professional who prescribes an opioid antagonist

A healthcare professional or pharmacist, in compliance with the standard of care, who dispenses an opioid antagonist

A person, other than a healthcare professional who administers an opioid antagonist.

Arkansas Naloxone Protocol Dispensing Guidelines

•An Arkansas Licensed Pharmacist may initiate therapy to an individual at risk for opioid overdose or a family member, friend or other person who might assist the individual at risk.

- Risk factors for opioid overdose:
 - Opioid use including prescription or illicit drugs
 - History of opioid intoxication, overdose, and/or emergency medical care for acute opioid poisoning
 - High opioid dose prescribed (>50 morphine milligram equivalents daily)
 - Suspected or known concurrent alcohol use
 - Concurrent prescriptions or use of benzodiazepines, tricyclic anti-depressants (TCA's), skeletal muscle relaxants and other medications
 - Treatment of opioid use disorder with either buprenorphine or methadone.
 - Concurrent history of smoking/COPD or other respiratory illnesses or obstruction

Arkansas Naloxone Protocol Dispensing Guidelines

- Product Availability: Naloxone products that may be dispensed/provided under this standing order:
 - Narcan[®] Nasal Spray (naloxone HCl) 4 mg/0.1 mL Nasal Spray Directions for use: Administer one (1) spray of Narcan[®] in one nostril. Repeat after three (3) minutes if no response.
 - Naloxone HCl Solution 1 mg/mL in a 2 mL pre-filled Luer-Lock Syringe Directions for use: Spray 1 mL (1/2 of syringe) into each nostril. Repeat after three (3) minutes if no response
 - Evzio[®] (naloxone HCl injection) 0.4 mg/0.4 mL autoinjector Directions for use: Follow audio instruction from device. Place on thigh and inject 0.4 mL. Repeat after three (3) minutes if no response.

Arkansas Naloxone Protocol Dispensing Guidelines

- Abrupt reversal of opioid effects in a person with a physical dependence on opioids can cause acute withdrawal symptoms such as, but not limited to, the following: nausea/vomiting, diarrhea, fever, body aches, sweating, sneezing, yawning, shivering/trembling, irritability, chills, anxiety, combativeness/disorientation.
- •Abruptly reversing the effects of opioids could result in a pain crisis due to neutralization of the analgesic effects of the opioid.
- •Naloxone should be used with caution in patients with a history of seizures and/or cardiovascular disease.
- •Naloxone will have no effect on respiratory depression caused from non-opioid substances.
- •Whenever naloxone is administered to reverse a potential opioid overdose, medical follow-up is needed as naloxone's effects wear off quickly resulting in the need for further medical care.
- •Naloxone should be considered a temporary overdose reversal agent with the potential need for multiple doses under acute medical care.

Resources for More Information



AR-IMPACT website: arimpact.uams.edu

AR-IMPACT email address: <u>AR-IMPACT@uams.edu</u>

Twitter: @ArkansasImpact

References

•CDC Guideline for Prescribing Opioids-United States 2016

- https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- Arkansas State Medical Board
 - https://www.armedicalboard.org
- •Arkansas State Act 284
 - http://www.arkleg.state.ar.us/assembly/2017/2017R/Acts/Act284.pdf
- PDMP
 - http://www.arkansaspmp.com/files/2017/2016 Annual Report FINAL.pdf
 - https://cji.edu/site/assets/files/1011/arkansas_prescription_drug_monitoring_program.pdf
 - www.healthy.arkansas.gov/programs-services/topics/prescription-monitoring-program

•Arkansas Naloxone Protocol