

In person or virtually,

Welcome!

Drug Diversion Training and Best Practice Prescribing of Controlled Substances

Tracy Hendershot, DC, MD, FAAFP

For the

Family Medicine Foundation of West Virginia

Huntington, WV

November 5, 2020

Credentials

Dr. Hendershot, MD, DC, FAAFP is a past Paul Ambrose Health Policy Fellow. He trained at Marshall University's Joan C. Edwards School of Medicine with completion of a family practice residency at the same.

He's worked in private practice as a chiropractor from 1996-2004, observing the WV opioid crisis develop from the vantage point of a non-prescribing provider. Since becoming an MD he's worked at the Ebenezer Clinic- a free clinic blocks from Huntington, WV's initial opioid epicenter. He's been CMO of a rural FQHC and Past Chair of the WV PCA CMO committee. He's now employed in the WVU Medicine Health System. At each location he's been handed his share of chronic opioid patients. He manages < 30 chronic opioid patients in the outpatient setting.

Finally, Dr. Hendershot has served as Past President of the WVAFP, currently serving as WVAFP Delegate to the AAFP Congress of Delegates. He also serves as chair of the WVAFP Legislative Committee.



Dr. Hendershot has **no** conflicts of interest or disclaimers to announce.

The use of brand specific names are not meant as an endorsement, But to ensure familiarity of the prescriber with the common opioid products.

I receive no renumeration from any manufacturer.



- 1. Review the climate and trends in WV that contribute to opioid overdose deaths.
- 2. Review best practice prescribing of controlled substances.
- 3. Review drug diversion concerns and best practices.
- 4. Encourage the appropriate use of Naloxone and MAT.

Agenda

The First 30 min.	The Next hour:	The Hour after that	The Last 30 min.
Why We Are here	Starting Patients on Opioids	Prescribing Opioids	The latest opioid bill
		Opioid equivalents	
The current	Assessment of		How to help the
situation	Need	Testing: Urine	Heroin users
	Assessment of Risk	Pill counts	
	BOP	Stopping Opioids	

Contracts

Why We Are Here...its required

Mandatory Controlled Substance CME for all Licensees

(SB 437 passed 2012)

"Physicians who have prescribed, administered, or dispensed any controlled substance in any jurisdiction in the two year license cycle preceding renewal, are required to complete three hours of Board-approved CME in drug diversion and best practices prescribing of controlled substances **during each reporting period**. **This is not a one-time only requirement**.

A physician who has **not prescribed any controlled substances whatsoever during the reporting period may seek a waiver** of this requirement by attesting on the renewal application that he or she has not prescribed, administered or dispensed any controlled substances whatsoever since July 1, 2016."

Why We Are Here...its a state objective

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Reports		Complete P0	James Jeffries, MS	WV DHHR, Division of I	
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http://sempguidelines.org/wp-content/uploads/2016/09/W

WVBM and WVBOM Approved Courses:

The Boards of Medicine maintain a list of all three-hour courses that have been approved..

-Thank you for attending this lecture

https://wvbom.wv.gov/Cont_Med_Education.asp

https://www.wvbdosteo.org/article.asp?action2=showArticle&id=14&ty=CTTS

WV Boar	d of Osteopathic Medi	cine	iten - Elle a Gerenisiat			
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	Verification of Licensure to Another State Board	Diversion: The West Virginia Requirement, #91601 or #91602				

Opioid Regulation is Not New:

Narcotic Regulation, slow steady



Cumulative number of states authorizing prescription drug abuse-related laws by type of law, United States, 1970-2010 http://www.cdc.gov/homeandrecreationalsafety/Poisoning/laws/

<u>index.html</u>

Recent Appalachian Region Prescription Opioid Strike force Takedown:

In April, 2020, 53 medical professionals, were charged for unlawfully distributing opioids and other controlled substances:

Local, specific cases included Physician(s) in:

Saint Clairsville, OH, was charged with health care fraud, etc., for an alleged scheme to cause <u>submissions for unperformed health care services</u>, and <u>to prescribe controlled substances (CS)</u> while he was out of the state or country.

Saint Clairsville, OH, for alleged participation in the unlawful prescription of CS outside of the course of professional practice and without a legitimate medical purpose, and <u>health care fraud</u> for the submission of claims for services which were medically unnecessary and/or performed below medically-accepted standards.

Vienna, Ona, and multiple physicians in Charleston, WV were charged with allegedly unlawfully distributing CS without a legitimate medical purpose.



Recent Appalachian Region Prescription Opioid Strike force Takedown:

Local, specific cases included Physician(s) in:

Wheeling, WV, was charged with diversion of CS for alleged participation in the unlawful prescription of CS <u>outside of the course of professional practice and without a legitimate medical purpose.</u>

Huntington, WV, pleaded guilty to illegal drug distribution including dextroamphetamine, methylphenidate and amphetamine salt to a patient who did not have a medical need for the drugs. The physician <u>did not perform examinations **of any kind**</u> prior to dispensing the narcotics even though the <u>patient had a history of abusing narcotics</u>.

Charleston, WV, pleaded guilty to illegal distribution of CS without legitimate medical purposes, <u>including methadone pills.</u>

THE SETTICE PARTMENT OF JUSTICE



U.S. Attorney Mike Stuart of the Southern District of West Virginia:

"We have taken a very tough stance against those that fuel the opiate crisis at every level including **pill writers**, pill fillers, and drug dealers,"

"The unlawful distribution of controlled substances ...is **one of our highest priorities for prosecution** as we continue with our efforts to protect the public and the people of West Virginia.

Assistant Attorney General Brian A. Benczkowski

of the Justice Department's Criminal Division.

"To the doctors, pharmacists, and other medical professionals engaged in this egregious criminal behavior across Appalachia.. **the data in our possession allows us to see you and see you clearly**, no matter where you are,"

"Medical professionals who violate their solemn oaths and peddle opioids for profit should know that we will find you and ensure that the justice system treats you like the drug dealer you are."





Common Perception of Opioid Users:





Opioid Overdoses:





https://www.featureshoot.com/2012/09/photographing-a-heroin-addict-through-despair-horror-and-hope/

https://www.pri.org/stories/2016-04-27/photos-getting-know-person-behind-heroin-addiction Aaron Goodman

Common Terms:

- **Opiates:** refer to natural opioids such as heroin, morphine, and codeine.
- Opioids: refers to all natural, semisynthetic (hydrocodone, oxycodone, hydromorphone..), and synthetic opioids (excludes methadone, includes tramadol and fentanyl)
- MAT: Medication assisted treatment for opioid use disorder when combined with counseling and behavioral therapies.
- **MME:** Morphine milligram equivalents, accounts for different drug types and strengths.



https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.legalgenealogist.com%2F2017%2F03%2F24%2Fdont-buy-that book%2F&psig=AOvVaw0THAzloUqGPxH7vXfhUEzU&ust=1603140274387000&source=images&cd=vfe&ved=2ahUKEwivvvSFgb_sAhVFR6wKHfrkDtkQr4kDegUIAR

Common Terms:

- Illicit drugs: drugs prohibited by law or illicitly manufactured drugs, i.e. fentanyl, ecstasy.
- **Drug Misuse:** The use of drugs in a manner other than prescribed by a doctor.
- **Tolerance:** Reduced response to a drug with repeated use.
- Dependence: adaption to a drug that produces symptoms of withdrawal when drug is stopped.
- **Drug addiction**: Preferred term is Substance Use Disorder, a problematic pattern of opioid use that causes significant impairment or distress.
 - Unsuccessful efforts to reduce.
 - Use resulting in personal, social, and/or work problems



The Current Threat:

The Press Herald, January 24, 2018

Man arrested in Boston had more than 5 kilos of fentanyl, authorities say.

Prosecutors say the 26-year-old Guatemalan was scheduled to deliver the drug to a witness cooperating with the U.S. Drug Enforcement Administration..



Current National Trends?

The overall national opioid **prescribing rate** has declined from 2012 to 2018.

2018 prescribing rate had fallen to **51.4 prescriptions per 100 persons**

However, the prescribing rates continued to remain high in certain areas across the country.

In 11% of U.S. counties the rate is still 100:100

Some counties' rates were **6X higher** than that.

https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html#:~:text=The%20overall%20national%20opioid%20prescribing%20rate%20declined%20from%202012%20to,168%20million%20total%20opioid%20prescriptions).



In 2018, West Virginia providers wrote:

69.3 opioid prescriptions for every 100 persons,

(Still among the top ten rates in the U.S. that year)

Positive news?



This was the lowest WV rate since data became available in 2006

https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/west-virginia-opioid-involved-deaths-related-harms

Current National Trends?

The age-adjusted rate of **overdose deaths** decreased.

In 2018, 67,367 drug overdose deaths occurred in the USA.

A 4.6% drop from 2017 (21.7 per 100,000) to 2018 (20.7 per 100,000).

Synthetic opioids (other than methadone)—remain the main driver of drug overdose deaths.

67.0% of opioid-involved overdose deaths involve synthetic opioids.

https://www.cdc.gov/drugoverdose/data/statedeaths.html

Current National Trends?

In 2018, states with the highest rates of drug overdose deaths were :

West Virginia (51.5 per 100,000),

Delaware (43.8 per 100,000),

Maryland (37.2 per 100,000),

Pennsylvania (36.1 per 100,000),

Ohio (35.9 per 100,000), and

New Hampshire (35.8 per 100,000).

WV Trends?

WV Opioid Overdose Deaths



..WV follows national picture.

Current WV Trends?:



https://www.drugabuse.gov/opioid-summaries-by-state/west-virginia-opioid-summary. Source: CDC and CDC WONDER.



SOURCE: NCHS, National Vital Statistics System, Mortality. 2019



SOURCE: NCHS, National Vital Statistics System, Mortality. 2019



SOURCE: NCHS, National Vital Statistics System, Mortality. 2019

Figure 1. Age-adjusted drug overdose death rates, by sex: United States, 1999–2018





by age at death, 2013-17



Opioids excluding synthetics





http://www.wvdhhr.org/bph/hsc/pubs/other/SyntheticOpioidFastStats/Synthetic_Opioid_Fast_Stats.pdf

WV Demographics 2020

WV Fatal Overdoses by age and sex





https://dhhr.wv.gov/office-of-drug-control-policy/datadashboard/Pages/default.aspx 9/17/21

WV Overdose Death Rates

The following slides show the rise in death WV death rates since 2014

The slides report <u>WV death rates per 100,000 population and total</u> <u>deaths</u>, i.e. 35 and 627

Number and age-adjusted rates of drug overdose deaths by state, US 2014



https://www.cdc.gov/drugoverdose/data/statedeaths.html



41.5



Number and age adjusted rates of drug overdose deaths by state, US 2016

52.0


Number and age-adjusted rates of drug overdose deaths by state, US 2017







Fentanyl is Leading Opioid Deaths

It continues to be <u>illegal opioid</u> deaths, **not prescription opioids**, that drive the current national epidemic.

Please Note : as methadone decreased in use, opioid deaths have increased.



our Source for Credible Health Information

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016

NOLINCE: CIX VIX.EN, National Vital Statistics System, Mortality, CIX: WONDER, Arianta, GA: US Department of Health and Human Ser Vices, CIX 5, 2017. https://wonder.odc.gov/.

Trends in Annual Opioid Prescribing Rates by Overall and High-Dosage Prescriptions



80/100 is

benchmark

WV Opioid Rx Rates Have Declined Since 2009

The **physicians in WV began changing Rx habits by 2009**, before many current legislative efforts began.

The <u>physician community has supported the legislative efforts</u> at stopping the deaths resulting from this epidemic.

The following slides show <u>WV opioid Rxs per 100 persons</u>, i.e. 146 in 2009.

Please Note: The national physician community has reacted similarly.



West Virginia

2010 Rate per 100 persons ~ 64.1 64.1 - 82.9 83.0 107.1 > 107.1 Inset maps

West Virginia



West Virginia



West Virginia

136.9

https://www.cdc.gov/drugoverdose/maps/rxstate2012.html



West Virginia

129

2014 Rate per 100 persons. < 64.1 64.1 82.9 83.0 - 107.1 > 107.1 🖂 🗌 Inset maps

West Virginia



West Virginia





In 2017, however, there were still almost 58 opioid prescriptions written for every 100 Americans



West Virginia

69.3

https://www.cdc.gov/drugoverdose/maps/rxstate2018.html

WV County Rx Data

By 2009 individual WV county physicians began to respond to the crisis.

At that time, **Mingo county** lead the state in Rx rates-With **nearly triple** the rate of other high prescribing counties.

This abruptly stopped by 2010 and Logan county alone has driven WV outlier status.

This because <u>it has a larger population than other outliers</u> and because its rate is triple the other outliers. (36,000 pop and 15th in WV)

Mingo, WV





Logan, WV





Logan, WV

291



Logan, WV





Logan, WV





Logan, WV

263





Logan, WV





Logan, WV





Logan, WV









Population: 54045





Population: 54045

WV Overdose Fatalities 2020



WV Opioid Reduction Not Tied to Fewer Deaths



In 2017, the number of doses of prescribed controlled substances — dispensed in West Virginia **fell by 31.3 million compared with 2016**.

https://www.cnbc.com/2018/01/22/west-virginia-saw-drop-in-opioid-painkillers-prescribed deaths-rose.html

WV Rx Reduction Not Tied to Fewer Deaths



WV Opioid Reduction Not Tied to Less Deaths

Opioid Deaths vs Opioid Rx rate 2009-2018



Heroin and Rx Opioids Often Mixed:



This is a primary rational for appropriate, ongoing, prescribing education as opposed to ongoing education regarding Addiction Treatment.

The Role of WV Prescribers

The above slides show **WV physician opioid prescribing continues to decline**.

Outlier counties continue to reduce usage, including the lead outlier, Logan county.

We are just now beginning to see fewer opioid related deaths.

Break



Agenda

The First 30 min.	The Next hour:	The Hour after that	The Last 30 min.
Why We Are here	Starting Patients on Opioids	Prescribing Opioids	The latest opioid
	•	Opioid equivalents	DIII
The current situation	Assessment of Need	Testing: Urine	How to help the Heroin users
	Assessment of Risk	Pill counts	
	BOP	Stopping Opioids	

Contracts
Reminder:

"Prescription opioid use is highly associated with risk of opioid-related death, with 1 of every 550 chronic opioid users dying within approximately 2.5 years of their first opioid prescription."

Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study. PLoS Med. 2017 Oct 3;14(10).



Clinical Practice Guideline Opioid Prescribing for Chronic Pain Affirmation of Value, April 2016



CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 Recommendations and Reports / March 18, 2016 / 65(1);1–49

Best Practices: from the Choose Wisely Campaign

Do Not Prescribe Opioids as first line medication for Non-Cancer Pain. American Society of anesthesiologist

Do Not prescribe Opioids as long term therapy for non-cancer pain until the risks are considered and discussed with the patient. American Society of anesthesiologist

Do not prescribe Opioids for Acute or long-term therapy for patients in safety sensitive jobs, such as driving or operating heavy equipment. American College of Occupational and environmental medicine.

https://www.aafp.org/afp/2016/0615/p982.html

The CDC guidelines are written for FPs and Internist

-Together they Rx ½ of all Opioids.

They inform the Physician regarding the Prescribing of Opioids

-Chronically and not acutely.

The guideline defines chronic pain as:

"-pain conditions that typically last >3 months or past the time of normal tissue healing.. in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care"

The Guidelines assume the physician is starting a patient on opioids for the first time, not continuing or extending the care initiated previously.

The guidelines have been converted into a **Checklist** on the CDC website.

The **Checklist** is outlined in the following slides:

Checklist for prescribing opioids for chronic pain For primary care previdenci institugadate (1860 with chronic pains 2) mentile, we hedry cancer, pallacies, and end of life care ALCOHOL: KEEDING. EVIDENCE AND IT OPEN THE MAPS When CONSIDERING long-term optical therapy Device of the Devicement Responsible and the set of the Device of the Dev Attracistic gets for printed function based on diagonity tog web control for the 0. Sixri any beening could be periods by pain instantial in faction Check that non-codeld theoretics into and extimized. Insufficient/weathers the long-local densities as Discuss benefits and side flag, addiction, coordeast with patient. IN MARK SHE WHERE WE RECEIVED. T. F.o. attention of here: at mission. NUM COMPANY THE MARKS Cocces rol: technology with patient L'OR GIORE O' COMUNICI P'UN EXPRESA UN REDICITE. Great secondation drug mentioning program (POMP) data. Har spinil and salisation, by: BMDs, 92%, \$48%, and consultantial. · Goah aine dag men. Physical Busiling Res. Section Terrary. IT Satesite is for stepping or cost using valids. ALC: NO. D Accession and an and function tog. PLG scalet. Deteriord instituted by (100) u Scheckle initial reacconcentrat within 1-4 weeks. PRODUCED INTELLER OF RECEIPTION FLP excite startagepoints way backlebage on particle klobage EVALUATING RESERVE MARKING MEDICAL work deption to reflectabel to service mon-Facen risk factors include. Biggl drugture, prectipien drugture for semicolical research. If RENEWING without patient visit Incorport Linkaker und destation of whitting D Cleak (at return visit is not scholed <2 mention from Lati sinit.</p> Mante bealth world terriby diver- Trees Charlesond Invaliding - Deversal bound angles on When REASSESSING at rolum vield Desirate minide safe dita scallening winische constanted improvements Using Grapheding: Clean in confirm presence is pair and function without significant side or beau. i ministrano and in andia THE REPORT OF THE PROPERTY OF B decryspension function log PHR; compare results in baselore Proselijike dug meelkeling program (*DM*1. a Datastic data di hare se induce. LIDDE TO BE Overse patient for signe of over addition or overdage field. 101107-0111-000 Hyper lapse data. EXERCISED FOR A PURCHER UTBREFTS TO A - Chash 7DMR PECKNIK - JANARY 2. Inflating states to per- Chack for considered words of a directed leg, difficulty controlling usek. STE BOTH AND EXCLOSED AND ADDRESS OF THE OWNER ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS ADDRESS Hype field for test seat We Weinwales Inv O. (Olevithesides) Check that non-opield through a collimized. porr pour at the cost wood/ Determine whether to canif we, adjust, taper, or stop-opioids. 6- "to pan"; 30- "wonf you can implica" D Criteralite opicial racoge accepting milligner senioritent OMAEL 02 Minimum in a Without in Sec. Rength partiest, for tocorder II.550 MM: Any Intel Cabiling hydrocodems, 533 mg capacitomit, an in support to the increase herpitaley of fellow up, econicity of being released During start; BA- tomper employees Aeid 500 #F.Edu (ab) 1580 multichemisses .x00mu exercited). 40: Watereda Ine 0-10-basis Ine. or carefully justify, consider specialist releval during the part must, pain her initialized with your general schedule' Schoolube reasonanti ali regular intervato (5.8 merilla). By Tribelant' Mar Taxandra attribution Mark 2007

Starting a Patient on Opioids AAFP Guidelines

The Checklist

□ Nonopioid pharmacologic therapies are preferred for chronic pain. Consider opioids when benefits for both pain and function outweigh risks. Opioids should be combined with nonopioid pharmacologic therapy as appropriate.

□ Assess Baseline Functional status (PEG)

Establish realistic treatment goals for pain and function before initiating opioid therapy. Stop opioid treatment if there is no meaningful improvement in pain and function.

Starting a Patient on Opioids AAFP Guidelines

The Checklist

For chronic pain, the lowest effective dose of immediate-release opioids should be prescribed instead of long-active (LA) opioids.

□ Reassess benefits and risks when increasing dosages to ≥50 morphine milligram equivalents (MME)/day. Dosages ≥90 MME/day should be carefully justified or avoided if possible.

The Checklist

Evaluate risk factors for opioid-related harms prior to initiation and periodically during treatment. Develop strategies to mitigate risk including offering naloxone to those at increased risk for overdose.

Use a prescription drug monitoring program (PDMP) to review past opioid history when starting opioid therapy and periodically during treatment.

□ Use urine drug testing (UDS) prior to initiating opioid therapy and periodically during treatment to assess compliance or illegal drug use.

The Checklist

Discuss benefits and risks (eg, addiction, overdose) with patient.

Set criteria for stopping or continuing opioids.

Execute an **informed consent** or Opioid Contract.

file:///C:/Users/thendershot/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/cdc_38025_DS1%20(1).pdf

The Checklist

For acute severe pain, the lowest effective dose in the smallest quantity of immediate-release opioids should be prescribed.

□ **Re-evaluate benefits and harms within 1 to 4 weeks of initiating** or escalating opioids for chronic pain and at least every 3 months thereafter.

□ If benefits do not outweigh the harms, start a plan to taper opioids and optimize other therapies.

The Checklist

Avoid co-prescription of opioids and benzodiazepines whenever possible.

Evidence-based treatment including medication-assisted treatment (MAT) with buprenorphine or methadone and behavioral therapies should be offered to patients with opioid use disorder.

Opioid Prescribing Flow:



Assessment of Need

My experience is that there are three categories of need:

- **1)** Accepted Causes: Cancer, End stage disease, Hospice, palliative care, hospital level care (CP, air hunger, interoperative, post-op)
- 2) Acute Pain: trauma, worrisome infection, organ stress/death (pancreatitis, biliary obstruction, Nephrolithiasis, etc.)

3) Chronic Pain:

- a) Progressive and considering new start: rare in last 10 years
- b) Continuation of Prescriptions: previous provider retiring/deceased/ incarcerated

Assessment of Need

Chronic somatic or neuropathic pain e.g., musculoskeletal pain, peripheral neuropathy, postherpetic neuralgia is at least partially responsive to opioids.

Chronic visceral or central pain syndromes e.g., abdominal or pelvic pain, fibromyalgia, headaches, are less responsive or nonresponsive.

Assessment of Need-The PEG

Baseline Functional Tool

PEG score = average 3 individual question scores

What number, from 0 - 10 best:

Q1: Describes your

Pain in the past week?

Q2: Describes how, during the past week, pain has interfered with your **<u>Enjoyment</u>** of life?

Q3: Describes how, during the past week, pain has interfered with your <u>General activity</u>?

Does Risk Assessment Matter?

One open label, multi-primary care center study evaluated:

Potential for and incidence of aberrant drug-related behaviors among patients with..

Chronic, moderate-to-severe pain

To determine **investigator compliance** with a Universal Precautions (UP) approach to pain management.

Brown J, Setnik B, Lee K, Wase L, Roland CL, Cleveland JM, Siegel S, Katz N. Assessment, stratification, and monitoring of the risk for prescription opioid misuse and abuse in the primary care setting. J Opioid Manag. 2011 Nov-Dec;7(6):467-83.

Does Risk Assessment Matter?

The UP approach included:

- Treatment agreements,
- Screener and Opioid Assessment for Patients with Pain-Revised questionnaire,
- Pill counts,
- Pain-patient follow-up tool,
- Investigator assessment/plan, and
- Urine drug screens (UDS).



https://www.compliancesigns.com/OWE-8540.shtml

Does Risk Assessment Matter?

At baseline:

47% were considered low risk for opioid misuse/abuse,
52 % moderate, and
1% high.

UDSs were + for nonprescribed drugs in some patients throughout the study.

Brown J, Setnik B, Lee K, Wase L, Roland CL, Cleveland JM, Siegel S, Katz N. Assessment, stratification, and monitoring of the risk for prescription opioid misuse and abuse in the primary care setting. J Opioid Manag. 2011 Nov-Dec;7(6):467-83.

Does Risk Assessment Matter?

Study Results:

64% of investigators were compliant with major components of UP approach in greater than or = 75% of their patients.

But there was a <u>tendency for investigators to assign lower risk levels</u> than those that were protocol-specified.

Brown J, Setnik B, Lee K, Wase L, Roland CL, Cleveland JM, Siegel S, Katz N. Assessment, stratification, and monitoring of the risk for prescription opioid misuse and abuse in the primary care setting. J Opioid Manag. 2011 Nov-Dec;7(6):467-83. PubMed PMID: 22320029.

Evaluate for factors that could increase your patient's risk for harm from opioid therapy such as:

- Personal or family history of substance use disorder
- Anxiety or depression
- Pregnancy
- Age 65 or older
- COPD or other underlying respiratory conditions
- Renal or hepatic insufficiency

https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html

Measure risk using one of several partially validated measures:

The **Screener and Opioid Assessment for Patients with Pain** (SOAPP), The **Diagnosis, Intractability, Risk, and Efficacy inventory** (DIRE), The **Opioid Risk Tool** (ORT).

One small study predicting discontinuance for aberrant drug-related behavior found **the highest sensitivity for the clinical interview** (0.77) and the SOAPP (0.72), followed by the **ORT** (0.45) and the **DIRE** (0.17). Combining the clinical interview with the SOAPP increased sensitivity to 0.90.

Moore TM, Jones T, Browder JH, Daffron S, Passik SD. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. Pain Med. 2009 Nov;10(8):1426-33.

Assessment of Risk-ORT

Indicates the **probability of opioid-related aberrant behaviors**

In a study, 158 consecutive new patients treated in a pain clinic took the Opioid Risk Tool (ORT). It measured valid risk factors associated with substance abuse. All patients were monitored for aberrant behaviors for 12 months after their initial visits.

The ORT displayed **excellent discrimination** for both the male (c = 0.82) and the female (c = 0.85) prognostic models.

<u>Webster LR</u>, <u>Webster RM</u>. Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool. <u>Pain Med.</u> 2005 Nov-Dec;6(6):432-42.

Assessment of Risk-ORT

Those Scored as..

- Low Risk: scores of 0-3, 17 out of 18 (94.4%) did not display an aberrant behavior.
- Moderate risk: Score of 4-7
- High Risk: Score of > or = to 8, 40 out of 44 (90.9%) did display an aberrant behavior.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	з	3
illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	n
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

Assessment of Risk-SOAAP

The Screener and Opioid Assessment for Patients with Pain (SOAPP)[®] helps determine how much monitoring a patient on long-term opioid therapy might require. It comes as a short and a standard form.

SOAPP endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The SOAPP is less good at identifying who is not at-risk.

The SOAPP is scored as > than 4 or less than 4.

Assessment of Risk-SOAAP

The tool asks interesting risk factors:

How often do you have mood Swings?

How often do you smoke a cigarette within an hour after you wake up?

How often have you had legal problems or been arrested?

	SOAPP Version	SOAPP Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ratio
[Short Form	Score 4 or above	.86	.67	.69	.85	2.59	.20
	Standard	Score 7 or above	.91	.69	.71	.90	2.94	.13

SOAPP ^e Version 1.0 - SF					
Name: Date:					
The following are some questions given to all patients at the Pain Management Center who are on or being considered for opioids for their pain. Flease answer each question as honestly as possible. This information is for our records and will remain confidential. Your answers alone will not determine your treatment. Thank you.					
Please answer the questions below using the following scale:					
0 = Never, 1 = Seldom, 2 = Sometimes, 3 = Often, 4 = Very Often					
1. How often do you have mood swings?	0	1	2	3	4
 How often do you smoke a cigarette within an hour after you wake up? 	0	1	2	3	4
3. How often have you taken medication other than the way that it was prescribed?	0	1	2	3	4
 How often have you used illegal drugs (for example, marijuana, occaine, etc.) in the past five years? 	0	1	2	3	4
 How offen, in your lifetime, have you had legal problems or been arrested? 	0	1	2	3	4

Please technics any additional information you wish about the above answers. Thank you.

What to do with the results?

Low risk: Treat the patient in-house.

Moderate risk: Either in-house or refer. If inhouse, check more frequently and tighten up encounters, i.e. more frequently, only one script at a time, drug testing quarterly, etc.



High risk: Most refer.

BOP

Evaluating for Misuse

Prescription Drug Monitoring Programs (PDMPs) collect data from pharmacies on dispensed controlled substance prescriptions and make those data available to authorized users through a secure, electronic database. Currently, all states have operating PDMPs. More than 20 have joined a shared database.

Some EMRs can pull PDMP data. Making a query more convenient.



https://www.aafp.org/afp/2016/0615/p982.html#sec-1. https://www.cdc.gov/drugoverdose/pdmp/states.html. Missouri.

Warning Signs for Opioid Misuse

- Early refills
- The same or similar prescriptions from multiple physicians simultaneously (doctor-shopping)
- Dangerous drug-drug interactions (opioids and benzodiazepines)
- Total morphine milligram equivalents exceeding 120 mg per day

False Signs of Opioid Misuse

- Patients who are receiving care in a group/academic practice, where doctors cover for each other, should not be confused with patients who are doctor-shopping.
- Patients who are receiving prescriptions for limited quantities (e.g., a two-week prescription as part of an opioid taper) may not be getting early refills.



In order to receive controlled medications, patients often sign a:

"Pain Contract," or
"Treatment Consent Form," or
"Narcotic Contract, " or
"Opioid Treatment Agreement" (OTA),

There is some criticism that OSAs are ethically suspect, if not unethical, and should be used with extreme care.



Rager JB, Schwartz PH. Defending Opioid Treatment Agreements: Disclosure, Not Promises. Hastings Cent Rep. 2017 May;47(3):24-33. doi: 10.1002/hast.702.

Contracts

Use an agreement that defines the terms and expectations of therapy

It should outline:

- Appropriate intervals for follow-up,
- Refill policies,
- Participation in any indicated multimodal management plan (e.g., physical therapy, psychological treatment),
- Use of only one prescriber and one pharmacy for all controlled medications, and prohibition of illicit substance use or prescription diversion.
- Should be part of an ongoing treatment plan for all patients receiving chronic opioid therapy, thereby avoiding reliance on physician judgment, suspicion, or bias.

https://www.aafp.org/afp/2016/0615/p982.html#sec-1

D. BERLAND, MD, and P. RODGERS, MD, Rational Use of Opioids for Management of Chronic Nonterminal Pain. Am Fam Physician. 2012 Aug 1;86(3):252-258

Contracts

Controlled Substance Agreements (CSAs)

One retrospective cohort study evaluated the opioid dosing for 1066 patients with CSAs in a primary care practice.

Patients were prescribed :

•an average of 40.8 MME/day,
•21.5% of patients were receiving ≥50 MME/day and
•9.7% were receiving ≥90 MME/day.

The Authors' Conclusions?

CSAs present an opportunity to engage patients taking higher doses of opioids in discussions about opioid safety, appropriate dosing and tapering.

Philpot LM, Ramar P, Elrashidi MY, Mwangi R, North F, Ebbert JO. Controlled Substance Agreements for Opioids in a Primary Care Practice. J Pharm Policy Pract. 2017 Sep 12;10:29.

Breaks



Agenda

The First 30 min.	The Next hour:	The Hour after that	The Last 30 min.
Why We Are here	Starting Patients on Opioids	Prescribing Opioids	The latest opioid bill
	-	Opioid equivalents	
The current situation	Assessment of Need	Testing: Urine	How to help the Heroin users
	Assessment of Risk	Pill counts	
	BOP	Stopping Opioids	

Contracts

Initial Dosing

Controlled Substances Act, (1970)

WV Code: Chapter 60A

Schedule	Definition	Examples	WV Rx Authority
1	Drugs with potentially severe physiological and psychological dependence. Considered to have no acceptable medicinal qualities.	Heroin, Marijuana, MDMA (ecstasy), Lysergic acid diethylamide (LSD), GHB (date rape drug), Mescaline, Cathinone (used in bath salts), Peyote, Psilocybin and psilocin (mushrooms)	(For Details check w/ Licensing Boards)
2	Commonly abused and causing dependency. They have a legitimate medical use. Must be prescribed to a patient by their provider and received from a pharmacist	Cocaine, OxyContin, Dilaudid, Methadone, Fentanyl, Vicodin, Methamphetamine, Dexedrine, Adderall, Ritalin	MD/DO
3	Drugs with a moderate to low potential for dependence and have accepted medicinal qualities. Only legally obtained with a provider's prescription.	Ketamine, Tylenol with codeine , Buprenorphine (Suboxone, Subutex), Anabolic steroid, Testosterone,	MD/DO. PA: Prescribe. NP Prescribe, Dispense, Administer
4	Less chance of addiction or abuse. Providers allowed to include 5 refills in a 6 month period without additional consultation.	Xanax, Valium, Klonopin, Ambien, Sonata, Lunesta, Phenobarbital (long acting barbiturate), Modafinil (Stimulant-like drug), lomotil	MD/DO. PA: Prescribe. NP Prescribe, Dispense, Administer
5	Lowest likelihood for abuse, don't require a prescription and may be refilled.	Robitussin AC, Pyrovalerone (for chronic fatigue/ appetite suppressant), Some anticonvulsants (Lyrica, gabapentin)	MD/DO. PA: Prescribe. NP Prescribe, Dispense, Administer

Initial Dosing

Non-opioids

Seldom should pain be treated w/ opioids alone.

There is **A level evidence** that **TCA or SSNRIs** should be included in patients with **chronic** nonterminal pain with a neuropathic component.



https://www.vivehealth.com/blogs/resources/best-ice-pack-for-knee


Opioids should be initiated as a trial, Continue IF:

Progress is documented toward functional goals, and

There is no evidence of complications, including misuse or diversion.



C level evidence

Expect Adverse Effects:

Most Common - Constipation Greatest Mortality - Respiratory Depression Other serious Mortality - Dependence, Hyperalgesia, Addiction

Other concerns: Sedation, Falls, Hypogonadism, Sweating, Miosis, Urinary Retention.

Why Respiratory Depression?

When opioid receptors in the **locus coeruleus** (brainstem) are activated they **prevent the release of noradrenaline** – decreasing alertness and blood pressure, increasing drowsiness, slow respiration (breathing), and induce analgesic (pain relieving) effects.



https://www.workithealth.com/blog/science-of-suboxone.https://en.wikipedia.org/wiki/Locus_coeruleus.

Why Respiratory Depression?

Opioid receptor activation in the **nucleus accumbens releases dopamine**, stimulating feelings of pleasure.



Expect Adverse Effects:

Identify Risk of Respiratory Depression

- Elderly, Debilitated
- Co-administered with other Resp Depressants
- Opioid Naive patients
- Contraindicated in those with Respiratory Suppression risks (COPD?)



http://oxygenadvantage.co.za/2017/02/15/ simulate-high-altitude-training-acclimatization/

Expect Adverse Effects:

Greatest Mortality-Respiratory Depression

- Discuss risk with patient
- Explain how hypercapnia exacerbates the sedating effect of opioids
- Urge supervision during initial use
- Encourage immediate use of 911 if respiratory depression suspected
- Offer Opioid Antagonists-Naloxone

Low, Slow, and Steady

Stabilize patient with one opioid.

Limit continuous use of short-acting opioids for breakthrough therapyespecially when transitioning to LA therapy.

Avoid polypharmacy with multiple opioids or co-treatment with benzodiazepines.

Sustained-release preparations..

Offer more consistent drug levels.

Use caution when a patient demands only short-acting medication.

High potential for abuse or diversion:

fentanyl (Duragesic) patches oxycodone (Roxicodone) methadone (but easily monitored)

Lower risk, and has less abuse potential: sublingual or transdermal buprenorphine

Black Box Warnings:

All opioid agonist-

- Addiction, abuse, misuse.
- Respiratory Depression.
- Accidental Ingestion.
- Neonatal withdrawal syndrome.
- CYP450 3A4 interactions.
- Risk of Concomitant use w/ Benzo./ CNS Depressants.

Acetaminophen warning-for acute liver failure.

MOA: Opioid Receptor Agonist.

Safety and Monitoring

Renal Dosing: Cr at baseline, then if severe renal disease or >65YOA check periodically.

Hepatic Dosing: if acetaminophen check LFTs, esp if severe hepatic disease.

Pregnancy/Lactation: may result in androgen deficiency-limited studies. Weigh risk/benefit if prolonged use. Risk of NAS. The risk of fetal harm is low. Acetaminophen is analgesic drug of choice while breast feeding.

Simplify Dosing

Consolidate any other opioid therapy into one medication using an **equianalgesic calculator** (narculator.com).

When exceeding a **morphine equivalent of 100 mg per day**:

-Use extra caution.

-Consider referral to a pain management team.

D. BERLAND, MD, and P. RODGERS, MD, Rational Use of Opioids for Management of Chronic Nonterminal Pain. Am Fam Physician. 2012 Aug 1;86(3):252-258

Low, Slow, and Steady

Morphine: should be the 1st choice for chronic potent opioid therapy. **Morphine doses are the units on which opioid equianalgesic calculations are based**.

Side Effects: constipation, nausea, pruritus, and drowsiness, all of which are more common than morphine allergy.

Use with caution in patients with renal failure.

D. BERLAND, MD, and P. RODGERS, MD, Rational Use of Opioids for Management of Chronic Nonterminal Pain. Am Fam Physician. 2012 Aug 1;86(3):252-258

Butalbital/Acetaminophen

Brand Name: Bupap, Allzital

DEA Schedule II-V, status by state laws

MOA: Butalbital produces sedation/Selective COX-2 inhibitor. **Half-life 35 hours.**

Tension HA: 1-2 tabs PO q 4h prn. Limit to <300mg/day butalbital, 1g/4hrs and 4 g/day acetaminophen





Butalbital/Acetaminophen/Caffeine/Codeine

Brand Name: Fioricet with Codeine, 50/300/40/30

DEA Schedule III status by state laws

MOA: Butalbital produces sedation/Selective COX-2 inhibitor/binds to opioid receptors.

Tension HA: 1-2 caps PO q 4hrs prn. Max 6 caps a day. Limit to <300mg/ day butalbital, 1g/4hrs and 4 g/day acetaminophen, 360 mg/day codeine.



Taper: 25-50% q 2-4 days

Acetaminophen/Codeine

Brand Name: Tylenol No. 3 (300/30mg)

DEA Schedule III with Black Box warnings

MOA: Selective COX-2 inhibitor /Binds to Opioid receptors

Mild to Mod pain:15-60mg of codeine PO q 4-6hrs PRN, >60mg not more effective.



Tramadol

Brand Name: Ultram (50mg, ER 100, 200, 300mg)

DEA schedule IV, Black Box warnings

Half-life: 6-8 hours, Renal Dosing CrCl < 30.

MOA: Binds to MU Opioid receptors (Central opioid agonist) and inhibits Norepinephrine/serotonin reuptake.

Mod-severe pain: Start 25 mg PO q AM. Increase 25 mg Q 3 days. Titrate to Q 4 hrs., Max 400mg. PRN, >60mg not more effective.

Chronic, Mod-severe Pain: ER PO Q day increase by 100 mg/day q 5 days, Max of 300 Q day. Conversion from IR 1:1



https://drugsdetails.com/wp-content/uploads/2016/03/tramadol-50mg-100ct-3.jpg

Tramadol-Associated Deaths



The opioid painkiller Tramadol has increased from less than **1 million pills in 2011 to 35.7 million last year..**

"It's way less potential for abuse, way less diversion," (Mike) Goff said.

- Eric Eyre WV Gazette. Jan 21, 2017

https://www.wvgazettemail.com/news/health/opioid-alternative-linked-to-spike-in-wv-overdose-deaths/article Eric Eyre Jan 21,2017 WV Drug Overdose Deaths Historical Overview 2001-2015. Jim Justice, Bill Couch, Rahaul Gupta, MD. August 17, 2017.

Hydrocodone/Acetaminophen

Brand Name: Norco, Vicoden, Lortab, etc.

DEA Schedule II

Pain, Moderate-Moderate Severe 2.5-10mg hydrocodone PO q**4**-6hrs PRN. DO NOT Exceed 1g/4hr or 4 g/ day of acetaminophen from all sources



Oxycodone/Acetaminophen

Brand Name- Percocet. An alternative for patients with morphine intolerance or allergy.

DEA Schedule II.

Pain, Moderate-Moderate Severe 2.5-10mg oxycodone **PO 6hrs PRN**. May use Q 4 four hours for uncontrolled pain/tolerance.



Oxycodone

An alternative for patients with morphine intolerance or allergy.

Has a higher risk of abuse use with caution in patients with higher risk scores.

Long-acting oxycodone: not recommended for patients with chronic pain because it is not truly long-acting, is expensive, and has a high street value.



Oxycodone

Brand Names: Roxicodone, Oxycontin

DEA Schedule II

Pain, Mod-Severe: 5-15mg PO q 4-6hrs, PRN, Titrate slowly in elderly, (renal). Taper dose 25-50% q 2-4 days.

Pain Severe, Chronic: Start 10 mg ER PO q 12 increase 25-50% q1-2 days. Titrate slowly in elderly. Reduce dose 50% in debilitated pt > 65YOA. >40mg ER for use in opioid tolerant patients only.



Transdermal Fentanyl

More steady, may be a better alternative, it is expensive and can produce tolerance relatively quickly. DO NOT use on opioid naive patients.

DEA/FDA schedule II

Fentanyl is lipophilic, and absorption is affected in patients with little subcutaneous fat and in those prone to edema at application sites



https://www.ctvnews.ca/health/fentanyl-patch-return-program-saves-lives-ontario-politician-says-1.2536908

Transdermal Fentanyl

The pkg insert has conversion tables. Adjust dose after three days, then no more frequently than Q 6 days. Do not cut patch.

Start lower dose in the elderly. Renal/Hepatic dosing-moderate impairment, start dose at 50%.



To discontinue: Taper dose 50% q 6days.

Chris Christou, Rema A Oliver, John Rawlinson, William R. Walsh Transdermal fentanyl and its use in ovine surgery. Research in Veterinary Science. Volume 100, June 2015, Pages 252-256

Methadone

Effective for many patients, may produce less tolerance than other opioids.

DEA/FDA schedule II,

It is inexpensive, long-acting, and has a combination of opioid and *N*-methyl-Daspartate receptor activity that may make it **a good choice for patients with mixed somatic and neuropathic pain.**

However, physicians who prescribe methadone must be familiar with its use.

D. BERLAND, MD, and P. RODGERS, MD, Rational Use of Opioids for Management of Chronic Nonterminal Pain. Am Fam Physician. 2012 Aug 1;86(3):252-258

Methadone

Unique pharmacokinetics!

Very **long elimination half-life**(12 hrs.), and its MME conversion ratio increases as dosages increase.

Jan Methadone Hydrochioride DTF Img/Ind Orai Solution

Starting dosages in opioid-naive patients are 2.5 to 5 mg q 8-12 hours.

https://www.saukvalley.com/2018/04/24/lawmakers-push-to-havemedicare-cover-methadone-treatment-to-combat-opioid-addiction/aiwdh6z/

Methadone

Brand Name: Methadose, 40mg dispersible tab

Can be used for treatment of **opioid dependence**

Start: 15-30 mg PO X1 then 5-10 mg PO q 2-4 hours PRN.

Max: 40 mg on day 1, stabilize dose Q 2-3 days, **then decrease dose** by up to 20% q 24-48 hours. Document if using > 40 mg.

D. BERLAND, MD, and P. RODGERS, MD, Rational Use of Opioids for Management of Chronic Nonterminal Pain. Am Fam Physician. 2012 Aug 1;86(3):252-258

Methadone

After initial control of symptoms, dosages should be titrated slowly and no more than once per week.

Side Effects: Methadone can prolong the QT interval, avoid co-use with other QT-prolonging medications. Serum drug levels can be used for monitoring.

Methadone does not interfere with urine testing for other opioids.



Methadone

Onset of Action-0.5-1 hour.

Peak effect: 1-7.5 hours.

Steady state w/ continuous dosing: 3-5 days

Methadone can prolong the QT interval, avoid co-use with other QTprolonging medications. Serum drug levels can be used for monitoring.

Methadone:

Metabolized by CYP 3A4

Elimination of methadone is **by hepatic metabolism**, followed by renal and fecal excretion.

Transformed to :

2-ethylidene-1,5-dimethyl-3,3diphenlypyrroline (EDDP) and 9 other metabolites. So plasma concentrations are **increased** by:

Macrolides, fluoroquinolones, SSRIS, TCAs (decrease dose by 25%), and

Decreased by:

Antiepileptics, Antipsychotics, antiretrovirals. (encourage rescue medications)

https://www.painweek.org/assets/PAINWeekEnd%20Slides/2018/Dallas/ Saturday_06_IV%20Methadone%20(Aljassem).pdf



Buprenorphine Transdermal

Brand Names: Butrans

DEA/FDA schedule III

Dosed by Equivalents:

Opioid Naïve: 5 mcg patch Q 7 days.

<30 MME mg/day: Start 5 mcg patch, increase q 72 hours. Max is 20 mcg.

30-80 MME mg/day: Start 10mcg patch, increase q 72 hours. Max is 20 mcg.

Half Life: 26 hours. Watch Resp Depression onset-24-72 hours



20mcg/hour

http://www.newbridgerecovery.com/spotlight-buprenorphine-patches

Buprenorphine

DEA/FDA schedule III partial opioid agonist that is less likely to produce tolerance.

It is effective for treatment of pain, has lower abuse potential, and is easily monitored.

It is expensive, and its use requires special prescriber training (except for the transdermal patch).

May use while breast feeding.





Buprenorphine

Sublingual Form

Used for opioid dependence. NOT for Maintenance therapy.

Begin: 8-12 hrs. after last opioid use or per symptomsStart: 2-8 mg SL Q day X 1 day,Then: 8-16 mg Q day X 1-2 days,

Consider 50% reduction for Hepatic impairment.



Buprenorphine

Brand Name: Buprenex

Max IV dose 300 mCg q6-8 hrs. May repeat 300 mcg after 30-60 min.

Max IM dose 600 mcg Q 6-8 hrs.

Decrease dose 50% if Resp Dz or elderly, debilitated. EKG if QT interval is concern. Taper gradually if long term use.



Buprenorphine/Naloxone

Suboxone

Used for opioid dependence.

MOA:

Buprenorphine: agonist at Delta receptors, Partial Agonism at MU Receptors, and antagonistic at Kappa receptors. (opioid agonist-antagonist)

Naloxone: opioid antagonist

Consider 50% reduction for Hepatic impairment.





Buprenorphine/Naloxone

Brand Name: Suboxone

Used for opioid dependence. NOT for Maintenance therapy.

Begin: 8-12 hrs. after last opioid use or per symptomsStart: 2-8 mg SL Q day X 1 day,Then: 8-16 mg Q day X 1-2 days,

Consider 50% reduction for Hepatic impairment.



Gabapentin

Brand Name: Neurontin

Scheduled-IV. States regulate for association with overdoses.

MOA: blocks voltage dependent calcium channel

Post Herpetic Neuralgia: Start 300 mg PO Q Day X 1 day, then 300 mg PO BID, then 300 Mg TID, Max 1800 mg. Taper dose over 7 days to D/C.



https://www.painnewsnetwork.org/stories/2016/1/30/lyrica-and-neurontin-face-uk-restrictions
Gabapentin

Neuropathic Pain:

```
Start 300 mg PO Q Day X 1 day,
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Then 300 mg PO BID,

Then 300 mg TID. Max 3600 mg.

Taper dose over 7 days to D/C.



Neurontin Associated w/ Opioid Overdose?

A **population-based nested case-control study** among opioid users who were residents of Ontario, Canada, between August 1, 1997, and December 31, 2013 was published in 2017.

Cases, defined as **opioid users who died of an opioid-related cause**, were matched with up to 4 controls.

Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study. PLoS Med. 2017 Oct 3;14(10).

Neurontin Associated w/ Opioid Overdose?

After multivariable adjustment, gabapentin use was associated with a nearly **60% increase in the odds of opioid-related death** relative to no concomitant gabapentin use.

What about in WV..?

Gomes T, Juurlink DN, Antoniou T, Mamdani MM, Paterson JM, van den Brink W. Gabapentin, opioids, and the risk of opioid-related death: A population-based nested case-control study. PLoS Med. 2017 Oct 3;14(10).

WV Gabapentin Associated Deaths



https://dhhr.wv.gov/oeps/disease/ob/documents/opioid/wv-drug-overdoses-2001 2015.pdf

Data Source. WV Health Statistics Center, Vital Statistics System 2015 Preliminary Data

Pregabalin

Brand Name: Lyrica

DEA Scheduled V. States may regulate for association with overdoses.

MOA: Binds Alpha2-Delta subunit of voltage dependent calcium channel reducing neurotransmitter release

Diabetic Neuropathic Pain Start 50 mg PO TID X 1 week, then 100 mg PO TID if needed. Taper dose over 7 days to D/C.

Post Herpetic Neuralgia or Other Neuropathic Pain Start 75 mg PO BID X 1 week, then 150 mg PO BID X 2 week, then 300 mg BID if needed. Taper dose over 7 days to D/C.

Recent Lyrica Concerns

A 2018 study describe **Australian patterns of pregabalin use** and intentional poisoning and identify people potentially at high risk of misuse.

Pregabalin dispensing **increased by between 2013 and 2016** and there were 88 pregabalin-associated deaths, a 57.8% yearly increase per year of intentional pregabalin poisonings.

Cairns R, Schaffer AL, Ryan N, Pearson SA, Buckley NA. Rising pregabalin use and misuse in Australia: trends in utilisation and intentional poisonings. Addiction. 2018 Aug 11.

Recent Lyrica Concerns

Patients overdosing on pregabalin commonly co-ingested opioids, benzodiazepines, and illicit drugs, and had high rates of psychiatric and substance use comorbidities.



http://prescriptionassistance123.com/blog/ lyrica-prescription-assistance-programs/

14.7% of pregabalin users were at high-risk of misuse.

Cairns R, Schaffer AL, Ryan N, Pearson SA, Buckley NA. Rising pregabalin use and misuse in Australia: trends in utilisation and intentional poisonings. Addiction. 2018 Aug 11.

Recent Lyrica Concerns

Those at high-risk of misuse were more likely to be:

- Younger
- Male
- Co-prescribed benzodiazepines or opioids
- Have more individual prescribers, and
- Have higher pregabalin strengths dispensed

Cairns R, Schaffer AL, Ryan N, Pearson SA, Buckley NA. Rising pregabalin use and misuse in Australia: trends in utilisation and intentional poisonings. Addiction. 2018 Aug 11.

Naloxone

Routes: Pre-filled syringe, Vial, intranasal routes

MOA: opioid antagonist, blocks opioids. ½ life is 60-90 minutes.

Opioid Overdose (child or adult):

Narcan Nasal Spray: 4 mg dose sprayed into one nostril

Naloxone Nasal via Atomizer: 2 mg dose sprayed into the nostrils (half in each nostril)

Evzio Auto-injector: 2 mg dose of naloxone injected into the outer thigh

Call 911, Repeat after 4 min if symptoms reoccur.

https://dhhr.wv.gov/office-of-drug-control-policy/Documents/Naloxone%20Video%20End%20User%20approved%2011-2019.pdf



Initial Dosing-Naloxone



https://dhhr.wv.gov/office-of-drug-control-policy/Documents/Naloxone%20Video%20End%20User%20approved%2011-2019.pdf

Initial Dosing-Naloxone



https://dhhr.wv.gov/office-of-drug-control-policy/Documents/Naloxone%20Video%20End%20User%20approved%2011-2019.pdf



Kanawha: 1905

Cabell: 1608

Berkeley: 1154

Break



Agenda

The First 30 min.	The Next hour:	The Hour after that	The Last 30 min.
Why We Are here	Starting Patients on Opioids	Prescribing Opioids	The latest opioid bill
		Opioid equivalents	
The current situation	Assessment of Need	Testing:	How to help the Heroin users
	Assessment of Risk	Pill counts	
	BOP	Stopping Opioids	
	Contracts		

https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf

Continuing Opioid Prescriptions:



CDC Checklist

If renewing opioids without patient visit check that a return visit is scheduled ≤ 3 months from last visit



https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf

Reassessing at Return Visit:

- Assess pain and function (e.g., PEG); compare results to baseline.
- Evaluate risk of harm or misuse:
- Observe patient for signs of over-sedation or overdose risk.
 If yes: Taper dose.
- Check PDMP.
- Check for opioid use disorder if indicated (eg, difficulty controlling use). – If yes: Refer for treatment.

Reassessing at Return Visit:

- **Check** that non-opioid therapies optimized.
- **Determine** whether to continue, adjust, taper, or stop opioids.
- Calculate opioid dosage morphine milligram equivalent (MME).

If \geq 50 MME /day total (\geq 50 mg hydrocodone; \geq 33 mg oxycodone), increase frequency of follow-up; **consider offering naloxone**.

Avoid \geq 90 MME /day total (\geq 90 mg hydrocodone; \geq 60 mg oxycodone), or carefully justify; consider specialist referral. Schedule reassessment at regular intervals (\leq 3 months).

https://www.cdc.gov/drugoverdose/pdf/Assessing_Benefits_Harms_of_Opioid_Therapy-a.pdf

Keeping Patients on Opioids-The PEG

Checking for Functional Improvement

What number, from 0 - 10 best:

Q1: Describes your <u>Pain</u> in the past week?

Q2: Describes how, during the past week, pain has interfered with your **<u>Enjoyment</u>** of life?

Q3: Describes how, during the past week, pain has interfered with your **<u>General activity</u>**?

PEG score = <u>30% improvement from baseline is clinically meaningful</u>.

Therapeutic Changes

As with any medication, consider increasing or decreasing dosage, or even drug switching to reach therapeutic goals.

If medication not resulting in improved function, can begin to taper off medication.

If medication is helping, consider a lower or more sustainable dose.

Therapeutic Changes

Why Change from Short Acting to Long Acting?

- Reduce numbers of Pills.
- Improve control-consistent blood levels, Longer control.
- Sleep disruption caused by pain and by opioid withdrawal.
- Improved adherence.

Caution: Higher Dosage, Higher Risk

Higher dosages of opioids are associated with higher risk of overdose and death—even relatively low dosages (20-50 morphine milligram equivalents (MME) per day) increase risk.

Higher dosages haven't been shown to reduce pain over the long term.

One randomized trial found **no difference in pain or function** between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME).

https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Caution: Higher Dosage, Higher Risk

In a national sample of Veterans Health Administration patients with chronic pain receiving opioids from 2004–2009.. patients who died of opioid overdose were prescribed an average of 98 MME/day, while other patients were prescribed an average of 48 MME/day.

https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Determine the total daily amount of each opioid the patient takes.

Convert each to MMEs—multiply the dose for each opioid by the conversion factor.

Add them together.

Warning: Do not use the calculated dose in MMEs to determine dosage for converting one opioid to another—the new opioid should be lower to avoid unintentional overdose caused by incomplete cross-tolerance and individual differences in opioid pharmacokinetics. Consult the medication label.

Calculating morphine milligram equivalents (MME)

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR	
Codeine	0.15	
Fentanyl transdermal (in mcg/hr)	2.4	
Hydrocodone	1	
Hydromorphone	4	
Methadcne		
1-20 mg/day	4	
21-40 mg/day	8	
41-60 mg/day	10	
≥ 61-80 mg/day	12	
Morphine	1	
Oxycodone	1.5	
Oxymorphone	3	

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

50 MME/day:

90 MME/day:

50mg Hydrocodone: 10 tablets of hydrocodone/ acetaminophen 5/300

33mg of oxycodone: 2 tablets of oxycodone sustained-release 15 mg

12mg of methadone: <**3** tablets of methadone 5 mg

90mg Hydrocodone: 9 tablets of hydrocodone/ acetaminophen 10/300

60 mg of oxycodone: 2 tablets of oxycodone sustained-release 30 mg

20 mg of methadone: 4 tablets of methadone 5 mg

Case Study:

Your employer has recently lost three long established family physicians and management has informed you that, as a physician, you will have to assume the care of their patients on controlled medications. Your area has lost it's only non-interventionist pain specialist to a recent drug sweep.

On Monday, after this conference, the first patient presents. He's a 56 years of age former timber worker on disability for the last 22 years after being crushed by a tree and suffering a flailed chest and multiple vertebral fractures. He smokes, has COPD, his A1C is 9.8% and his LDL is 140.

He's on Metformin, Pro-air, and hydrocodone 5 mg TID. He's been on these meds for the last 6 years. He has refused preventative efforts and your EMR informs you of multiple care gaps including colonoscopy and immunizations.



Preparing for the 15 minute visit (he's established in the system) you prioritize your efforts.

Which of the following is the most worrisome health concern?

A) His socioeconomic statusB) His lack of preventative careC) His uncontrolled diabetesD) His chronic opioid use

Rx Opioid Overdose 17.2 per 100,000 Diabetes mellitus 47.6 per 100,000 Diseases of heart 267.0 Malignant neoplasms 256.3 Chronic lower respiratory diseases 92.6 Cerebrovascular diseases 58.3



You decide to focus on his diabetes during todays visit, but recognize you must address his opioid use as well.

You decide to make an effort to reduce his opioid use by limiting his number of pills but not his total MMEs.

What is his current MME use:

A) 50 MME
B) 30.5 MME
C) 15 MME
D) 5 MME



What choice or choices offer an equivalent MME?

A) Oxycodone 7.5mg BID

B) Hydrocodone 7.5 mg BID

C) Oxycodone 10mg QHS

D) Hydrocodone 10mg Q AM

- Taking a controlled substance for a long period of time (new patients)
- Refusing to grant permission to obtain old records or communicate with previous physicians

 Demonstrating reluctance to undergo a comprehensive history, physical examination, or diagnostic testing (especially urine drug screening)

- Requesting a specific drug (often because of the higher resale value of a brand name)
- Professing multiple allergies to recommended medications
- Resisting other treatment options



Other aberrant behavior

- Issuing threats or displaying anger
- Targeting appointments at the end of the day or during off hours (nights or weekends)



• Giving excessive flattery

- Calling and visiting a physician's associates
- Repeatedly losing a prescription
- Requesting a dose escalation
- Demonstrating noncompliance with prescription instructions
- Demonstrating other evidence of alcohol or illicit drug misuse



Testing:

Schedule patients additional time:

For example, writing a new prescription for a controlled substance would require evaluating the patient for a history of abuse or addiction, and may include screening.





Schedule Patients Additional Time:

A history of substance misuse **does not preclude** opioid analgesia;

however, patients in recovery may require boundary setting, clear delineation of the rules, and participation in an active recovery program.

Urine drug screening is also useful before increasing patients' dosages of analgesics or referring patients to a pain or addiction specialist.


Schedule Patients Additional Time:

A **negative urine drug screening** result **does not exclude** occasional or even daily drug use.

Infrequent drug use is difficult to detect regardless of testing frequency, the benefits of frequent drug testing are greatest in patients who engage in moderate drug use.



There are two main types of Urine Drug Screening:

- immunoassay testing, and
- chromatography (i.e., gas chromatography/mass spectrometry [GC/ MS] or high-performance liquid chromatography
- Immunoassay tests are the preferred initial test for screening. They use antibodies to detect the presence of drugs. These tests can be processed rapidly, are inexpensive.

Opioids Metabolism



https://premierbiotech.com/innovation/opi-vs-oxy/

Opioids Metabolism



http://insourcedx.com/services/compliance/udt/drug_metabolism.html

Benzodiazepines Metabolism



Lorazepam 14hr ½ life

Alprazolam 11-20hr ½ life

→ Alpha-hydroxy alprazolam

http://insourcedx.com/services/compliance/udt/drug_metabolism.html

Urine Drug Screens

The most commonly ordered drug screens are for:

- Cocaine metabolites
- Amphetamines
- Phencyclidine
- Marijuana metabolites
- Opiate metabolites.

The **U.S. Department of Transportation requires testing for these five substances** when conducting urine drug screenings for transportation employees



https://www.protocoldrugtesting.com/

Urine Drug Screens

The Accuracy of Immunoassay It varies..

-high predictive value for marijuana and cocaine,

-lower predictive value for opiates and amphetamines.

Many commonly prescribed medications can cause positive immunoassay tests



https://www.wcpo.com/news/national/urine-screens-are-big-business-report-shows-costs-quadrupled-from-2011-to-2014

Reducing UDS Tampering

- Request removal of any unnecessary outer clothing
- Remove anything in the collection area that could be used to adulterate or substitute a urine specimen
- Request the display and removal of any items in the patient's pockets, coat, hat, etc.



https://www.synthetix5.com/synthetic-urine-belt-kit/ https://peepack.com/product/peepack-sterile-urine-kit-3-pack/

Reducing UDS Tampering



- Require all other personal belongings (e.g., briefcase, purse) to remain with the outer clothing
- Instruct the patient to wash and dry his or her hands (preferably with liquid soap) under direct observation and not to wash again until after delivering the specimen
- Place a bluing agent in the commode and turn off the water supply to the testing site

Methods and Criteria for UDS

Collection Methods and Criteria

- Direct observation of specimen collection (when required)
- Sample size: 30 mL or more
- Temperature: between 90°F (32.2°C) and 100°F (37.7°C)
- Urine pH: 4.5 to 8.5
- Use of an approved chain of custody form to track specimen handling

Methods and Criteria for UDS

Findings Suggestive of Adulterated, Diluted, or Substituted Specimens

General: Temperature < 90°F or > 100°F Unusual appearance (e.g., bubbly, cloudy, clear, dark)

Adulterated: Nitrite concentration >5 mg per dL Urine pH < 3 or \ge 11

Diluted/Substituted: Creatinine concentration < 2.0 mg per dL

Opiates

Dextromethorphan, fluoroquinolones, quinine, verapamil‡

diphenhydramine, **poppy seeds,** rifampin,

Duration of Detectability: One to three days

‡—In methadone assays only.

Phencyclidine

dextromethorphan

diphenhydramine ibuprofen imipramine

ketamine

thioridazine

venlafaxine

meperidine

tramadol

Duration of Detectability: 7 to 14 days

Benzodiazepines

Oxaprozin and Sertraline

Duration of Detectability: 3 days for short-acting agents (e.g., lorazepam). Up to 30 days for long-acting agents (e.g., diazepam).

Cocaine

Topical anesthetics containing cocaine

Duration of Detectability: 2-3 days with occasional use, Up to 8 days with heavy use.

Amphetamines

Amantadine (Symmetrel), Bupropion (Wellbutrin), Chlorpromazine, Desipramine (Norpramin), Fluoxetine (Prozac),

L-methamphetamine (in nasal decongestants*), Labetalol (Normodyne), Methylphenidate (Ritalin), **Phentermine,** Phenylephrine, Phenylpropanolamine, **Promethazine**(Phenergan), Pseudoephedrine, Ranitidine (Zantac), Thioridazine, **Trazodone** (Desyrel)

Duration of Detectability: Up to 3 days. *Current immunoassays have corrected the false-positive result for nasal decongestants containing L -methamphetamine.

Tetrahydrocannabinol

Dronabinol -(Marinol),

NSAIDs-ibuprofen, naproxen (Naprosyn), and sulindac (Clinoril),

PPIs- (pantoprazole [Protonix])

Duration of Detectability: 3 days with single use, 5-7 days with use around 4X per week, 10-15 days with daily use, **More than 30 days with long-term, heavy use**

The main goal of a pill count is to prevent diversion, misuse and abuse.



https://www.affirmhealth.com/blog/pill-counts-a-tool-for-medication-adherence-and-diversion-reduction

Request that the patient bring all unused pills to an appointment in the original container.

Notify the patient the day before or the same day as the appointment.

Check if the number of pills in the container match what the expected number would be if the patient followed the prescribed dosage.

Do Pill Counts Work?

One recent, but small, study followed frequency of medication nonadherence using methods including **pill counts**.

The results: Patient indicated they missed 25% of their prescribed doses. However, **objective measures including pill counts showed that participants missed 40% to 43% of their prescribed doses**. (p < 0.01 for pill counts).

Conclusions: individuals tend to overestimate their adherence when self-reporting. Physicians should exercise caution with patient report of adherence and **use objective measures when possible.**

Schaefer MR, Wagoner ST, Young ME, Rawlinson AR, Kavookjian J, Shapiro SK, Gray WN. Subjective Versus Objective Measures of Medication Adherence in Adolescents/Young Adults with Attention-Deficit Hyperactivity Disorder. J Dev Behav Pediatr. 2018 Jul 11.

Do Pill Counts Work?

One case study on the topic revealed two concerns:

1) The **assumption** that if a patient has the correct number of pills for that point in a prescription interval then they are unlikely to be abusing their opioids.

2) Patients describe <u>short term rental of opioids</u> from illicit dealers in order to circumvent pill counts.

The study concluded that :

Pill counts do not assure non-diversion of opioids and provide additional cash flow to illicit dealers.

Viscomi CM, Covington M, Christenson C. Pill counts and pill rental: unintended entrepreneurial opportunities. Clin J Pain. 2013 Jul;29(7):623-4.

Do Pill Counts Work?

A 2012 study evaluated <u>adherence to practice guidelines</u> including the use of **Universal Precautions**, in primary care clinics located in Caldwell County, NC. The study's intervention was the:

- 1) signing of pain contracts;
- 2) Requiring of patients to undergo random urine drug testing; and
- 3) requiring of random pill counts.
- 4) Use of PDMP

The outcome measure was opioid pill confiscations by the County Narcotics before, during, and after intervention.

Bujold E, Huff J, Staton EW, Pace WD. Improving use of narcotics for nonmalignant chronic pain: a lesson from Community Care of North Carolina. J Opioid Manag. 2012 Nov-Dec;8(6):363-7.

Do Pill Counts Work?

The North Carolina study showed **opioid pill confiscations decreased by 300%.**

60% of providers report an improvement in the management of chronic pain patients,65 % increased confidence when treating patients with chronic pain; and,60% reported using the opioid registry.

Pill counts <u>when combined with Universal Precautions</u> did result in improved management of opioid use.

Bujold E, Huff J, Staton EW, Pace WD. Improving use of narcotics for nonmalignant chronic pain: a lesson from Community Care of North Carolina. J Opioid Manag. 2012 Nov-Dec;8(6):363-7.



Your 55 YO tree harvester has returned for his second visit. His A1C is now 10.2% You refer him to a local endocrinologist and focus on his opioid use.

What is the best way to determine he's using his opioids as ordered?

A) UDS

B) BOP

C) A pill count

D) the word of his wife who is here to attest to his need of opioids and his compliance



To set the appropriate expectations, you complete a UDS today. The results come back the next day and show THC.

At this point the best course of action is to:

- A) Inform the patient he will be dismissed.
- B) Repeat the test.
- C) Order a confirmation on the same sample.
- D) Ask the patient to return for an interview.

"It must be done slowly and carefully," says Adm. Brett P. Giroir, MD, assistant secretary for health for HHS. "If opioids are going to be reduced in a chronic patient it really needs to be done in a patient-centered,



https://twitter.com/aafp 11 Oct 2018 With Dr. Cook Physician of the

HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

After nucleasing new year lar movel has a decade, an and optical paramptions in the black of these period at 255 million in 161 than their decrement of the millionic 260°. More the lines optical analysis, presenting can be orbit millionic and parameters well as publisheadth when spicial analysis, use is limited to situation when benefits of spin-should likely to suffer prior and are reacted on significant presenting charges, such and are reaction, clear weak-the or other situation and the particular structures in a mountability deliberative, costs beam of longture optical analysis, have potential to have or put patients with the lines much in a mountability deliberative, costs beam or put patients with the server is more costs of the server of the server of the server and the reactions of the server of the server of the server in the server is a mountability, deliberative, costs beam or put patients with the server is many server.

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needs.⁴⁷⁹Locadmetion across the best the constant is critical. Clinicizes have a reportubility to provide or wrange for consultant for averagement of pointer/Spin and opticit deleted positions; and they though never aborden position? *Many* spointer, pulsance follows; compiled from published quidelines there for Constraint for their string quark the Association and the WH of II for our Parther is actioner test quark therapy for Chevil; (Rain) and their particle strends are discussed.

Consider¹⁰ taparing to a reduced opioid dosage, or taparing and discontinuing opioid therapy, when • Pair interact²

- mprever-
- The patient respects decage reduction or discontinuation²²⁰
- Pain and function are not meaningfully improved^{ast}
- The patient is receiving higher opioid draws without exidence of hereofit from the higher of ex²⁰
- The patient have month within and opinish size set?
- The patient experimences its offset W that disinishing solity of New impair function?
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- The painset to recovery medicalizes (in g., beneral-integrated) or has marked conditions (e.g., largedrawes, singr-spread, line discourt, kinney discourt, billitic), advanced apply functionness risk for solverst outcomes¹⁰

 The patient has been mound with opioids for againinged paried (e.g., years), and consultance fit-hears before is under an analysis.

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- Hyperal dependence could with date around the checking strategies in more thank the date and include could with a contract the checking sequences in the strategies with repartice optimized and the prediction of the set of the prediction of the prediction of the set of the prediction of the prediction of the prediction of the set of the prediction of the set of the prediction of the predi
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https://www.npr.org/sections/health-shots/2019/10/10/768914092/dont-force-patients-offopioids- abruptly-new-guidelines-say-warning-of-severe-ri

Consider tapering to a reduced opioid dosage when The patient:

- Requests a dosage reduction.
- Does not have clinically meaningful improvement in pain and function (e.g., at least 30% improvement on the 3-item PEG scale)
- Is on dosages ≥ 50 MME/day without benefit or opioids are combined with benzodiazepines

Consider tapering to a reduced opioid dosage when:

- Patient shows signs of substance use disorder (e.g. work or family problems related to opioid use, difficulty controlling use), Or
- experiences overdose or other serious adverse event, or
- shows early warning signs for overdose risk such as confusion, sedation, or slurred speech.

Tapering plans

Should be **individualized** and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications.



Stopping Opioids-Go Slow

Tapering plans

A decrease of **10% of the original dose per we** is a reasonable starting point.

Slower tapers (e.g., 10% per month) for long term opioid users.

Discuss the increased risk for overdose if patients quickly return to a previously prescribed higher dose
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Stopping Opioids-Consult



Tapering plans

Coordinate with specialists and treatment experts as needed—especially for patients at high risk of harm such as pregnant women or patients with an opioid use disorder.

Use extra caution during pregnancy due to possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal.

Stopping Opioids-Support

Tapering plans

Make sure patients receive appropriate **psychosocial support**.

If needed, work with mental health providers, arrange for treatment of opioid use disorder, and

Offer naloxone for overdose prevention.



Stopping Opioids-Encourage

Let patients know that most people have improved function without worse pain after tapering opioids. Some patients even have improved pain after a taper, even though pain might briefly get worse at first. Tell patients "I know you can do this" or "I'll stick by you through this."



https://drugfree.org/learn/drug-and-alcohol-news/another-opioid-epidemic-challenge-addiction-counselors/

Stopping Opioids-Follow up

Adjust, Monitor, Reduce

Adjust the rate and duration of the taper according to the patient's response.

Don't reverse the taper; however, the rate may be slowed or paused while **monitoring** and managing withdrawal symptoms.

Reduce: Once the smallest available dose is reached, the interval between doses can be extended and **opioids may be stopped when taken less than once a day.**

Despite tapering, **Patients may have withdrawal symptoms when opioids are completely discontinued**. These symptoms should be managed supportively.

Traditional withdrawal management medications such as: clonidine, tramadol, and muscle relaxants are generally ineffective.

Temporary use of **nonbenzodiazepine** sleep aids can be helpful.

Follow-up visits should be scheduled frequently fc ongoing multimodal pain management and encouragement that **function will improve over** weeks to months.



https://www.mooremedical.com/index.cfm?/Trazodone-HCl-Tablets/&PG=CTL&FN=ProductDetail&PID=1143&spx=1

Break


Agenda

The First 30 min.	The Next hour:	The Hour after that	The Last 30 min.
Why We Are here	Starting Patients on Opioids	Prescribing Opioids	The latest opioid bill
		Opioid equivalents	
The current	Assessment of		How to help the
situation	Need	Testing: Urine	Heroin users
	Assessment of Risk	Pill counts	
	BOP	Stopping Opioids	

Contracts

West Virginia Legislature

2ND SESSION OF THE 83RD LEGISLATURE



A summary of **SB 273** is available on the WVBOM website:

https://wvbom.wv.gov/article.asp? id=55&action2=showArticle&ty=CTTS

The entirety of **SB 273**:

https://legiscan.com/WV/bill/SB273/2018



SB 273 was amended during the 2019 by passage of **HB 2768**

HB 2768's amendments to the ORA became **effective on June 7, 2019.**

https://www.wsaz.com/content/news/Members-of-WVaHouse-of-Delegates-respond-to-education-omnibus-bill-passing-in-Senate-505327291.html

- Clarifies that the Opioid Reduction Act applies only to Schedule II opioid drugs;
- Clarifies that the Opioid Reduction Act does not apply to a patient being prescribed, or ordered, any medication in an inpatient setting at a hospital;
- Clarifies that a prescription for a four-day supply of a Schedule II opioid drug issued to a patient in the emergency room for outpatient use is not an initial prescription;

 Clarifies that, "[t]he physical exam should be relevant to the specific diagnosis and course of treatment, and should assess whether the course of treatment would be safe and effective for the patient;"

 Clarifies that a narcotics contract is not required until the issuance of a third prescription for a Schedule II opioid drug and adds a new provision that <u>a narcotics contract must include whether another</u> <u>physician is approved to prescribe to the patient</u>;

 Clarifies that a pharmacist is not responsible for enforcing the requirements of the Opioid Reduction Act;

 Allows for a subsequent Schedule II opioid drug prescription less than six days after the initial prescription; and,

- Amends the ORA in circumstances when a practitioner acquires a patient from another practitioner, at a different practice or practice group. .
- The first Schedule II opioid drug prescription issued by the new practitioner to the acquired patient is considered an initial prescription, such that the prescription must be limited to a seven-day supply, unless the acquiring physician and the previous prescriber are members of the same practice group.

§16-5H-2. Definitions.

"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**. For purposes of this article, "chronic pain" does not include pain directly associated with a terminal condition.

More Definitions..

ARTICLE 3A.

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

"Acute pain" means a time limited pain caused by a specific disease or injury.

"Chronic pain" means a noncancer, non-end of life pain lasting more than three months or longer than the duration of normal tissue healing.

"Pain management clinic" means all privately-owned pain management clinics, facilities, or offices not otherwise exempted from this article and which meet both of the following criteria:

(1) Where in any month more than 50% of patients of the clinic are prescribed or dispensed Schedule II opioids or other Schedule II controlled substances specified in rules promulgated pursuant to this article for chronic pain resulting from conditions that are not terminal; and

(2) The facility meets any other identifying criteria established by the secretary by rule.

"Addiction" means a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Addiction is characterized by inability to consistently abstain; impairment in behavioral control; craving; diminished recognition of significant problems with one's behaviors; interpersonal problems with one's behaviors and interpersonal relationships; a dysfunctional emotional response; and as addiction is currently defined by the American Society of Addiction Medicine.

Steps to Compliance:

- 1. Determine if patient is **exempt**.
- 2. Determine the **type of controlled substance** being used.
- Determine if controlled substance treatment began prior to 1/1/2018.

Who is Exempt?

- Patients with active cancer
- Hospice patients
- Palliative care patients
- Patients in long term care facilities
- Controlled substances being used to treat a substance use disorder
- Patients in an inpatient setting at a hospital-HB 2768

Management Determined by TYPE and TIME

TYPES:

1. Schedule II Opioids,

- 2. Schedule II Non-Opioids-Benzodiazepines, per HB 2768
- 3. Non-Schedule II Opioids, per HB 2768

TIME: Either before or after **1/1/18**

Opioids That Are C II and Began Prior to 1/1/18..

No changes

Yearly review of PDMP and documentation

Physical Exam every **3** months. Not from SB273 but per professional guidelines and standards of care.

Opioids that are Not C II

No changes

Review PDMP prior to prescribing and at least yearly. Document the review.

Examples: Tramadol, Some formulation of codeine

C II Opioids began on/after 1/1/18 **First Prescription**

1. Ask if the patient has a Non-Opioid Advanced Directive? NOAD

- **2.** Inform the patient .. they can fill the Rx in a lesser quantity.
- **3.** Are there multiple serious **risks** from opioids?

4. If the patient is a **minor** then **the parent or guardian must be aware** of the reasons why the prescription is necessary.

5. Limited to **seven** days worth of medication by PCP.

C II Opioids began on/after 1/1/18 **First Prescription -Document:**

- 6. Non-opioid medications that have been tried.
- 7. Non-Pharmacological approaches tried.
- 8. Substance abuse history.
- **9**. Plan for determining the cause of pain.
- **10.** CSMP/PDMP database reviewed.

C II Opioids began on/after 1/1/18 Second Prescription

HB 2768 allows a subsequent prescription **less than six days after issuing the initial prescription**.

HB 2768 provide that the **narcotics contract is not required until the third prescription** for the Schedule II opioid drug.

C II Opioids began on/after 1/1/18 Second Prescription-Document:

1. Rationale for the 2nd Prescription.

2. That there is not an undue **risk** of abuse, addiction or diversion.

3. Discussion of the risks of addiction, dependence, and overdose and the dangers of taking opioids with alcohol, benzodiazepines, or other depressants;

4. **Discussion** of alternative treatments.

C II Opioids began on/after 1/1/18 Third Prescription

1. Consider referral to pain management.

2. Discuss the benefits of being referred and the risks of choosing not to be referred.

3. If the patient declines pain management then you must:

4. **Document: that the patient knowingly declined treatment** from a pain clinic or pain specialist.

C II Opioids began on/after 1/1/18

Third Prescription

Review, every three months,

- the course of treatment,
- any new information about the etiology of the pain, and
- the patient's progress toward treatment objectives and
- document the results of that review.

Periodically make efforts to either..

- stop the use of the controlled substance,
- decrease the dosage,
- try other drugs or treatment modalities and
- document with specificity the efforts undertaken.

Assess the patient risk of dependence and document the assessment.

West Virginia Controlled Substances Monitoring Act §60A-9-7. Criminal penalties; and administrative violations.

(f) Any practitioner who fails to register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database as required .. shall be subject to an administrative penalty of \$1,000 by the licensing board of his or her licensure .. The provisions of this subsection shall become effective on July 1, 2016

Prescribers are required to register with the WVBOP and Check BOPs!!

The WVBOP

Compiles and reports to licensing boards provider prescriber data.

§30-3A-4. Abnormal or unusual prescribing practices.

(a) Upon receipt of the quarterly report .. the licensing board shall notify the prescriber that he or she has been identified as a potentially unusual or abnormal prescriber. The board may take appropriate action, including .. an investigation or disciplinary action based upon the findings .. in the report.

(b) A licensing board may upon receipt of .. information independent of the quarterly report .. initiate an investigation into any alleged abnormal prescribing or dispensing practices of a licensee.

§60A-5-509. Unlawful retaliation against health care providers.

(a) A .. provider has the right to exercise .. professional judgment to decline to .. prescribe narcotics without being subject to actual or threatened acts of reprisal.

(b) It shall be unlawful for any person .. to engage in any form of threats or reprisal .. the purpose of which is to punish, embarrass, deny, or reduce privileges or compensation .. as a result of, or in retaliation for, the refusal of .. that provider to .. prescribe narcotics.

(c) Any person or entity who violates the foregoing .. shall be liable in the amount of three times the economic loss sustained as a direct and proximate result of the reprisal.

Break



- Continue efforts at responsible prescribing.
- Connect patients to new, well funded, statewide efforts at treatment.

Comprehensive Behavioral Healthcare Centers			
United Summit Center - Main Office			
Nental health and substance abuse services for: Harrison Marion Lawis Doddridge Taylor Gimer Bracton and Preston Counties.			
EMRS Health Systems Inc Main Office			
Nental health and substance abuse services for: Layette Monroe Raleigh and Summers Counties.			
Appalachian Community Bealth Center - Main Office			
Mental health and substance abuse services for: Randolph Barbour Upshur and Tucker Counties.			
Eastridge Health Systems - Main Office			
Nental health and substance abuse services for: Cerkeley Jefferson and Morgan Counties.			
HealthWays Inc Main Office			
Nental health and substance abuse vervices for: Brooke and Hancock Counties.			
Logan Minop Area Hental Health Inc. Main Office			
Nental health and substance abuse services for: Logan and Mingo Counties.			
Northwood Health Systems Inc Main Office			
Mental health and substance abuse services for: Marshall Chio and Wetzel Counties.			
Potomac Highlands Guild - Main Office			
Mental health and substance abuse services for: Grant Hampshire Hardy Mineral and Pendleton Counties-			
Prestera Center - Main Office			
Nental health and substance abuse services for: Boone Caball Clay Kanawha Uncoln Logan Nason Putnam and Wayne Counties.			
Seneca Health Services Inc Main Office			
Nental health and substance abuse services for: Greenbuer Nicholas Pocahontas and Webster Countes.			

Improved Funding for Treatment :

Figure 5: Opioid Spending Per Capita FY2017





\$13.29 per person

file:///C:/Users/Tracy/AppData/Local/Microsoft/Windows/INetCache/IE/72LIXKAY/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf

Improved Funding for Treatment :

Figure 6: Opioid Spending Per Capita FY2018



file:///C:/Users/Tracy/AppData/Local/Microsoft/Windows/INetCache/IE/72LIXKAY/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf

Improved Funding for Treatment :



file:///C:/Users/Tracy/AppData/Local/Microsoft/Windows/INetCache/IE/72LIXKAY/Tracking-Federal-Funding-to-Combat-the-Opioid-Crisis.pdf

Get Involved

In the last year's round of funding, the U.S. Department of Health and Human Services awarded agencies in WV more than \$35M to address substance abuse. Those grants include:

State Opioid Response Grants: \$28M to the WVDHHR Expanding Access to Quality Substance Use Disorder and Mental Health Services: \$7.5M to more than 20 WV FQHCs Rural Communities Opioid Response Program: \$400,000 to MU Research and Community Care of WV Behavioral Health Workforce Education and Training Program: \$200,000 to WVU Rural Health Opioid Program: \$179,000 to Community Connections, Inc.

Wendy Holdren, West Virginia receives more than \$35 million to fight opioid epidemic Register-Herald Reporter,

The Role of WV Physicians

- Become accepted partners in the opioid death epidemic.
- Turn the focus to Illegal Medications and addictions.
- Identify at risk patients.
- Guide them to treatment.
- We should be offering MAT, (House Bill 3132 passed in 2019 with goal of making office-based treatment more accessible)

Rapid screening for substance misuse or substance use disorders can be performed in the primary care setting with a validated single-question screening tool. (LOE: C)

Patients with hazardous substance use or substance use disorders may benefit from **brief** counseling by their primary care physician. (LOE: B)

Office-based pharmacotherapy for opioid dependence using buprenorphine is safe and effective. (LOE: A)

A Primary Care Approach to Substance Misuse, B. Shapiro, MD; D. Coffa; and E. McCance-Katz, MD PhD, Am Fam physician. 2013 Jul 15;88(2):113-121.

Patients with substance use disorders may benefit from identification and treatment of comorbid psychiatric disorders. (LOE: A)

Patients with substance use disorders should be routinely screened for intimate partner violence. (LOE: C)

A Primary Care Approach to Substance Misuse, B. Shapiro, MD; D. Coffa; and E. McCance-Katz, MD PhD, Am Fam Physician. 2013 Jul 15;88(2):113-121.

Single-question screen for Substance Use Disorders

"How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?"

If positive you can expand to the 10 question screening tool.

This tool has 90% to 100% sensitivity and 74% specificity for substance use disorder.

Scoring:

1-3 points= moderate risk, monitor and reassess patient.

> 3 points= substance abuse or dependence.
Drug Abuse Screening Test-10

- 1. Have you used drugs other than those required for medical reasons?
- 2. Do you use more than one drug at a time?
- 3. Are you always able to stop using drugs when you want to?
- 4. Have you ever had blackouts or flashbacks as a result of drug use?
- 5. Do you ever feel bad or guilty about your drug use?
- 6. Does your spouse (or parents) ever complain about your involvement with drugs?
- 7. Have you neglected your family because of your use of drugs
- 8. Have you engaged in illegal activities to obtain drugs?
- 9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?
- 10. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding)?

It takes a Community

CDC Director, Dr. Robert Redfield :

"Clearly, this area has seen and experienced the opioid epidemic in the flesh...I think that experience has really galvanized the community here to come together in a thoughtful way to try to develop an approach to make an impact on this epidemic."



http://wvmetronews.com/2018/08/27/cdc-director-visits-west-virginia-to-understand-opioid-crisis-response/

Mutual Help Meetings

Examples and Resources:

- Alcoholics Anonymous (<u>http://www.aa.org</u>)
- Narcotics Anonymous (<u>www.na.org</u>)

Appropriate Patients: Patients at any stage of readiness, including ongoing substance use

Medically Supervised Withdrawal ("detoxification")

Examples and Resources: Outpatient or inpatient treatment

Appropriate Patients: Patients with **physical dependence** on alcohol, opioids, benzodiazepines, etc., and have withdrawal syndrome

Outpatient Treatment

Examples and Resources: Outpatient drug-free treatment, opioid agonist therapy (office or outpatient), naltrexone therapy

Appropriate Patients: Patients with relatively stable and safe living environments

Residential Treatment

Examples and Resources:

- Therapeutic community model,
- short-term residential treatment,
- 12-step residential treatment,
- intensive inpatient treatment

Appropriate Patients: Patients who need stable living environment; patients with severe addiction/comorbidities who may be at high risk of relapse, emotional crisis, or behavioral problems

Have an Organizational Plan:

Review your local resources and if you cannot provide care directly, then refer as appropriate.

If your organization has an **opioid crisis action plan**, review it. If not, help to create one.

The state has put together a resource to help the individual seeking treatment, but, the site can be used to help build your organization's action plan.

1-844-HELPOWV ONE Call. ONE Text. ONE Click. INSTANT HELP.

Get Help

1-844-Help-4-WV For immediate help for any West Virginian struggling with an addiction or mental health issue - call or text 24/7.

Done.



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- https://www.aafp.org/afp/2016/0615/p982.html
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- In April 19, 2016 CDC released Guidelines for Prescribing Opioids for Chronic Pain.
- WE have noticed some change in the number of prescription.
- Many patients switched to street drugs instead.
- In 2016, West Virginia had the highest rate of opioid-related overdose deaths in the United States—a rate of 43.4 deaths per 100,000—and up from a low 1.8 deaths per 100,000 in 1999.
- the majority of deaths attributed to synthetic opioids and heroin.
- This epidemic started by Physicians in our state.