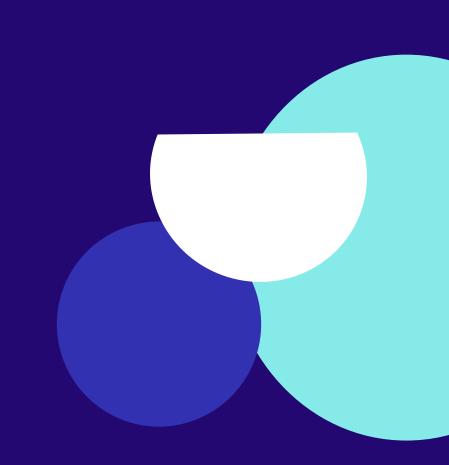
The Pharmacists Role in the Dispensing of Controlled Substances

Joseph Cammilleri, PharmD, BCACP, CPE



# Disclosure

I do not have (nor does any immediate family member have) a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.

Joseph Cammilleri, PharmD, BCACP, CPE

# **Presentation Objectives**

Describe how to ensure access to controlled substances for all patients with a valid prescription

Use the Prescription Drug Monitoring Program's Database

Assess prescriptions for appropriate therapeutic value

Detect prescriptions that are not based on a legitimate medical purpose

Discuss the laws and rules related to the prescribing and dispensing of controlled substances, proper patient storage and disposal of controlled substances, and protocols for addressing and resolving problems recognized during the drug utilization review

Provide education on section 381.887, F.S., emergency treatment for suspected opioid overdoses and on the State Surgeon General's Statewide Standing Order for naloxone

Counsel patients with opioid prescriptions

Provide available treatment resources for opioid physical dependence, addiction, misuse, or abuse

# Oath of a Pharmacist

"I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:

I will consider the welfare of humanity and relief of suffering my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.

*I will respect and protect all personal and health information entrusted to me.* 

I will accept the lifelong obligation to improve my professional knowledge and competence.

I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.

*I will embrace and advocate changes that improve patient care.* 

I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."

## The Opioid Epidemic

DRUG TYPE	(DEATHS 2021)	
Synthetic Opioids (fentanyl)	71,238	
Psychostimulants (meth)	32,856	
Cocaine	24,538	
Natural/semi-synthetic (prescription)	13,503	
	JAMA 2003; 290: 2470-5 http://www.cdc.gov/drugoverdose/data Accessed July2023	

## Timeline



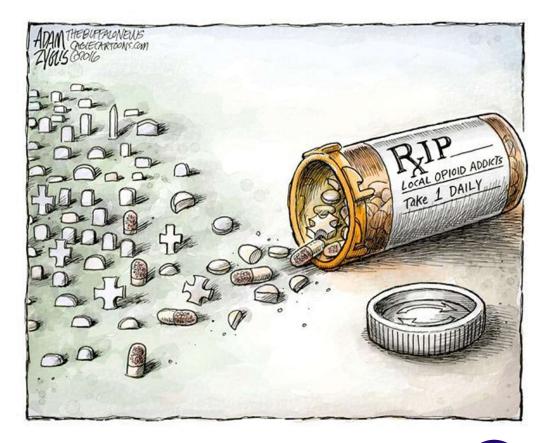
### Approximately how many deaths occur daily in the United States due to opioid overdose?

(A) 480

(B) 23

(C) 136

(D) 92



## Events Leading to the Opioid Epidemic



Weak regulatory oversight of pain management practices



No statewide prescription drug monitoring program

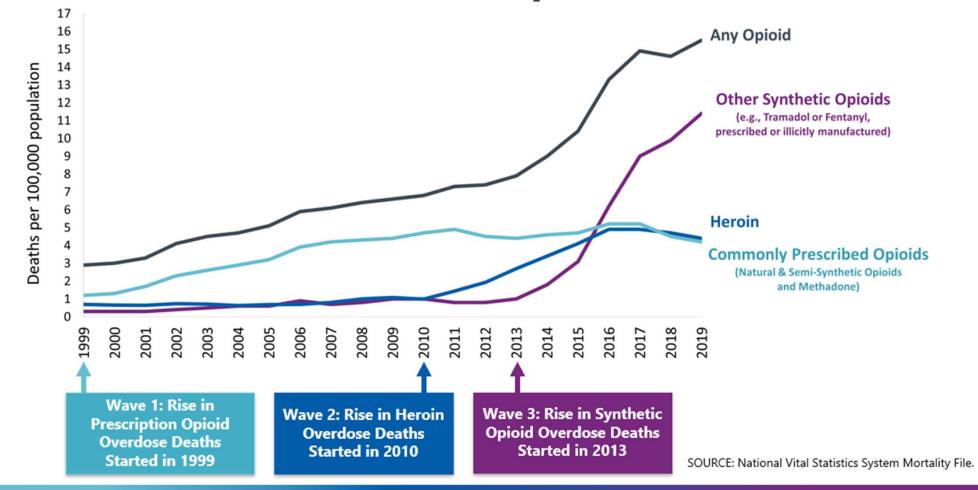


Limited supervision of physician dispensing habits



Criminal enterprises exploited Florida's regulatory system

### **Three Waves of the Rise in Opioid Overdose Deaths**









OF THOSE WHO BEGAN ABUSING OPIOIDS IN THE 2000S, REPORTED THAT THEIR FIRST OPIOID WAS A PRESCRIPTION DRUG

# 80%

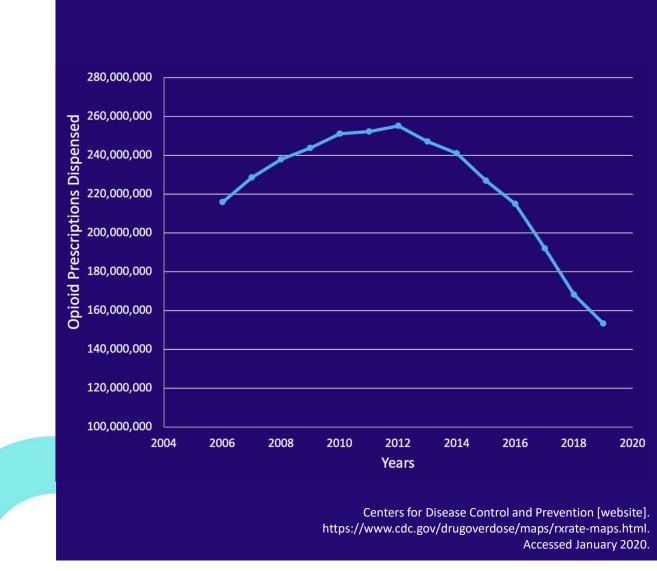
OF HEROIN USERS REPORTED USING PRESCRIPTION OPIOIDS PRIOR TO HEROIN

> Cicero TJ, Ellis MS, Surrat HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. JAMA Psychiatry. 2014;71(7):821-826. Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013;132(1-2):95-100. Lankenau SE, Tett M, Sitva K, Jackson Bloom J, Harocopos A, Treese M. Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012;23(1):37-44

## Opioid Prescribing Making the Climb

Total number of opioid prescriptions dispensed in the United States

2006-2019



## **Changing the Trajectory**

### Public Health and Legislative Initiatives



Prescription Drug Monitoring Program (PDMP) E-Forcse, RxAware®

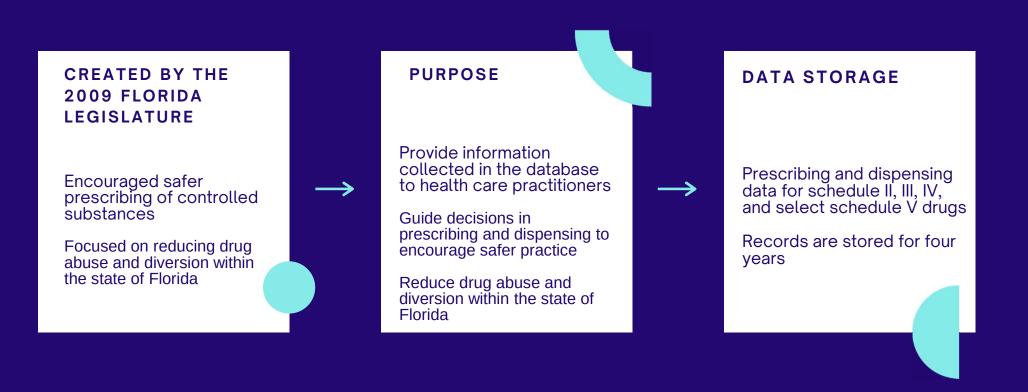


### Board of Pharmacy 64B16-27.81

New Provider Guidelines

Florida Legislative Changes House Bill 21, 451, 831 Senate Bill 544, 321

ELECTRONIC-FLORIDA ONLINE REPORTING OF CONTROLLED SUBSTANCE EVALUATION PROGRAM





### PRESCRIBERS OR THEIR DELEGATES

- Must query the PDMP each time a prescription for a controlled substance is written for a patient age 16 years or older
- All schedule II V controlled substances (except non-opioid schedule V)

#### PHARMACISTS MUST REVIEW PDMP BEFORE DISPENSING

- Applies to new or refilled controlled substances (all schedule II V controlled substances except non-opioid schedule V)
- Report the telephone number of patient, the individual picking up the controlled substance and identification

### **TECHNICAL DIFFICULTIES**

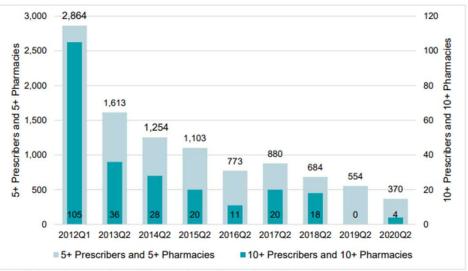
- Prescriber must document the reason in the medical record and may not prescribe more than a 3-day supply of a controlled substance
- Pharmacist may only dispense a 3-day supply

www.floridahealth.gov/statistics-anddata/e-forcse



## **E-Forcse RxAware**®

**Frequently Asked Questions** 



\*Controlled substance schedules II-IV before July 1, 2018; schedules II-V after July 1, 2018.

http://www.floridahealth.gov/statistics-and-data/e-forcse/

### MULTI-STATE SEARCH FUNCTIONALITY

• When searching outside of Florida utilize the E-Forcse RxAware® website

ELECTRONIC MEDICAL RECORD INTEGRATION



### **EXEMPTIONS FOR REPORTING TO THE PDMP**

- Directly administered to patients
- Dispensed in the health care system of the Department of Corrections
- Patients under the age of 16



### MORPHINE EQUIVALENT INTERPRETATION

- Based on Center for Disease Control Conversion (CDC) Factors
- Caution interpreting pregabalin and buprenorphine MME values

	Patient Rx Request Tutorial Can't view the file? Get Adobe Acrobat Reader * Indicates Required Field
Last Name*	
Partial Spelling	
	<ul> <li>Partial Spelling</li> <li>Date of Birth Range</li> </ul>

0	PMP Interconnect	⊖ RxChec	k	O None		
To se	earch in other states as w	ell as your home state for pat	ient information, select th	e states you wish to include in your	search.	
А	□Alabama					
с	Colorado	Connecticut				
D	Delaware					
G	Georgia					
I .	□ldaho					
L	Duisiana					
м	□Maine	Massachusetts	Michigan	Military Health System	⊡Minnesota	Mississippi
Ν	□North Carolina					
0	Ohio					
Р	□Pennsylvania					
R	□Rhode Island					
s	☐South Carolina					
т	Tennessee					
v	□Virginia					
w	Wisconsin					

Search

Also Search			
○ PMP Interconnect	RxCheck	⊖ None	

To search in another state as well as your home state for patient information, select the state you wish to include in your search.

- K CKentucky
- M Maryland
- W Washington

### Search

Filled 🔻	Drug 🍦	QTY 🛓	Days 🛓	Prescriber 👙	Dispenser 🛔	PMP 🛊
▶ 07/08/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Eb Pra	Sha (0574)	FL
▶ 06/10/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ju Joc	Sha (0574)	FL
✔ 05/13/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ju Joc	Sha (0574)	FL
✓ 04/14/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ju Joc	Sha (0574)	FL
✔ 03/17/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ju Joc	Sha (0574)	FL
✔ 02/16/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ma Jam	Sha (0574)	FL
✔ 01/19/2022	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ro Jon	Sha (0574)	FL
▶ 12/22/2021	Hydrocodone-Acetamin 5-325 Mg	84.00	28	Ma Jam	Sha (0574)	FL
✔ 11/24/2021	Hydrocodone-Acetamin 5-325 Mg	56.00	28	Eb Pra	Sha (0574)	FL
✔ 10/28/2021	Hydrocodone-Acetamin 5-325 Mg	54.00	27	Eb Pra	Sha (0574)	FL

# Learn How to Share

Following review of the PDMP document your findings in the medical record

Do NOT scan PDMP information into the Electronic Medical Record (EMR) or provide print outs to others



http://www.floridahealth.gov/statistics-and-data/e-forcse/

### **Pharmacists Caught in the Balancing Act**

### **Decrease Diversion While Maintaining Patient Access**

### PHARAMCIST VS PROVIDER

"Can you give me his diagnosis? Do you have MRI scans? When was their physical examination? Have you tried other modalities of care? It's like a whole laundry list of questions they ask you. They're a pharmacist. They're not really trained in making a clinical assessment. ... I think they're really walking outside of the box and stretching out beyond their expertise."

*Charles Friedman, MD* American Board of Anesthesiology American Board of Addiction Medicine



### PHARMACIST VS PATIENT

- Don't have the medicines in stock
- Worried about running out of the medications and leaving their longtime patients empty-handed
- Obeying mandates handed down by their employing corporations
- Afraid of being caught in a net cast by the U.S. Drug Enforcement Agency that has shuttered 13 Florida pharmacies since 2011

## **The 'Pharmacy Crawl'**

### **Opioid Pill Mill Crackdown Forces Patients to Shop Around**

"Lesley Young traveled to more than a dozen Jacksonville-area pharmacies before finding one that would fill her husband's prescriptions. You try and dress nice. You go into the drug store and speak well, and they look at you and say what do you need all this medication for and fling (the prescription) back at you, It's humiliating."

"Suzy Carpenter, diagnosed with Stage IV breast cancer, spent three days pleading with pharmacists at 13 drug stores before she received her pain medication"

"Three pharmacies rejected 4-year-old Aiden Lopez's prescriptions for narcotics after the tot underwent surgery for kidney cancer"

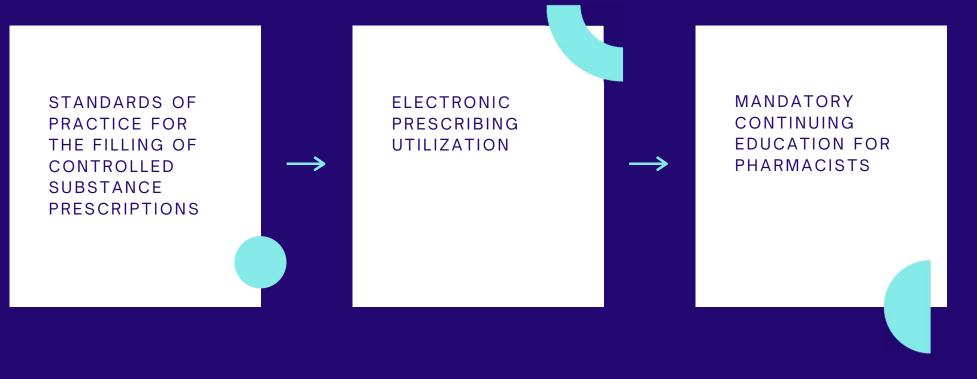
Image Source: http://tampa.suntimes.com/tpa-news/7/85/179934/pharmacy-crawl-leaving-patients-pain

### Florida's Initiative to Ensure Patient Access

"Decrease roadblocks to patients with a valid prescription and legitimate diagnosis to access the medications they need."

Pan Bonde

## Ensuring Appropriate Access 64B16-27.81





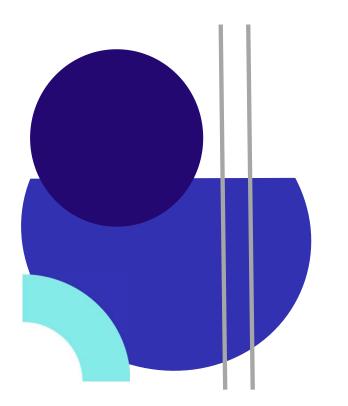
The Board of Pharmacy recognizes that it is important for the patients of the state of Florida to be able to fill valid prescriptions for controlled substances

In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment

Pharmacist should not fear disciplinary action from the Board or other enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice

Every patient situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind

Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription



### General Standards for Validating a Prescription 64B16-27.831(2),F.A.C

Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled.

Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

## **Definitions to Consider**

### VALID PRESCRIPTION

Based upon a practitioner-patient relationship and when it has been issued for a legitimate medical purpose

### VALIDATING A PRESCRIPTION

The process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose

### INAVLID PRESCRIPTION

If the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose

## Validating a Prescription

### Section 64B16-27.831(2)(a), (b) and (c), F.A.C.

Neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

The pharmacist shall ensure that all communication with the patient is not overheard by others. If at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

Title 21 Code of Federal Regulations 1306.04 Purpose of issue of prescription.



### **Prescribers**

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose"

### **Pharmacists**

" ... but a corresponding responsibility rests with the pharmacist who fills the prescription."

Title 21 Code of Federal Regulations 1306.04 Purpose of issue of prescription.

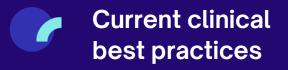


## Validating a Prescription

TITLE 21 CODE OF FEDERAL REGULATIONS 1306.04 LEGITIMATE PRESCRIPTIONS









Demonstrate benefit to the patient

Title 21 Code of Federal Regulations 1306.04 Purpose of issue of prescription.



JAIL

## Fears of Committing a Felony Offense

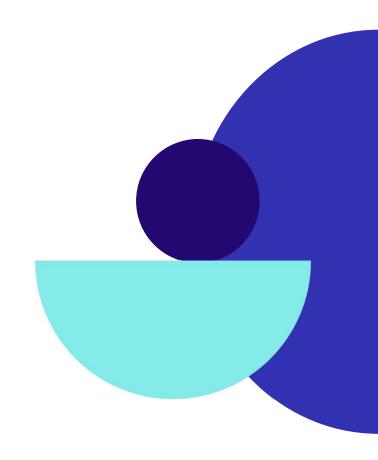
A Pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

Pharmacists Manual from the Drug Enforcement Agency. 2010.

## **Prospective Drug Utilization Monitoring**

A PHARMACIST SHALL REVIEW THE PATIENT RECORD AND EACH NEW AND REFILL PRESCRIPTION PRESENTED FOR DISPENSING IN ORDER TO PROMOTE THERAPEUTIC APPROPRIATENESS BY IDENTIFYING:

- (a) Over-utilization or under-utilization;
- (b) Therapeutic duplication;
- (c) Drug-disease contraindications;
- (d) Drug-drug interactions;
- (e) Incorrect drug dosage or duration of drug treatment;
- (f) Drug-allergy interactions;
- (g) Clinical abuse/misuse



## **Identifying Potential 'Red Flags'**

**Indicators Prompting Further Review** 





Cash pay only for controlled Multiple providers for similar substances medications



Multiple identities or addresses

--- --

"Out of area" prescriptions

Excessive quantities or high

volume prescribing patterns



Falsely phoned in or written prescriptions



Inappropriate urine drug screens



"Cocktails" of frequently abused controlled substances



Presenting altered after visitation or leaving the unit



PDMP history does not align with patient reported use



Review the PDMP

Speak to the patient



## **Talking to the Patient**

Ensure that all communication with the patient is not overheard by others



WHEN WAS YOUR LAST OFFICE VISIT? HOW LONG HAVE YOU BEEN SEEING DR. PERRY?



IT LOOKS LIKE YOU RECENTLY FILLED A SIMILAR MEDICATION, DID YOUR PROVIDER DISCUSS THE REASON FOR THIS PRESCRIPTION?



I HAVE MULTIPLE ADDRESSES AND PATIENT INFORMATION DUPLICATES ON FILE FOR YOU, CAN YOU HELP ME TO RECONCILE THEM?



YOUR URINE TOXICOLOGY DOES NOT ALIGN WITH YOUR CURRENT MEDICATION REGIMEN, COULD YOU TELL ME MORE ABOUT THAT?



WHEN WAS YOUR LAST DOSE OF THIS MEDICATION? DO YOU EVER FIND YOURSELF TAKING IT DIFFERENTLY THAN PRESCRIBED?



TO OUR PHARMACY HOW CAN WE HELP YOU TODAY?



# The Case of Mrs. Jones

Central Florida Pain Specialists 🛛 🔍
Michelle Smithson, M.D.
123 Mickey Mouse Trail
Orlando, FL 32801 Phone: (407)-826-4537 Fax: (407)-826-4538
040225123456 ME 100001 DEA 1234567
Name Jennifer Jones DOB 11/23/72 Date September 8th 2023
Address 4000 South 2nd street, Louisville, KY 40214
Diagnosis:
G90.50 Methadone 10 mg
Non-Acute Pain 3 tabs P.O. TID
$\begin{array}{c} -1 & -24 \\ \hline 25 & -49 \end{array} \qquad \begin{array}{c} + 270 \\ \hline \end{array}$
+ 270
□ 75-100 (two-hundred and seventy)
□ 101-150 ☑ 151 and over
Units Michelle Smithson M.D.
Refills INR 1 2 3 4 5 Signature







## The Case of Mrs. Jones

### Review the PDMP

Filled	Drug	QTY	Days	Prescriber	Dispenser	PMP
08/10/2023	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
07/11/2023	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
06/11/2023	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
05/12/2023	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL

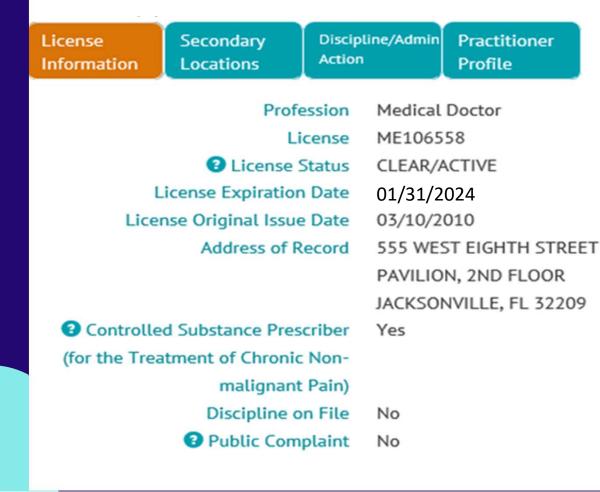
Mrs. Jones	I see that you are new to this pharmacy	Yes, I'm on vacation and couldn't fill it before I left	
	Your doctor is in Orlando however your address is Kentucky	I've been taking care of my mom in Orlando for the past few months	
Speak to the Patient	When was your last office visit?	Friday	
	Does this medication help your ability to function?	I couldn't function without it	
	Do you have insurance?	Yes, I have Kentucky Medicaid	
•			

# Mrs. Jones

Consult the provider

### SMITHSON MICHELLE

### License Number: ME100001



## Mrs. Jones



Profession	Medical Doctor
License Status	CLEAR/ACTIVE
Year Began Practicing	Not Provided
License Expiration Date	01/31/2024
O Controlled Substance Prescriber (for the Treatment of	Yes
Chronic Non-malignant Pain)	



#### **Specialty Certification**

This practitioner holds the following certifications from specialty boards recognized by the Florida board which regulates the profession for which he/she is licensed:

Specialty Board	Certification
AMERICAN BOARD OF ANESTHESIOLOGY	AN - ANESTHESIOLOGY
AMERICAN BOARD OF ANESTHESIOLOGY	AN - PAIN MANAGEMENT

# **CDC Guidelines**

Prescribing Opioids for Chronic Pain

Provides *recommendations* for *all clinicians* who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care

CDC guideline for prescribing opioids for chronic pain-United States 2022.

### Determining Initiation and Continuation of Opioids for Chronic Pain

#### OPIOIDS ARE NOT FIRST-LINE OR ROUTINE THERAPY FOR CHRONIC PAIN

Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

#### ESTABLISH AND MEASURE FUNCTIONAL GOALS

Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

#### DISCUSS RISKS AND BENEFITS OF OPIOIDS AND AVAILABILITY OF NONOPIOID THERAPIES

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

CDC guideline for prescribing opioids for chronic pain-United States 2022.

### **Selection and Management of Opioids for Chronic Pain**

#### IF NEEDED, BEGIN WITH IMMEDIATE RELEASE OPIOIDS

When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extendedrelease/long-acting (ER/LA) opioids.re are plenty of options.

#### START LOW AND GO SLOW

When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to  $\geq$ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to  $\geq$ 90 MME/day or carefully justify a decision to titrate dosage to  $\geq$ 90 MME/day.

#### PRESCRIBE NO MORE OPIOIDS THAN NEEDED AND DO NOT PRESCRIBE LONG ACTING OPIOIDS FOR ACUTE PAIN

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

#### FOLLOW-UP AND RE-EVALUATE RISK OF HARM

#### REDUCE DOSE, TAPER AND DISCONTINUE IF NEEDED

Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids

### Assessing Risk and Reducing Harm

### EVALUATE RISK FACTORS FOR OPIOID-RELATED HARMS

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

### EVALUATE THE PDMP HISTORY

Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

### CONDUCT URINE DRUG TESTING

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

#### AVOID CONCURRENT BENZODIAZEPINE AND OPIOID PRESCRIBING

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

CDC guideline for prescribing opioids for chronic pain-United States 2022.

ARRANGE TREATMENT FOR OPIOID USE DISORDER IF NEEDED

# Misapplication of the CDC Guidelines

#### MISAPPLICATION OF RECOMMENDATIONS TO POPULATIONS OUTSIDE OF THE GUIDELINE'S SCOPE

The Guideline is intended for primary care clinicians treating chronic pain for patients 18 and older. Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.

### MISAPPLICATION OF THE GUIDELINE'S DOSAGE RECOMMENDATION THAT RESULTS IN HARD LIMITS OR "CUTTING OFF" OPIOIDS

The Guideline states, "When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should... avoid increasing dosage to  $\geq$ 90 MME/day." The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.

#### THE GUIDELINE DOES NOT SUPPORT ABRUPT TAPERING OR SUDDEN DISCONTINUATION OF OPIOIDS

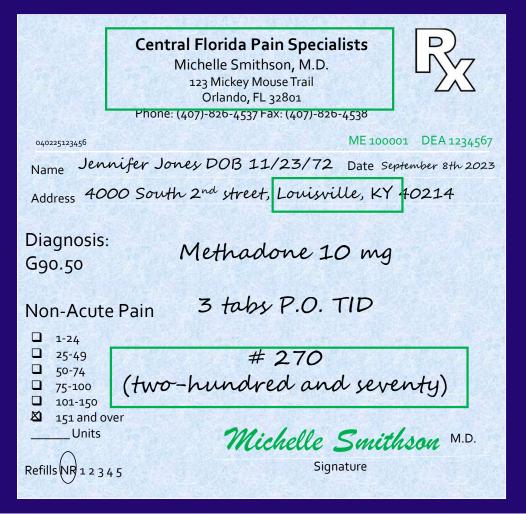
These practices can result in severe opioid withdrawal symptoms including pain and psychological distress, and some patients might seek other sources of opioids. In addition, policies that mandate hard limits conflict with the Guideline's emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient.

#### MISAPPLICATION OF THE GUIDELINE'S DOSAGE RECOMMENDATION TO PATIENTS RECEIVING OR STARTING MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDER

The Guideline's recommendation about dosage applies to use of opioids in the management of chronic pain, not to the use of medication-assisted treatment for opioid use disorder. The Guideline strongly recommends offering medication-assisted treatment for patients with opioid use disorder.

CDC guideline for prescribing opioids for chronic pain-United States 2019.

# The Case of Mrs. Jones







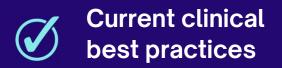


### Validating a Prescription

TITLE 21 CODE OF FEDERAL REGULATIONS 1306.04 LEGITIMATE PRESCRIPTIONS









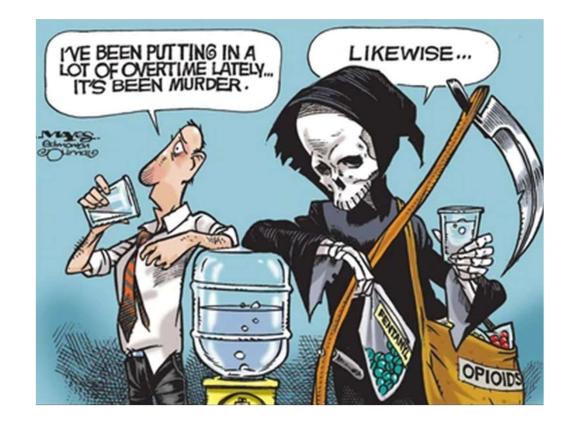
Title 21 Code of Federal Regulations 1306.04 Purpose of issue of prescription.

"The process implemented by the pharmacist to determine that a prescription was issued for a legitimate medical purpose" is known as:

(A) Validating a prescription

(B) Invalid prescribing

(C) Valid prescribing



## Minimum Standards Before Refusing to Fill

Section 64B16-27.831(3)(a), F.A.C.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

# Refusing to Fill

"I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:

I will consider the welfare of humanity and relief of suffering my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.

*I will respect and protect all personal and health information entrusted to me.* 

I will accept the lifelong obligation to improve my professional knowledge and competence.

I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.

*I will embrace and advocate changes that improve patient care.* 

I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."

### Potentially Negative Consequences from Refusing to Fill



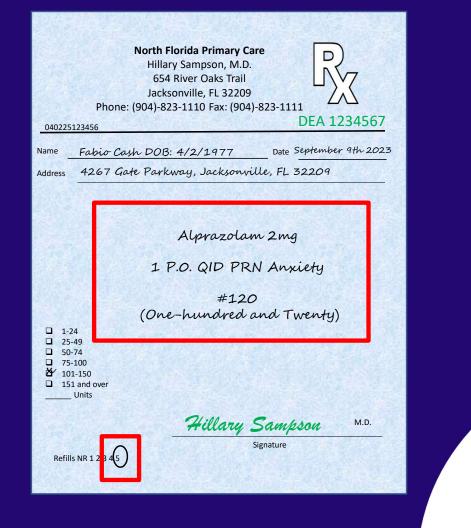
WITHDRAWAL WHICH MAY LEAD TO SELF MEDICATING



SEIZURES



SUICIDAL IDEATION OR ACTION



Filled	Drug	QTY	Days	Prescriber	Dispenser	РМР
4/23/2022	Alprazolam 1mg	10	5	Mi, Mat	Walgreens (2518)	FL
1/20/2022	Oxycodone HCL 15mg	55	30	Ja, Mar	Walmart (3909)	FL

Speak to the

Patient

Is this a new medication for you?

What else have you tried for anxiety?

I have taken it before. It's the only thing that works.

Depression medications, they make me feel funny.

Consult the provider

According to the PDMP Mr. Flash has not received Alprazolam since 2022.

I'm concerned with starting at a dose of 8mg/day. The recommended starting dose is 0.25-0.5mg TID. He told me that's what works for him so just fill the prescription.

### VALIDATING A PRESCRIPTION



Based on sound clinical judgment



Current clinical best practices



Appropriately Documented



Demonstrate benefit to the patient







### Pharmacist's Duty to Report

Section 64B16-27.831(4), F.A.C.

If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions.2016.

Florida Primary Care Petra Franks, M.D. 1975 APPLE CT JACKSONVILLE, FL 32209 PHONE: (904)-369-8490 FAX: (904)-369-8491	Florida Primary Care Petra Franks, M.D. 1975 APPLE CT JACKSONVILLE, FL 32209 PHONE: (904)-369-8490 FAX: (904)-369-8491		
040225123456 DEA PF1234567	040225123456 DEA PF1234567		
NameHope Lewis DOB: 6/5/2001Date September 9th 2023Address429 Greenery way, Jacksonville FL 32209	Name Hope Lewis DOB: 6/5/2001 Date September 9th 2023 Address 429 Greenery way, Jacksonville FL 32209		
Cheratussin AC 100mg-10mg/5ml	Amoxil 500mg		
Take 10ml q4-6hrs prn	Take 1 po TID #21		
$ \begin{array}{c}                                     $	<ul> <li>1-24</li> <li>25-49</li> <li>50-74</li> <li>75-100</li> <li>101-150</li> <li>151 and over Units</li> <li>Detra Franks M.D.</li> <li>Signature</li> </ul>		

Neview the PDMP









Called the phone number on the RX and voice mail was that of a different office

Looked up doctor in the pharmacy computer system and called that number

No record of the doctor seeing the patient



### **The Joint Commission Pain Standards**





NON-PHARMACOLOGIC PAIN TREATMENT





PATIENT CONSULTATION AND TREATMENT REFERRAL RESOURCES





https://www.jointcommission.org/resources/patient-safety-topics/ pain-management-standards-for-accredited-organizations Accessed January 2020.

### Florida House Bill

**HB 21** 

#### Prescribing of Controlled Substances

Requires pain management clinics to register valid certificate of exemption

The department inspect the painmanagement clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Medicine

# Standards for the Treatment of Chronic Non-Malignant Pain

The complete medical history and a physical examination, including history of drug abuse or dependence

Diagnostic, therapeutic, laboratory results as well as urine drug screen results

Evaluations, consultations, treatments

Discussion about treatment objectives and documentation of risks and benefits

Medications, including date, type, dosage, and quantity prescribed

Instructions and agreements

Periodic reviews (every 3 months at minimum)

A photocopy of the patient's government-issued photo identification

If a written prescription for a controlled substance is given to the patient, a duplicate record of the prescription

The registrant's full name presented in a legible manner

Board eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist are excluded

### **Acute Pain**

The normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness

HB 21

### **Excludes**

- Malignant Pain
- Palliative care
- Terminal Patients
- Patients with an Injury Severity Score > 9



### **Opioid Prescribing for Acute Pain**

#### ACUTE PAIN

Maximum of a 3-day supply of a Schedule II Opioid

#### ACUTE PAIN EXCEPTION

The prescriber must document the medical condition and lack of treatment alternatives that justify providing up to a 7-day supply for a Schedule II opioid prescription

"Acute pain exception" must be printed/written on the prescription

#### CHRONIC PAIN

"Non-Acute Pain" on the prescription for a Schedule II opioid prescription

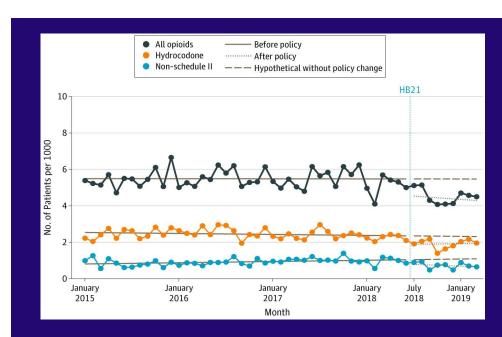
### Impact of HB 21

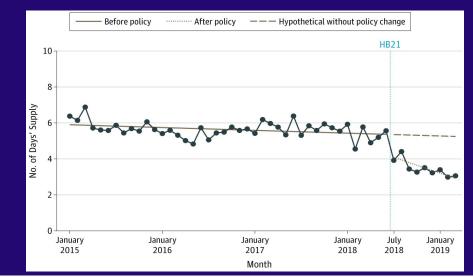
### **Expenditure versus Earnings**

Decline in total opioid prescriptions following implementation

Decrease in non-schedule II opioid prescribing followed

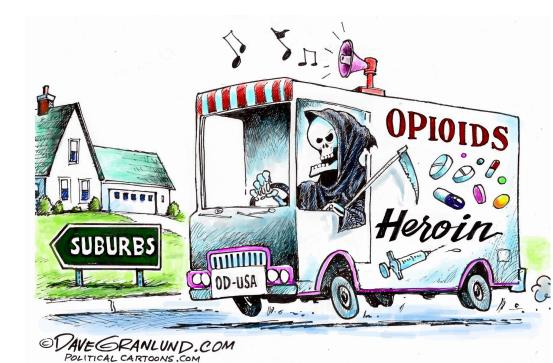
Day supply of medication decreased from >5 days in 2018 to < 4 in fall of 2019





Which statement about the CDC guidelines for chronic pain is false?

- (A) Avoid concurrent opioid and benzodiazepine prescribing
- (B) Establish goals for pain and function
- (C) Provides recommendations for all clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
- (D) Do not prescribe ER/LA opioids for acute pain







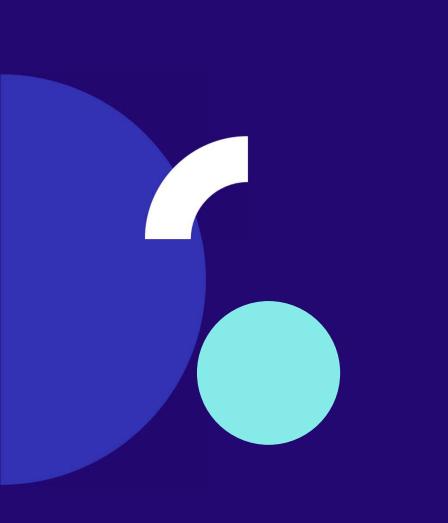


Requiring that the pamphlet provided to the patient be printed;

Authorizing a health care practitioner to discuss nonopioid alternatives with, and provide the pamphlet to, the patient's representative rather than the patient:

Specifying that only those health care practitioners ordering or prescribing or providing care that requires the administration of anesthesia using an opioid must meet the requirements and removing the requirement to address non-opioid alternatives when a drug is dispensed or administered; and

Exempting health care practitioners providing hospice Services and providing care in a hospital critical care unit or emergency department from the requirement to discuss non-opioid alternatives with a patient or the patient's representative and provide a printed copy of the pamphlet



#### Florida House Bill

# HB 831

Section 456.42

A health care practitioner licensed by law to prescribe a medicinal drug who maintains a system of electronic health records as defined in s. 408.051(2)(a), or who prescribes medicinal drugs as an owner, an employee, or a contractor of a licensed health care facility or practice that maintains such a system and who is prescribing in his or her capacity as such an owner, an employee, or a contractor, may only electronically transmit prescriptions for such drugs.

Exceptions include hospice, research, waivered practitioners, and in situations where electronic prescribing a prescription would be a barrier to the patient obtaining medication



### **Telehealth and Controlled Substance Prescribing**

### **FL** Legislation

- FL SB 312 approved by Gov on 4/6/22
- Anticipated effective date: July 1, 2022
- · Narrows restrictions on Rx of controlled substances via telehealth
  - Prescribing Schedule II not allowed via telehealth, unless:
  - Exception for treatment of psychiatric disorder (ADHD, Anxiety), patients receiving hospice services, or patients located in hospital or SNF
- Schedule III, IV, V are now allowed
  - Includes: Testosterone, Xanax, Several Anti-Epileptic Drugs
- · Does not allow for prescribing or refilling narcotics via Telehealth

Senate Bill 312 (2022) - The Florida Senate (flsenate.gov

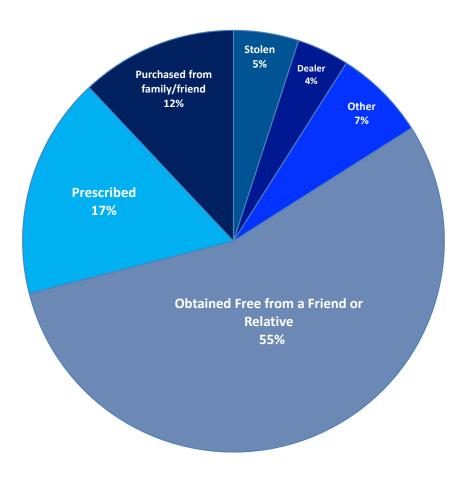
### **Get Involved**

#### Pharmacists working against the Opioid Epidemic



### Don't Let the Medicine Cabinet Become Your Communities Dealer





http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf

### Safe Storage of Controlled Substances



Store all opioids in their **original packaging** so you retain the prescription information, directions for use and expiration date.



Keep opioids in a **locked cabinet or lockbox** away from family members and house guests.



If you wear a fentanyl patch, consider **covering it with adhesive film** to make sure it doesn't fall off and regularly check to make sure it is still in place.<sup>v</sup>



Be sure to keep these **medicines out of reach** of young children. For more information on safe medicine storage visit <u>www.upandaway.org</u>.



Be sure to **monitor the medicine you take** and how much you have left so you will know if there is any missing medicine.

https://againstopioidabuse.org Accessed January 2020.

### **Proper Drug Disposal**



DEA NATIONAL DRUG TAKE-BACK DAY

National Prescription Drug Take Back Day



DEA AUTHORIZED COLLECTOR IN THE COMMUNITY DEA-authorized collector



HOME DISPOSAL (FLUSH OR TRASH)

list of medicines

www.fda.gov Accessed January 2020.

# **FDA Flush List**

Active Ingredient	Found in Brand Names				
Benzhydrocodone /Acetaminophen	Apadaz				
Buprenorphine	Belbuca, Bunavail, Butrans, Suboxone, Subutex, Zubsolv				
Fentanyl	Abstral, Actiq, Duragesic, Fentora, Onsolis				
Diazepam	Diastat/Diastat AcuDial rectal gel				
Hydrocodone	Anexsia, <u>Hysingla ER</u> , Lortab, <u>Norco</u> , Reprexain, Vicodin, <u>Vicoprofen</u> , <u>Zohydro ER</u>				
Hydromorphone	Dilaudid,Exalgo				
Meperidine	Demerol				
Methadone	Dolophine, Methadose				
Methylphenidate	Daytrana transdermal patch system				
Morphine	Arymo ER, Embeda, Kadian, Morphabond ER, MS Contin, Avinza				
Oxycodone	Combunox, Oxaydo (formerly Oxecta), OxyContin, Percocet, Percodan, Roxice Roxicodone, Roxybond, Targiniq ER, Xartemis XR, Xtampza ER				
Oxymorphone	Opana, Opana ER				
Tapentadol	Nucynta, Nucynta ER				
Sodium Oxybate	Xyrem oral solution				

"FDA believes that the known risk of harm, including death, to humans from accidental exposure to the medicines listed above, especially potent opioid medicines, far outweighs any potential risk to humans or the environment from flushing these medicines."

www.fda.gov Accessed January 2020.

# Medication Disposal



Remove the drugs from their original containers and mix them with something undesirable, such as used coffee grounds, dirt, or cat litter



Put the mixture in something you can close (a re-sealable zipper storage bag, empty can, or other container) to prevent the drug from leaking or spilling out



Scratch out all your personal information on the empty medicine packaging to protect your identity and privacy



Throw the container and drug packaging away

www.fda.gov Accessed January 2020

#### **Opiold Analgesic REMS**

#### Patient Counseling Guide

#### What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

#### What are opioids?

Objoids are strong prescription medicines that are used to manage severe pain

- What are the serious risks of using opioids?
- · Opioids have serious risks of addiction and overdose. - Too much opioid medicine in your body can cause your breathing to stop - which could lead to death. This risk is greater for people taking other medicines that make you feel sleepyor people with sleep apnea.
- Addiction is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require orgoing treatment.

#### Risk Factors for Opioid Abuse:

You have:

Opioid

Program

**REMs** 

- a history of addiction
- + a family history of addiction
- You take medicines to treat mental health problems.
- You are under the age of 65 (atthough anyone can abuse opioid medicines)
- You can get addicted to opioids even though you take them exactly as prescribed, especially if taken for a long time.
- . If you think you might be addicted, talk to your healthcare provider right away.
- . If you take an opioid medicine for more than a few days, your body becomes physically "dependent." This is normal and it means your body has gotten used to the medicine. You must taper off the opioid medicine (slowly take less medicine) when you no longer need it to avoid withdrawal symptoms.

#### How can I take opioid pain medicine safely?

- . Tell your healthcare provider about all the medicines you are taking, including vitamins, herbal supplements, and other over-the-counter medicines.
- · Read the Medication Guide that comes with your prescription.

#### Take your opioid medicine exactly as prescribed.

- . Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask: > How long should I take it?
- + What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- Do not share or give your opioid medicine to anyone else. Your healthcare provider selected this opioid and the dose just
- and death for someone else. Also, it is against the law. Store your opioid medicine in a safe place

where it cannotbe reached by children or stolen by family or visitors to your home. Many teenagers like to experiment with pain

medicines. Use a lock- box to keep your opioid medicine safe, Keep track of the amount of medicine

you have.

. Do not operate heavy machinery until you know how your opioid medicine affects you. Your opioid medicine can make you sleepy, dizzy, or lightheaded.

#### What should I avoid taking while I am taking opioids?

- Unless prescribed by your healthcare provider, you should avoid taking alcohol or any of the following medicines with an opicid because it may cause you to stop breathing, which can lead to death
- Alcohol: Do not drink any kind of alcohol while you are taking opioid medicines.
- Berzodiazepines (like Vallum of Xanax)
- · Muscle relaxants (like Some or Flexeril)
- Sieco medicines (like Ambien or Lunesta)
- · Other prescription opioid medicines

Page 1 of 2

#### **Opioid Analgesic REMS**

#### What other options are there to help with my pain?

Opioids are not the only thing that can help you control your pain. Ask your heathcare provider if your pain might be helped with a non-opioid medication, physical therapy exercise, rest, acupuncture, types of behavioral therapy, or

- + Naloxone is a medicine that treats opioid overdose. It is sprayed inside your nose or injected into your body.
- emergency room right away #:
  - You or someone else has taken an opioid medicine and is having trouble breathing, is short of breath, or is unusually sleepy
- A child has accidentally taken the opioid medicine or you think they might have
- taken an opioid medicine will not hurt them.

911 or go to the emergency room if you've used or given naloxone.

#### What things should I know about the specific opioid medicine that I am taking?

- + Your healthcare provider has prescribed information provided by your pharmacy,
- . Remember this other important information about your opicid medicine:

Dosing instructions:

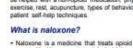
Any specific interactions with your medicines:

#### What if I have more questions?

- + Read the Medication Guide that comes with your opioid medicine prescription for more specific information about your
- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- + Visit: www.fda.cov/opioids for more information about opioid medicines.

#### Page 2 of 2

www.fda.gov/Drugs/DrugSafety Accessed January 2020.



- . Use nalokone if you have it and call 911 or go to the
- Giving naloxone to a person, even a child, who has not
- Naloxone is never a substitute for emergency medical care. Always call

#### + Tell your family about your naloxone and keep it in a place where you or your family can get to it in an emergency. When you no longer need your opioid medicine,

dispose of it as quickly as possible. The Food and Drug Administration recommends that most opioid medicines be promptly flushed down the toilet when no longer needed, unless a drug take-back option is immediately available. A list of the opioid medicines that can be flushed down the toilet is found here: https://www.fda.gov/drugdisposal

for you. Read the Medication Guide for this medicine, which is

**Patient Counseling Guide** 

+ There are some naioxone products that are designed for

+ Naloxone is available in pharmacies. Ask your healthcare

provider about how you can get naloxone. In some states,

. When you get your naioxone from the pharmacy read the

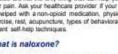
Patient Information on how to use naloxone and ask the

Where can I get naloxone?

you may not need a prescription.

pharmacist if anything is unclear.

people to use in their home.



for you. A dose that is okay for you could cause an overdose

### **Get Involved**

#### Pharmacists working against the Opioid Epidemic



Promote Safe Prescribing and Disposal Practices



Substance Use Disorder Treatment

2-	

Prevent Overdose Deaths

# Buprenorphine

# Methadone

Naltrexone

Kampman K, et al. J Addict Med. 2015;9(5):358-367.

## Accessing Treatment for OUD

RECOMMENDED PATIENT AND FAMILY RESOURCES

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMSHA)

CENTERS FOR DISEASE CONTROL AND PREVENTION

ASSOCIATION OF TERRITORIAL HEALTH OFFICIALS

NATIONAL ASSOCIATION OF STATE ALCOHOL AND DRUG ABUSE DIRECTORY

PROJECT SAVE LIVES

www.samhsa.gov. Accessed January 2020.

### Myths About Medications Used to Treat Opioid Use Disorder



Methadone and buprenorphine substitutes one addiction for another



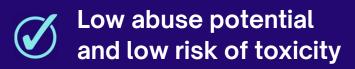
Patients commonly use buprenorphine to get high Patients on methadone or buprenorphine for opioid use disorder (OUD) should not receive pain medications during hospitalization

National Institute on Drug Abuse [website]. https://www.drugabuse.gov. Accessed January 2020.

# Considerations for OUD Treatment Selection



Compliance and good retention rates





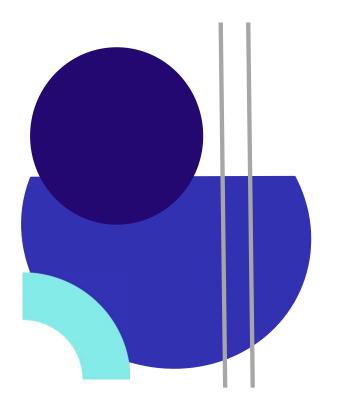
Accessible to the patient



Limits withdrawal symptoms and cravings

Kampman K, et al. J Addict Med. 2015;9(5):358-367.

### **Ensuring Access to Treatment**



#### **METHADONE**

Clinic based dosing only Limited take home dose privileges may be considered

#### **BUPRENORPHINE**

Office based or home induction available Medication may be obtained in clinic or pharmacy

#### 1) INDUCTION

Minimize withdrawal symptoms and cravings



#### **STABILIZATION**

No cravings or withdrawal symptoms Drug testing indicates patient compliance



#### MAINTENANCE

Continue treatment indefinitely

## The Case of Mr. Timely

040225123456	Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville , FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491 DEA TD1234567	Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville, FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491 0402251234567		
Name Timothy Timely DOB: 7/23/97 Date September 8th 2023				
Address 429 Greenery way, Jacksonville FL 32209		Address 429 Greenery way, Jacksonville FL 32209		
	Adderall 30mg	Suboxone Film 8/2mg Xanax 2 mg		
	Take 1 tablet BID for ADHD	Take 1 film BID for opioid 1 P.O. BID PRN for anxiety dependence		
□ 1-24 □ 25-49	#60 (sixty)	#60 (Sikty) - 1-24		
■ 25-49 ₩ 50-74 ■ 75-100 ■ 101-150 ■ 151 and ove Units Refills (IR) 2 3 4	Signature	-       -		

# The Case of Mr. Timely Review the PDMP

Filled	Drug	QTY	Days	Prescriber	Pharmacy	PMP
08/10/2023	Bup/Nal 8/2mg	60	30	Th Dum	Walg (0332)	FL
08/10/2023	Dex-Amph 30mg	60	30	Th Dum	Walg (0332)	FL
08/10/2023	Alprazolam 2mg	60	30	Th Dum	Walg (0332)	FL
07/11/2023	Bup/Nal 8/2mg	60	30	Th Dum	Walg (0332)	FL
07/11/2023	Dex-Amph 30mg	60	30	Th Dum	Walg (0332)	FL
07/11/2023	Alprazolam 2mg	60	30	Th Dum	Walg (0332)	FL

PATIENT HAS BEEN ON THE SAME REGIMEN FOR A YEAR

# The Case of Mr. Timely

Speak to the

Patient

Are you aware of the risk for breathing problems with alprazolam and Suboxone?

What else have you tried for anxiety?

Are the medications helping you?

I have taken been on this for a long time with no problems

Depression medication, but it makes me feel funny

I have been clean for 2 years and working full time

# Mr. Timely



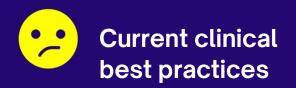
Recommend alternative agents to the provider for Mr.Timely's anxiety and attention deficit disorder indications

### Validating a Prescription

TITLE 21 CODE OF FEDERAL REGULATIONS 1306.04 LEGITIMATE PRESCRIPTIONS









Demonstrate benefit to the patient

## The Case of Mr. Timely

040225123456	Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville , FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491 DEA TD1234567	Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville, FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491 0402251234567		
Name Timothy Timely DOB: 7/23/97 Date September 8th 2023		Name Timothy Timely DOB: 7/23/97 Date September 8th 2023		
Address 429	Greenery way, Jacksonville FL 32209	Address 429 Greenery way, Jacksonville FL 32209		
	Adderall 30mg	Suboxone Film 8/2mg Xanax 2 mg		
	Take 1 tablet BID for ADHD	Take 1 film BID for opioid 1 P.O. BID PRN for anxiety dependence		
□ 1-24 □ 25-49	#60 (sixty)	#60 (Sikty) - 1-24		
<ul> <li>25-49</li> <li>20-74</li> <li>75-100</li> <li>101-150</li> <li>151 and ove Units</li> <li>Refills (IR) 2 3 4</li> </ul>	Signature	-       -       25.49         -       -       50.74         -       75.100         -       101.150         -       151 and over        Units       Thomas Dumas         Refills (NR) 2345       M.D.		

### The Case of Mr. Timely... 2 weeks Later

Westshore ER William Fox, M.D. 8200 Fake Street Jacksonville, FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491 040225123456 DEA WF1234567 Timothy Timely Name Date September 16th 2023 Address 429 Greenery way, Jacksonville FL 32209 Percocet 10/325mg Take I tablet Q4-6 hrs prn pain #10 A 1-24 (Ten) 25-49 50-74 75-100 101-150 151 and over William Fox M.D. Units Signature Refills NR 12345



TALK TO THE PATIENT Mr. Timely reports that he broke his arm



#### CONTACT THE EMERGENCY DEPARTMENT

Ensure the provider is aware patient is taking buprenorphine/naloxone



#### CONTACT THE OUD PROVIDER Inform provider of the injury and the opioid prescription provided by the ER practitioner

OFFER THE PATIENT NALOXONE

### **Get Involved**

#### Pharmacists working against the Opioid Epidemic



Promote Safe Prescribing and Disposal Practices



Substance Use Disorder Treatment



Prevent Overdose Deaths in the Community

### Risk Factors Associated with Opioid Overdose



Combining opioids with alcohol or certain other drugs



Taking more opioids than prescribed



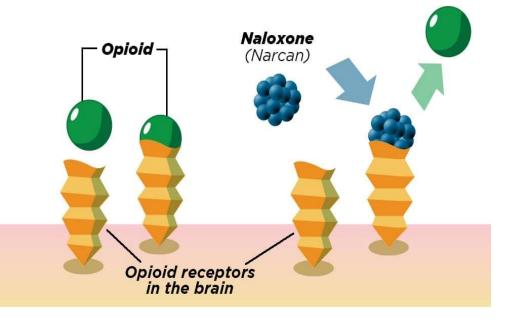
Taking high daily dosages of prescription opioids



Patients greater than 65 years of age

Medical conditions, such as sleep apnea, mental health issues, or reduced kidney or liver function

> Community management of opioid overdose. WHO. 2014; 1-88 Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain. 2016;65(No. RR-1):1–49.



# Patient and Family Education

Death from an opioid overdose happens when too much of the drug overwhelms the brain and interrupts the body's natural drive to breathe

Naloxone is a fast-acting medication used to reverse overdoses; however, it is not a replacement for contacting 9-1-1

May be injected into the muscle or sprayed in the nose to block opioids from binding to receptors in the brain



### Signs and Symptoms of Opioid Overdose

SMALL, CONSTRICTED "PINPOINT PUPILS"

FALLING ASLEEP OR LOSS OF CONSCIOUSNESS

SLOW, SHALLOW BREATHING

CHOKING OR GURGLING SOUNDS

LIMP BODY

PALE, BLUE, OR COLD SKIN

## Responding to an Opioid Overdose

Call 911 immediately

2 Administer naloxone, if available

3) Try to keep the person awake and breathing

4 Lay the person on their side to prevent choking



5 Stay with the person until emergency workers arrive

# FDA Recommendations for Naloxone

All patients prescribed opioid pain relievers All patients taking medications for opioid use disorder or concomitant CNS depressants Patients with a history of substance use disorder or have experienced an overdose in the past Patients with household members, including children who are at risk for accidental ingestion or overdose

### Intranasal Naloxone Patient Education



Tilt head back, support the patients neck

Do **NOT** prime prior to administration

Administer naloxone nasal spray as quickly as possible

Seek immediate medical attention after administration and rotate patient on their side Re-administer naloxone nasal spray in opposite nostril in 2 to 3 minutes if the patient does not respond or relapses

Narcan Nasal Spray. Package Insert. 2016.1-2.

An authorized health care practitioner may prescribe and dispense an emergency opioid antagonist to a

# OTC Approved March 29<sup>th</sup> 2023

experiencing an opioid overdose, regardless of whether that person has a prescription for an emergency opioid antagonist.

381.887(3) Emergency treatment for suspected opioid overdose.2016.

# Naloxone Dispensing

Surgeon General's Statewide Standing Order for Naloxone

Authorizes pharmacists who maintain a current active license practicing in a pharmacy located in Florida that maintains a current active pharmacy permit to dispense naloxone to emergency responders for administration to persons exhibiting signs of opioid overdose. Emergency responders include law enforcement officers, firefighters, paramedics and emergency medical technicians

Florida Executive Order 17-146 May 2017.

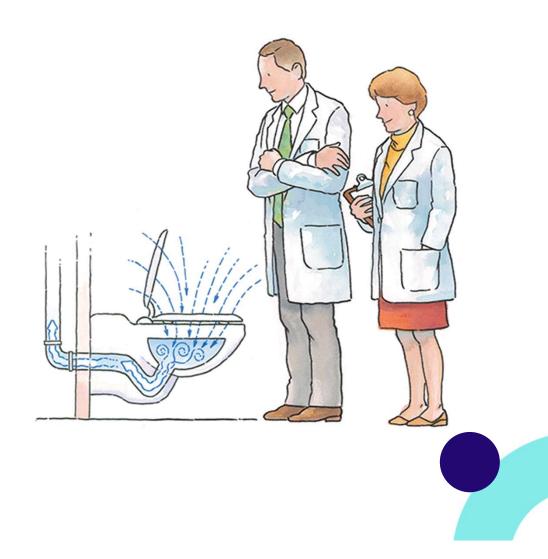
### Which of the following are approved medication disposal methods?

(A) Flushing down to toilet

(B) Mixed with unpalatable substance and thrown in trash

(C) Take to drug take back location

(D) All of the above



# **Summary & Resources**

Pharmacists play an essential role as the gatekeepers to appropriate therapy for patients receiving controlled substances

64B16-27.831 outlines the expectations for pharmacists validating controlled substance prescriptions



Federal law resources may be referenced in the DEA Pharmacists Manual The Pharmacists Role in the Dispensing of Controlled Substances

Joseph Cammilleri, PharmD, BCACP, CPE

