

# Validation and Counseling of Prescriptions for Controlled Substances and Opioids

Joseph Cammilleri, Pharm.D., BCACP, CPE



1

---

---

---

---

---

---

---

---

## Speaker Bio



Dr. Cammilleri graduated from Palm Beach Atlantic University with a doctorate of pharmacy and completed his training with a postgraduate residency program at Shands hospital in Jacksonville, Florida. He achieved board certification in ambulatory care pharmacy in 2012 and successfully completed the ASHP Foundation pain management and palliative care traineeship program in 2014. Currently, Dr. Cammilleri serves as an ambulatory care clinical pharmacist at UF Health Jacksonville and also holds the position of program director for the PGY2 pain and palliative care residency program. His areas of expertise include pain management and overdose prevention.



2

---

---

---

---

---

---

---

---

## Speaker Disclosures

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.



3

---

---

---

---

---

---

---

---

# Learning 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;
- Define the laws and rules related to the prescribing and dispensing of controlled substances;
- Describe proper patient storage and disposal of controlled substances;
- Describe 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; and Provide available treatment resources for opioid physical dependence, addiction, misuse, or abuse.



4

---

---

---

---

---

---

---

---

---

---

"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."

5

---

---

---

---

---

---

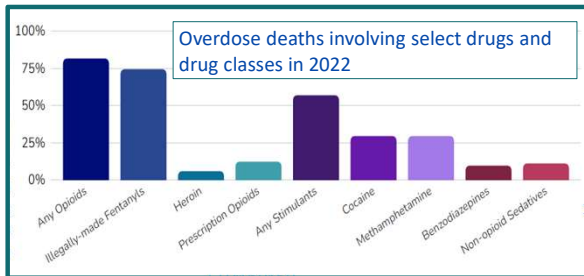
---

---

---

---

# The Opioid Epidemic



JAMA 2003; 290: 2470-5  
<http://www.cdc.gov/drugoverdose/data> Accessed June 2024

6

---

---

---

---

---

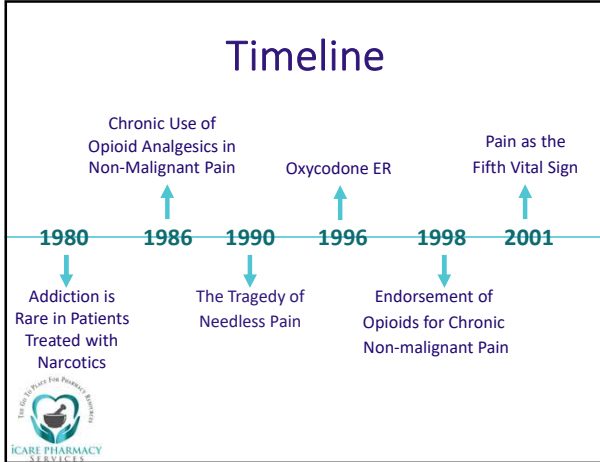
---

---

---

---

---



7

---

---

---

---

---

---

---

---

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

- (A) 480
- (B) 23
- (C) 136
- (D) 92

The 40 Years For Practical Nurses  
ICARE PHARMACY SERVICES

8

---

---

---

---

---

---

---

---

### 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

The 40 Years For Practical Nurses  
ICARE PHARMACY SERVICES

PBondi, Florida's Prescription Drug Diversion and Abuse Roadmap 2012-2015.

9

---

---

---

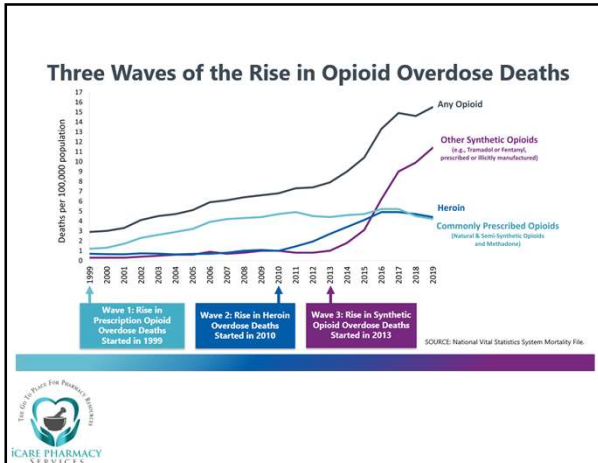
---

---

---

---

---



10

---

---

---

---

---

---

---

---

---

---

---

---

**75%**  
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

Clancy TL, Ellis ML, Serratt H, 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):823-30.  
Jorani DM. 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;133:219-26.  
Lankesha SC, Tall M, Shiv K, Jackson Bloom L, Harocopos A, Trevis M. Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012;23(3):317-21.

11

---

---

---

---

---

---

---

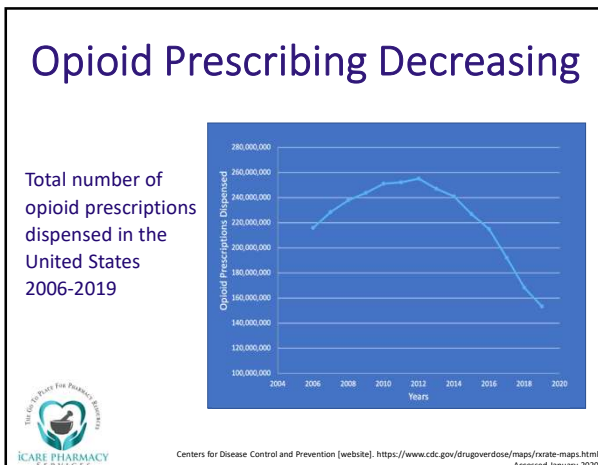
---

---

---

---

---



12

---

---

---

---

---

---

---

---

---

---

---

---

# 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



13

---

---

---

---

---

---

---

---

---

---

# E-Forcse, RxAware®

ELECTRONIC-FLORIDA ONLINE REPORTING OF CONTROLLED SUBSTANCE EVALUATION

### CREATED BY THE 2009 FLORIDA LEGISLATURE

- Encouraged safer prescribing of controlled substances
- Focused on reducing drug abuse and diversion within the state of Florida

### PURPOSE

- Provide information collected in the database to health care practitioners
- Guide decisions in prescribing and dispensing to encourage safer practice
- Reduce drug abuse and diversion within the state of Florida

### DATA STORAGE

- Prescribing and dispensing data for schedule II, III, IV, and select schedule V drugs
- Records are stored for four years



[www.floridahealth.gov/statistics-and-data/e-forcse](http://www.floridahealth.gov/statistics-and-data/e-forcse)

14

---

---

---

---

---

---

---

---

---

---

# E-Forcse, RxAware®

### PRESCRIBERS OR THEIR DELEGATES

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

### PHARMACISTS OR THEIR DELEGATES

- Must query the PDMP for 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-and-data/e-forcse](http://www.floridahealth.gov/statistics-and-data/e-forcse)

15

---

---

---

---

---

---

---

---

---

---

## E-Forcse, RxAware®

**ELECTRONIC MEDICAL RECORD INTEGRATION**

**MORPHINE EQUIVALENT INTERPRETATION**


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

**MULTI-STATE SEARCH FUNCTIONALITY**

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

**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



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

16

---

---

---

---

---

---

---

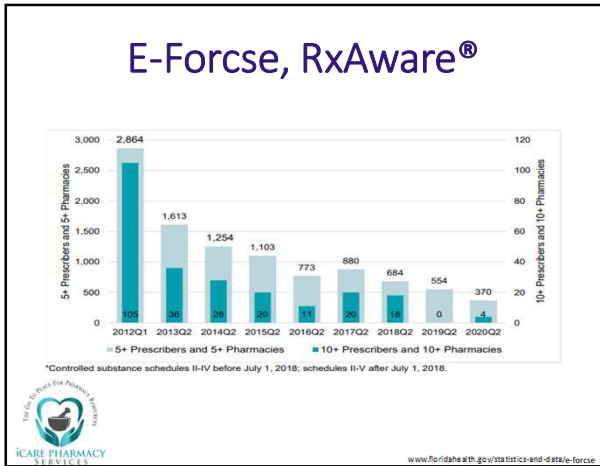
---

---

---

---

---



17

---

---

---

---

---

---

---

---

---


---

---

---

## E-Forcse, RxAware®

RxSearch - Patient Request




Version: 8/15/2023

**Patient Request**

Patient Info  
 Partial Spelling  
 First Name\*  Last Name\*   
 Partial Spelling  
 Date of Birth\*  Date of Birth Range   
 (MM/DD/YYYY)  Search using exact DOB

**Prescription Fill Dates**  
 No earlier than 2 years from today  
 From\*  To\*   
 (MM/DD/YYYY)  (MM/DD/YYYY)

**Patient Location**  
 Search accuracy can be improved by including the address  
 Zip Code



18

---

---

---

---

---

---

---

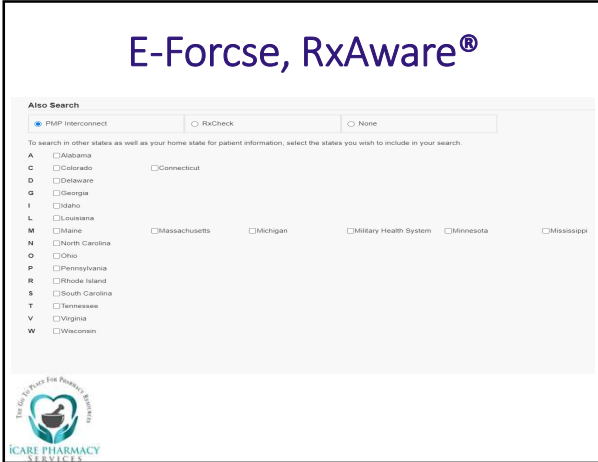
---

---

---

---

---



19

---

---

---

---

---

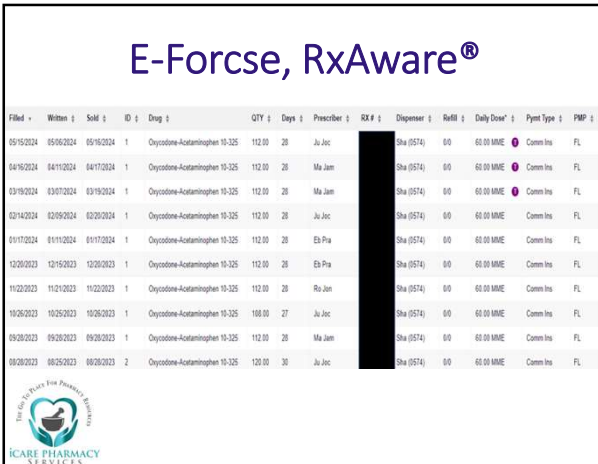
---

---

---

---

---



20

---

---

---

---

---

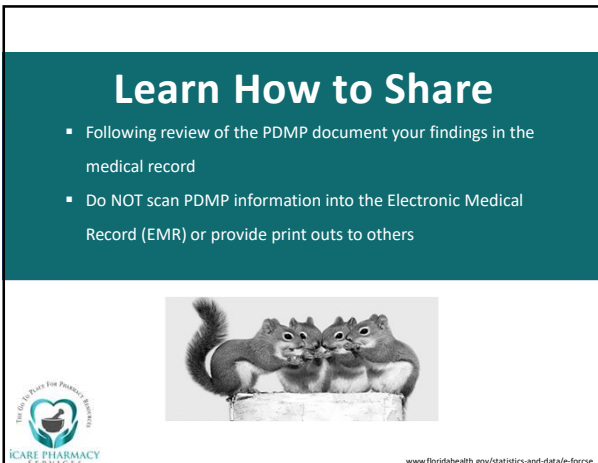
---

---

---

---

---



21

---

---

---

---

---

---

---

---

---

---

## Pharmacists Caught in the Balancing Act

Decrease Diversion While Maintaining Patient Access

### PHARMACIST 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 by the U.S. Drug Enforcement Agency that has shuttered 13 Florida pharmacies since 2011



22

---

---

---

---

---

---

---

---

---

---

## 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"



23

---

---

---

---

---

---

---

---

---

---

## Florida's Initiative to Ensure Patient Access

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

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



24

---

---

---

---

---

---

---

---

---

---



## Ensuring Appropriate Access

STANDARDS OF PRACTICE FOR THE FILLING OF CONTROLLED SUBSTANCE PRESCRIPTIONS

ELECTRONIC PRESCRIBING UTILIZATION

MANDATORY CONTINUING EDUCATION FOR PHARMACISTS

ICARE PHARMACY SERVICES

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

25

---

---

---

---

---

---

---

---

---

---

---

---

## Florida Board of Pharmacy

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

ICARE PHARMACY SERVICES

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

26

---

---

---

---

---

---

---

---

---

---

---

---

## General Standards for Validating a Prescription

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.

ICARE PHARMACY SERVICES

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

27

---

---

---

---

---

---

---

---

---

---

---

---

## Definitions to Consider

VALID PRESCRIPTION	VALIDATING A PRESCRIPTION	INVALID PRESCRIPTION
<ul style="list-style-type: none"> <li>Based upon a practitioner-patient relationship and when it has been issued for a legitimate medical purpose</li> </ul>	<ul style="list-style-type: none"> <li>The process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose</li> </ul>	<ul style="list-style-type: none"> <li>If the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose</li> </ul>



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

28

---

---

---

---

---

---

---

---

---

---

---

---

## Validating a Prescription

- 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.



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

29

---

---

---

---

---

---

---

---

---

---

---

---

### 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.

30

---

---

---

---

---

---

---

---

---


---

---


---

## Validating a Prescription


TITLE 21 CODE OF FEDERAL REGULATIONS 1306.04 LEGITIMATE PRESCRIPTIONS




Based on sound clinical judgment




Appropriately Documented



Current clinical best practices



Demonstrate benefit to the patient



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

31

---

---

---

---


---

---

---

---


GO TO



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.

32

---

---

---

---

---

---


---

---

## 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:

- Over-utilization or under-utilization
- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions
- Incorrect drug dosage or duration of drug treatment
- Drug-allergy interactions
- Clinical abuse/misuse



64816-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions, 2016

33

---

---

---

---

---

---

---

---

## Identifying Potential “Red Flags”

Indicators Prompting Further Review

Cash pay only for controlled substances	Multiple providers for similar medications	Excessive quantities or high volume prescribing patterns	Inappropriate urine drug screens	Presenting altered after visitation or leaving the unit
Multiple identities or addresses	"Out of area" prescriptions	Falsely phoned in or written prescriptions	"Cocktails" of frequently abused controlled substances	PDMP history does not align with patient reported use

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

34

---

---

---

---

---

---

---

---

---

---

---

---

## Resolving Red Flags

- Review the PDMP
- Speak to the patient
- Consult the provider

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

35

---

---

---

---

---

---

---

---

---

---

---

---

## Talking to the Patient

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

<p>WHEN WAS YOUR LAST OFFICE VISIT? HOW LONG HAVE YOU BEEN SEEING DR. PERRY?</p>	<p>IT LOOKS LIKE YOU RECENTLY FILLED A SIMILAR MEDICATION, DID YOUR PROVIDER DISCUSS THE REASON FOR THIS PRESCRIPTION?</p>	<p>I HAVE MULTIPLE ADDRESSES AND PATIENT INFORMATION DUPLICATES ON FILE FOR YOU, CAN YOU HELP ME TO RECONCILE THEM?</p>
<p>YOUR URINE TOXICOLOGY DOES NOT ALIGN WITH YOUR CURRENT MEDICATION REGIMEN, COULD YOU TELL ME MORE ABOUT THAT?</p>	<p>WHEN WAS YOUR LAST DOSE OF THIS MEDICATION? DO YOU EVER FIND YOURSELF TAKING IT DIFFERENTLY THAN PRESCRIBED?</p>	<p>I SEE THAT YOU ARE NEW TO OUR PHARMACY HOW CAN WE HELP YOU TODAY?</p>

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

36

---

---

---

---

---

---

---

---

---

---

---

---

## The Case of Mrs. Jones

**Central Florida Pain Specialists**  
Michelle Smithson, M.D.  
123 Mickey Mouse Trail  
Orlando, FL 32818  
Phone: (407) 828-4537 Fax: (407) 828-4538

**Rx**

Michelle Smithson, M.D.  
11-23-1972  
DOB: 11-23-1972  
Name: Jennifer Jones  
DOB: 11/23/72 Date: July 2, 199, 2024  
Address: 4000 Smith 2nd street Louisville, KY 40214

Diagnosis: Methadone 10 mg  
Ggo.50

Non-Acute Pain 3 tabs P.O. TID

# 270  
(two-hundred and seventy)

Michelle Smithson, M.D.  
Signature

**NO**

Hand holding cash

37

---

---

---

---

---

---

---

---

---

---

---

---

## The Case of Mrs. Jones

Review the PDMP

Filled	Drug	QTY	Days	Prescriber	Dispenser	PMP
06/20/2024	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
05/21/2024	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
04/21/2024	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL
03/22/2024	Methadone 10mg	270	30	Mi Smith	Walg (0332)	FL



38

---

---

---

---

---

---

---

---

---

---

---

---

Speak to the Patient

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
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



39

---

---

---

---

---

---

---

---

---

---

---

---




Consult the provider

SMITHSON MICHELLE

License Number: ME100001

License Information	Secondary Locations	Discipline/Admin Action	Practitioner Profile
Profession		Medical Doctor	
License		ME100001	
License Status		CLEAR/ACTIVE	
License Expiration Date		06/30/2025	
License Original Issue Date		05/10/2010	
Address of Record		123 Mickey Mouse Trail Orlando, FL 32801	
Controlled Substance Prescriber (for the Treatment of Chronic Non-malignant Pain)		Yes	
Discipline on File		No	
Public Complaint		No	



40

---

---

---

---

---

---

---

---

---

---

---


---

---

---

---

---



Consult the provider


Profession	Medical Doctor
License Status	CLEAR/ACTIVE
Has begun Practicing	Not Provided
License Expiration Date	06/30/2025
Controlled Substance Prescriber (for the Treatment of Chronic Non-malignant Pain)	Yes

General Information | Education & Training | Academic Appointments | Specialty Certification | Financial Responsibility | Proceedings & Actions | Optional Information | License Information

**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



41

---

---

---

---

---

---

---

---

---

---

---

---

---


---

---

---

## CDC Clinical Practice Guideline for Prescribing Opioids for 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



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-11):1-95.

42

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

## Determining Whether or Not to Initiate Opioids for Pain

### RECOMMENDATION 1

Nonopioid therapies are at least as effective as opioids for many common types of acute pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient. Before prescribing opioid therapy for acute pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy

### RECOMMENDATION 2

Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks

Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.

43

---

---

---

---

---

---

---

---

---

---

## Selecting Opioids and Determining Dosages

### RECOMMENDATION 3

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

### RECOMMENDATION 4

When opioids are initiated for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage. If opioids are continued for subacute or chronic pain, clinicians should use caution when prescribing opioids at any dosage, should carefully evaluate individual benefits and risks when considering increasing dosage, and should avoid increasing dosage above levels likely to yield diminishing returns in benefits relative to risks to patients



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.

44

---

---

---

---

---

---

---

---

---

---

## Selecting Opioids and Determining Dosages

### RECOMMENDATION 5

For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage. If benefits outweigh risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids. Unless there are indications of a life-threatening issue such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.

45

---

---

---

---

---

---

---

---

---

---

### Deciding Duration of Initial Opioid Prescription and Conducting Follow-up

#### RECOMMENDATION 6

When opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids

#### RECOMMENDATION 7

Clinicians should evaluate benefits and risks with patients within 1–4 weeks of starting opioid therapy for subacute or chronic pain or of dosage escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95

46

---

---

---

---

---

---

---

---

---

---

### Assessing Risk and Addressing Potential Harms of Opioid Use

#### RECOMMENDATION 8

Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss risk with patients. Clinicians should work with patients to incorporate into the management plan strategies to mitigate risk, including offering naloxone

#### RECOMMENDATION 9

When prescribing initial opioid therapy for acute, subacute, or chronic pain, and periodically during opioid therapy for chronic pain, 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 combinations that put the patient at high risk for overdose



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95

47

---

---

---

---

---

---

---

---

---

---

### Assessing Risk and Addressing Potential Harms of Opioid Use

#### RECOMMENDATION 10

When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances

#### RECOMMENDATION 11

Clinicians should use particular caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants

#### RECOMMENDATION 12

Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder. Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95

48

---

---

---

---

---

---

---

---

---

---



# Misapplication of the CDC Guidelines

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

The Guideline is intended for 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 ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day." The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95

49

---

---

---

---

---

---

---

---

---

---

# Misapplication of the CDC Guidelines

## 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.



Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95

50

---

---

---

---

---

---

---

---

---

---

# The Case of Mrs. Jones

**Central Florida Pain Specialists**  
Michelle Smithson, M.D.  
123 Mickey Mouse Trail  
Orlando, FL 32801  
Phone: (407) 516-4321 Fax: (407) 516-4328

**Prescription:** ME 1000001 CDE 111407

Name: Jennifer Jones DOB 12/23/72 Date: July 1-999-9924  
Address: 4000 South 2<sup>nd</sup> Street Louisville, KY 40214

Diagnosis: Methadone 10 mg  
G90.90

Non-Acute Pain 3 tabs P.O. TID

1-24  
 25-49  
 50-74  
 75-100  
 101-150  
 151 and over

Units: \_\_\_\_\_

# 270  
(two-hundred and seventy)

Michelle Smithson, M.D.  
Signature

Refills: NF 1, 2, 3, 4, 5

**DRIVER'S LICENSE**  
Annie's  
Louisiana DL  
License No. B04-122-350  
Expiry Date: 11-23-1972  
XXX XXXX  
4000 S 2ND ST  
LOUISVILLE KY 40214-1982  
JEFFERSON COUNTY  
Jennifer Jones

**NO**

UnitedHealthcare  
Health Plan: 918-8778-04  
Member ID: 9999999999999999  
Group ID: 00001-9999  
Plan Type: Individual  
Plan Year: 2024  
Plan Start: 01/01/2024  
Plan End: 12/31/2024

Hand holding cash

51

---

---

---

---

---

---

---

---

---

---

# Validating a Prescription

Mrs. Jones



Based on sound clinical judgment



Appropriately Documented



Current clinical best practices



Demonstrate benefit to the patient



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

52

---

---

---

---

---

---

---

---

---

---

“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



53

---

---

---

---

---

---

---

---

---

---

# Minimum Standards Before Refusing to Fill

(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.



64816-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions, 2016

54

---

---

---

---

---

---

---

---

---

---

## 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."

55

---

---

---

---

---

---

---

---

---

---

---

---

## Potentially Negative Consequences from Refusing to Fill



WITHDRAWAL WHICH MAY LEAD TO SELF-MEDICATING



SEIZURES



SUICIDAL IDEATION OR ACTION



56

---

---

---

---

---

---

---

---

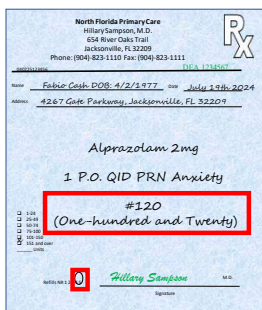
---

---

---

---

## The Case of Mr. Cash



57

---

---

---

---

---

---

---

---

---

---

---

---

# The Case of Mr. Cash

Review the PDMP

Filled	Drug	QTY	Days	Prescriber	Dispenser	PMP
04/23/2023	Alprazolam 1mg	10	5	Mi Mat	Walgreens (2518)	FL
01/20/2023	Oxycodone 10mg	45	30	Ja Mar	Walgreens (3909)	FL



58

---

---

---

---

---

---

---

---

# The Case of Mr. Cash

Speak to the Patient

- Is this a new medication for you?
  - I have taken it before. It's the only thing that works
- What else have you tried for anxiety?
  - Depression medications, they make me feel funny
- Why is the doctor giving you such a high dose?
  - I'm in a hurry, can you just fill the prescription!



59

---

---

---

---

---

---

---

---

# The Case of Mr. Cash

Consult the provider

- According to the PDMP Mr. Cash has not received Alprazolam since 2023.
  - 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!



60

---

---

---

---

---





---

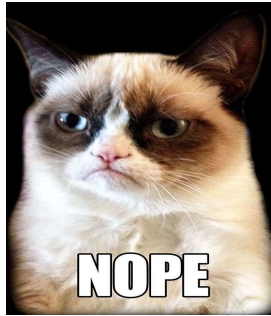
---

---

# Validating a Prescription

Mr. Cash

-  Based on sound clinical judgment
-  Current clinical best practices
-  Appropriately Documented
-  Demonstrate benefit to the patient



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

61

---

---

---

---

---

---

---

---

---

---

# Pharmacist's Duty to Report



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 Filing of Controlled Substance Prescriptions 2016

62

---

---

---

---

---

---

---

---

---

---

# The Case of Ms. Lewis

<p style="text-align: center;"><small>Florida Primary Care Petra Franks, M.D. 1076 APPACHE JACKSONVILLE, FL 32209 PHONE: (904) 900-6073 FAX: (904) 900-6091</small></p> <p style="text-align: center;"><small>DEA # 3514925</small></p> <p><small>Name: Hope Lewis DOB: 6/5/2001 Date: July 20th 2024 Address: 429 Greenway way Jacksonville FL 32209</small></p> <p style="text-align: center;">Cheratussin AC 100mg-10mg/5ml Take 10ml qd - 6hrs prn</p> <p style="text-align: center;"># 420ml (Four hundred and twenty)</p> <p><small>Signature: Petra Franks M.D.</small></p>	<p style="text-align: center;"><small>Florida Primary Care Petra Franks, M.D. 1076 APPACHE JACKSONVILLE, FL 32209 PHONE: (904) 900-6073 FAX: (904) 900-6091</small></p> <p style="text-align: center;"><small>DEA # 3514925</small></p> <p><small>Name: Hope Lewis DOB: 6/5/2001 Date: July 20th 2024 Address: 429 Greenway way Jacksonville FL 32209</small></p> <p style="text-align: center;">Amoxicil 500mg Take 1 po-TID #21</p> <p><small>Signature: Petra Franks M.D.</small></p>
--	--



63

---

---

---

---

---

---

---

---


---

---

## The Case of Ms. Lewis

★ Review the PDMP

Filled	Drug	QTY	Days	Prescriber	Pharmacy	PMP
No Records Found						



64

---

---

---

---

---


---


---

---

## The Case of Ms. Lewis

★  
Speak  
to the  
Patient





65

---

---

---

---

---

---

---

---


## The Case of Ms. Lewis

★  
Consult the  
provider

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



66

---

---

---

---

---

---

---

---

# The Case of Ms. Lewis




---

---

---

---

---

---

---

---

---

---

---

---

67

# Florida House Bill 21

- ✦ Requires pain management clinics to register with the department of health
- ✦ The department inspect the pain-management 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



Florida House Bill 21- Controlled Substance 2018

---

---

---

---

---

---

---

---

---

---

---

---

68

# 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



Florida House Bill 21- Controlled Substance 2018

---

---

---

---

---

---

---

---

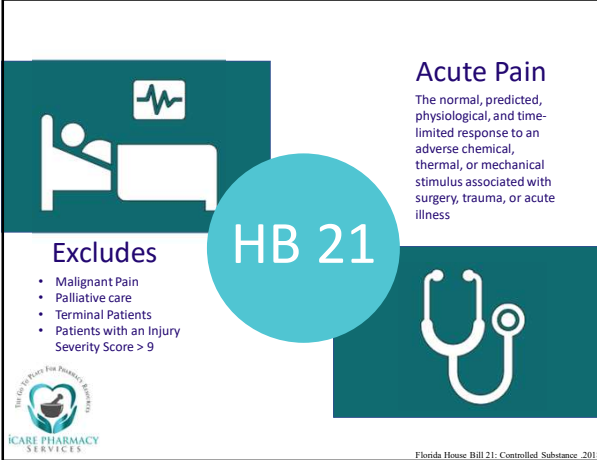
---

---

---

---

69



## 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

Florida House Bill 21: Controlled Substance - 2018

70

---

---

---

---


---

---

---

---

## 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 for a Schedule II opioid

**CHRONIC PAIN**  
“Non-Acute Pain” must be printed/written on the prescription for a Schedule II opioid

Florida House Bill 21: Controlled Substance - 2018

71

---

---

---

---

---

---

---

---

## Florida House Bill 451

### Non-Opioid Alternatives

Talk to your health care provider about how to treat your pain. Create a safe and effective treatment plan that is right for you.

**Alternatives to Opioid Medications**

Non-Opioid Alternatives	Non-Opioid Alternatives
<b>Acetaminophen (Tylenol)</b> Non-addictive, non-steroidal anti-inflammatory drug (NSAID). Commonly used for pain relief and fever reduction.	<b>Non-steroidal Anti-inflammatory Drugs (NSAIDs)</b> Commonly used for pain relief and fever reduction.
<b>Local Anesthetics</b> Used for numbing a specific area of the body.	<b>Antidepressants</b> Used for chronic pain management.
<b>Anticonvulsants</b> Used for chronic pain management.	<b>Physical Therapy, Chiropractic, Massage, Acupuncture, Yoga, and Exercise</b> Non-pharmaceutical approaches to pain management.
<b>Behavioral Pain Management</b> Cognitive-behavioral therapy (CBT) and other techniques.	<b>Non-Opioid Medications</b> Gabapentin, pregabalin, tramadol, etc.

Requires a health care practitioner to discuss non-opioid alternatives and provide the pamphlet to the patient or patient’s representative

Exempts 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

Florida House Bill 451: Controlled Substance - 2018

72

---

---

---

---

---

---

---

---



# Florida House Bill 831



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, waived practitioners, and in situations where electronic prescribing a prescription would be a barrier to the patient obtaining medication



73

---

---

---

---

---

---

---

---

# 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)



74

---

---

---

---

---

---

---

---

# Get Involved

Pharmacists working against the Opioid Epidemic



Educate on Safe Prescribing and Disposal Practices



Substance Use Disorder Treatment



Prevent Overdose Deaths



75

---

---

---

---

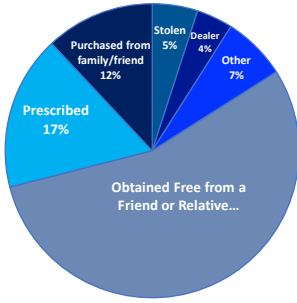
---

---

---

---

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



<http://www.cdc.gov/ostimms/pdf/201407-ostimms.pdf>

76

---

---

---

---

---

---

---

---

---

---

### 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.\*
- Be sure to keep these **medicines out of reach** of young children. For more information on safe medicine storage visit [www.upandaway.org](http://www.upandaway.org).
- Be sure to **monitor the medicine you take** and how much you have left so you will know if there is any missing medicine.



77

---

---

---

---

---

---

---

---

---

---

### Proper Drug Disposal



DEA NATIONAL DRUG TAKE-BACK DAY



DEA AUTHORIZED COLLECTOR IN THE COMMUNITY



HOME DISPOSAL (FLUSH OR TRASH)



[www.fda.gov](http://www.fda.gov) Accessed June 2024

78

---

---

---

---

---

---

---

---

---

---



**Opioid REMs Program**

#### 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 healthcare provider if your pain might be helped with an opioid medication, physical therapy, medical or behavioral therapy, acupuncture, or other non-drug therapies.

**What is naloxone?**  
 • Naloxone is a medicine that helps stop overdose. It is sprayed inside your nose or injected into your body.  
 • Get naloxone if you have a loved one, pet, or go to the emergency room right away.  
 • You or someone else has taken an opioid medicine and is having trouble breathing, is short of breath, or is unresponsive.  
 • A loved one has accidentally taken the opioid medicine or you think they might have.  
 • Giving naloxone to a person, even a child, who has had taken an opioid medicine will not hurt them.

**Naloxone is never a substitute for emergency medical care. Always call 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 provided information provided by your pharmacy.  
 • Read the Medication Guide for the medicine, which is found on the other important information about your specific medicine.

**Dozing 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 medicines.  
 • Talk to your healthcare provider or pharmacist and ask them any questions you may have.  
 • Visit [www.fda.gov/oc/oea](http://www.fda.gov/oc/oea) for more information about opioid medicines.

Page 2 of 2

www.fda.gov Accessed June 2024.

---

---

---

---

---

---

---

---

---

---

---

---

82

## Get Involved

Pharmacists working against the Opioid Epidemic



**Educate on Safe Prescribing and Disposal Practices**



**Substance Use Disorder Treatment**



**Prevent Overdose Deaths**

The City of Fort Worth For The Pharmacy Community  
 ICARE PHARMACY SERVICES

---

---

---

---

---

---

---

---

---

---

---

---

83

## Buprenorphine

---

## Methadone

---

## Naltrexone

The City of Fort Worth For The Pharmacy Community  
 ICARE PHARMACY SERVICES

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

---

---

---

---

---

---

---

---

---

---

---

---

84

## 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 DIRECTORS
- ◆ PROJECT SAVE LIVES



www.samhsa.gov. Accessed June 2024.

85

---

---

---

---

---

---

---

---

---

---

## 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 June 2024.

86

---

---

---

---

---

---

---

---

---

---

## Considerations for OUD Treatment Selection

- ◆ Compliance and good retention rates
- ◆ Low abuse potential and low risk of toxicity
- ◆ Accessible to the patient
- ◆ Limits withdrawal symptoms and cravings



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

87

---

---

---

---

---

---


---

---

---

---


## 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
- ② **STABILIZATION**  
No cravings or withdrawal symptoms  
Drug testing indicates patient compliance
- ③ **MAINTENANCE**  
Continue treatment indefinitely



88

---

---

---

---

---

---

---

---

---

---

---

---

## The Case of Mr. Timely

**Behavioral Health Services**  
Thomas Dumas, M.D.  
839 Boogie Drive  
Jacksonville, FL 32209  
Phone: (904)-369-8490 Fax: (904)-369-8491

DEA: TD124827

Name: Timothy Timely DOB: 7/23/97 Date: July 20th 2024  
Address: 424 Greentree way, Jacksonville FL 32209

Adderall 30mg

Take 1 tablet BID for ADHD

#60 (Sixty)

*Thomas Dumas* M.D. Signature

Refills: NR 1 2 3 4 5

**Behavioral Health Services**  
Thomas Dumas, M.D.  
839 Boogie Drive  
Jacksonville, FL 32209  
Phone: (904)-369-8490 Fax: (904)-369-8491

DEA: TD124827

Name: Timothy Timely DOB: 7/23/97 Date: July 20th 2024  
Address: 424 Greentree way, Jacksonville FL 32209

Suboxone Film 8/2mg      Xanax 2 mg

Take 1 film BID for opioid dependence      1 P.O. BID PRN for anxiety

#60 (Sixty)      #60 (Sixty)

*Thomas Dumas* M.D. Signature

Refills: NR 1 2 3 4 5

89

---

---

---

---

---

---

---

---


---

---

---

---

## The Case of Mr. Timely

Filled	Drug	QTY	Days	Prescriber	Pharmacy	PMP
06/20/2024	Bup/Nal 8/2mg	60	30	Th Dum	Walg (0332)	FL
06/20/2024	Dex-Amph 30mg	60		Th Dum	Walg (0332)	FL
06/20/2024	<b>PATIENT HAS BEEN ON THE SAME REGIMEN FOR A YEAR</b>				FL	
05/21/2024						FL
05/21/2024	Dex-Amph 30mg	60	30	Th Dum	Walg (0332)	FL
05/21/2024	Alprazolam 2mg	60	30	Th Dum	Walg (0332)	FL

90

---

---

---

---

---

---

---

---

---

---

---

---

## 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 medications, they make me feel funny

I have been sober for 2 years and working full time



91

---

---

---

---

---

---

---

---


---

---

## The Case of Mr. Timely

**Consult the provider**

It's Sunday, the office is closed



92

---

---

---

---

---

---

---


---


---


---


## Validating a Prescription


### Mr. Timely

 Based on sound clinical judgment

 Appropriately Documented

 Current clinical best practices

 Demonstrate benefit to the patient



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

93

---

---

---

---

---

---

---

---

---

---

# The Case of Mr. Timely

Behavioral Health Services		Behavioral Health Services	
Thomas Dumas, M.D. 878 Range Drive Jacksonville, FL 32209 Phone: (904)-309-8490 Fax: (904)-309-8491 DEA: TD1214567		Thomas Dumas, M.D. 878 Range Drive Jacksonville, FL 32209 Phone: (904)-309-8490 Fax: (904)-309-8491 DEA: TD1214567	
Name: <u>Timothy Timely</u> DOB: <u>7/23/47</u> Date: <u>July 20<sup>th</sup> 2024</u> Address: <u>429 Greenery way, Jacksonville FL 32209</u>		Name: <u>Timothy Timely</u> DOB: <u>7/23/47</u> Date: <u>July 20<sup>th</sup> 2024</u> Address: <u>429 Greenery way, Jacksonville FL 32209</u>	
<b>Adderall 30mg</b>		<b>Sibosone Film 8/2mg</b>	<b>Xanax 2 mg</b>
Take 1 tablet BID for ADHD		Take 1 film BID for opioid dependence      1 P.O. BID PRN for anxiety	
#60 (Sixty)		#60 (Sixty)	#60 (Sixty)
<input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input checked="" type="checkbox"/> 50-74 <input type="checkbox"/> 75-99 <input type="checkbox"/> 100-150 <input type="checkbox"/> 151 and over Units: _____		<input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input checked="" type="checkbox"/> 50-74 <input type="checkbox"/> 75-99 <input type="checkbox"/> 100-150 <input type="checkbox"/> 151 and over Units: _____	
Thomas Dumas M.D. Signature		Thomas Dumas M.D. Signature	
Refills NR 1 3 4 5		Refills NR 1 3 4 5	

---

---

---

---

---

---

---

---

---

---

94

# The Case of Mr. Timely

Westshore ER		2 weeks later	
William Fox, M.D. 8200 Fike Street Jacksonville, FL 32209 Phone: (904)-309-8490 Fax: (904)-309-8491 DEA: WF1214567		TALK TO THE PATIENT Mr. Timely reports that he broke his arm	
Name: <u>Timothy Timely</u> Date: <u>August 3<sup>rd</sup> 2024</u> Address: <u>429 Greenery way, Jacksonville FL 32209</u>		CONTACT THE EMERGENCY DEPARTMENT Ensure the provider is aware patient is taking buprenorphine/naloxone	
<b>Percocet 10/325mg</b>		CONTACT THE OUD PROVIDER Inform provider of the injury and the opioid prescription provided by the ER practitioner	
Take 1 tablet Q4-6 hrs prn pain		OFFER THE PATIENT NALOXONE	
#10 (Ten)			
<input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-99 <input type="checkbox"/> 100-150 <input type="checkbox"/> 151 and over Units: _____			
William Fox M.D. Signature			
Refills NR 1 3 4 5			

---

---

---

---

---

---

---

---

---

---

95

# Get Involved

Pharmacists working against the Opioid Epidemic

		
Educate on Safe Prescribing and Disposal Practices	Substance Use Disorder Treatment	Prevent Overdose Deaths




---

---

---

---

---

---

---

---

---

---

96



# Risk Factors Associated with Opioid Overdose

- Combining opioids with alcohol or certain other drugs
- Taking more opioids than prescribed
- Patients greater than 65 years of age
- Taking high daily dosages of prescription opioids
- 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, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95

97

---

---

---

---

---

---

---

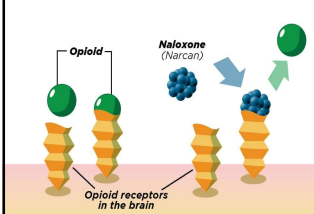
---

---

---

# Naloxone

## 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



Community management of opioid overdose. WHO. 2014; 1-88

98

---

---

---

---

---

---

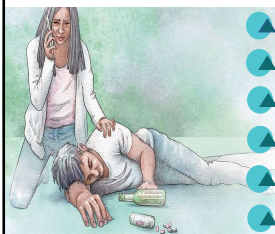
---

---

---

---

# 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



Community management of opioid overdose. WHO. 2014; 1-88

99

---

---

---

---

---

---

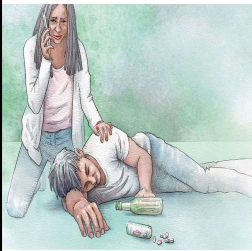
---

---

---

---

# Responding to an Opioid Overdose



- 1 Call 911 immediately
- 2 Administer naloxone
- 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



Community management of opioid overdose, WHO, 2014; 1-88

100

---

---

---

---

---

---

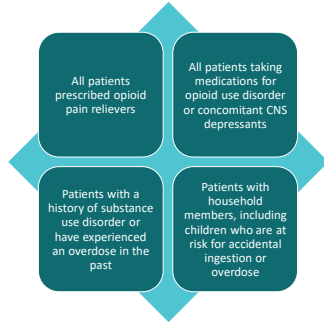
---

---

---

---

# FDA Recommendations for Naloxone



101

---

---

---

---

---

---

---

---

---

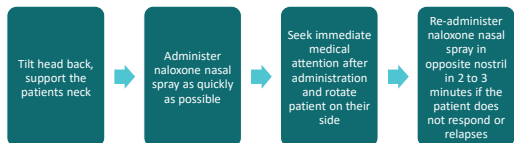
---

# Intranasal Naloxone

## Patient Education



Single dose, do NOT prime prior to administration



102

---

---

---

---

---

---

---

---

---

---

# 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.

103

---

---

---

---

---

---

---

---

# Naloxone Dispensing

Senate Bill 544: Drug-related Overdose Prevention

- Passed 2022
- Allows pharmacists to order and dispense naloxone to a patient or caregiver without a prescription
- The law also authorizes law enforcement officers, correctional officers, and child protective investigators to possess, store, and administer naloxone.
- It permits public schools to purchase and store the medication securely on school premises.
- The law requires hospital emergency departments and urgent care clinics to report incidents involving a suspected and actual overdose to the Florida Department of Health when the individual does not arrive via EMS or law enforcement transport.



104

---

---

---

---

---

---

---

---

# Naloxone Dispensing

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



105

---

---

---

---

---

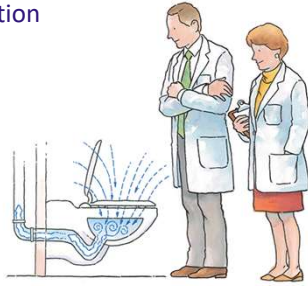
---

---

---

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



106

---

---

---

---

---

---

---

---

## 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



107

---

---

---

---

---

---

---

---

## Validation and Counseling of Prescriptions for Controlled Substances and Opioids

Joseph Cammilleri, Pharm.D., BCACP, CPE



108

---

---

---

---

---

---

---

---