

Validation and Counseling of Prescriptions for Controlled Substances and Opioids

Katie Maples, Pharm.D.



1

Speaker Bio



Dr. Katie Maples graduated from the University of Florida with a doctorate of pharmacy and completed both a PGY1 residency at Florida Hospital (now Advent Health) in Orlando, Florida as well as a Pain and Palliative Care Specialty Residency at H. Lee Moffitt Cancer Center in Tampa, Florida. She has worked as a Pain and Palliative Care Clinical Specialist for over 15 years in both the hospital and ambulatory care settings. Currently, Dr. Maples serves as the Pain and Palliative Care Coordinator and Opioid Stewardship Pharmacist at UF Health Jacksonville. She is passionate about the pharmacist’s role in palliative care, especially at end of life and frequently precepts both pharmacy students and PGY1 residents. She is interested in opioid overdose prevention and is a community distributor of free OTC Narcan nasal spray.



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.

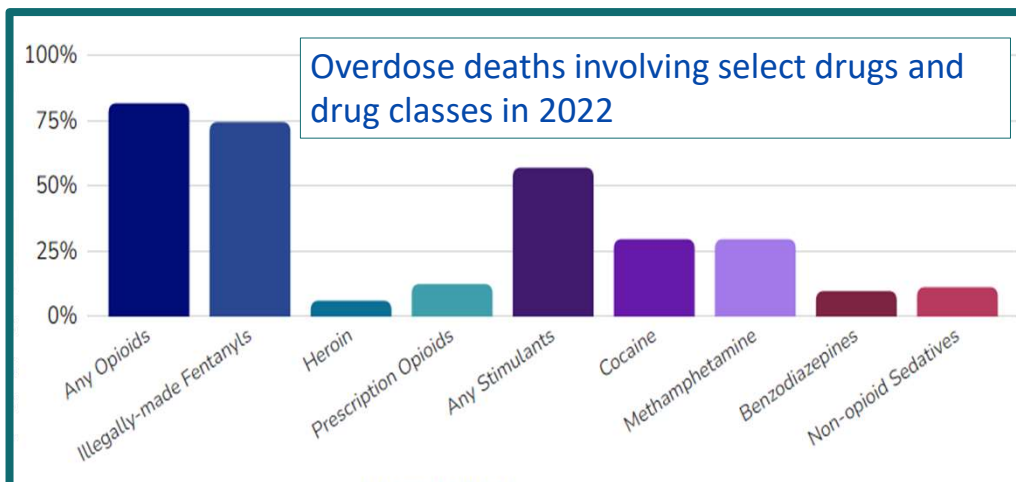
In fulfilling this vow:

- 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

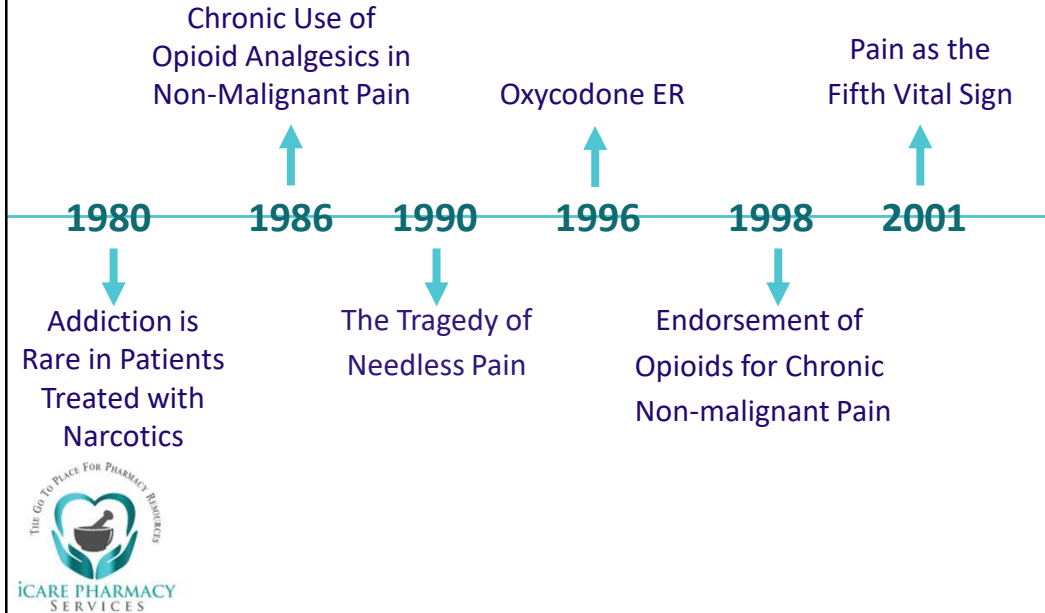
The Opioid Epidemic



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

6

Timeline



7

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

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



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



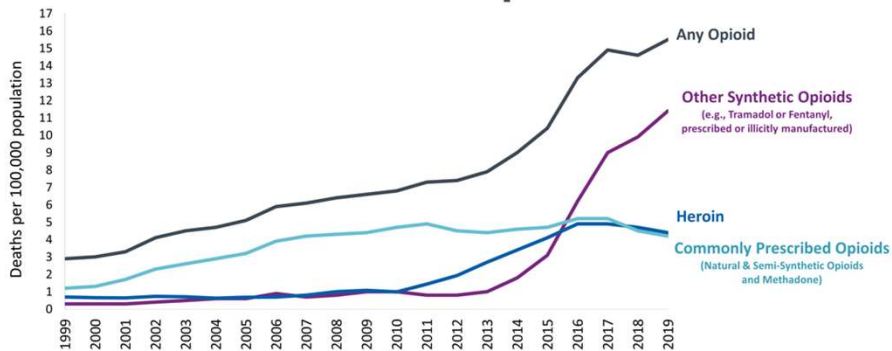
Criminal enterprises exploited Florida's regulatory system



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

9

Three Waves of the Rise in Opioid Overdose Deaths



Wave 1: Rise in Prescription Opioid Overdose Deaths Started in 1999

Wave 2: Rise in Heroin Overdose Deaths Started in 2010

Wave 3: Rise in Synthetic Opioid Overdose Deaths Started in 2013

SOURCE: National Vital Statistics System Mortality File.



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

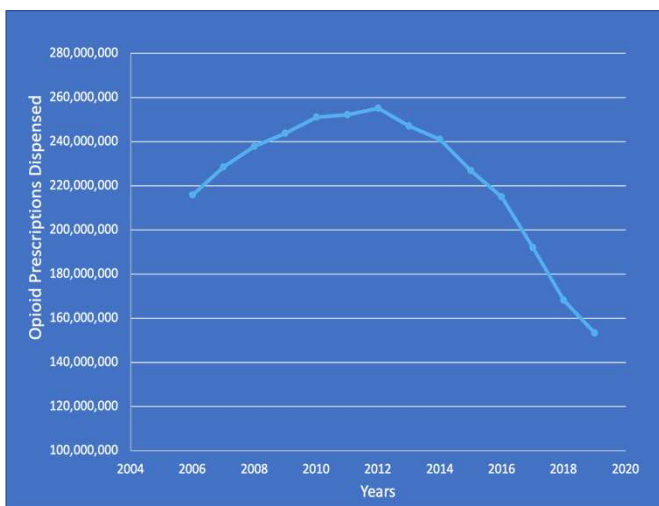


Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The changing face of heroin use in the United States: a retrospective analysis of the past 50 years. *JAMA Psychiatry*. 2014;71(7):821-826.
Jones CM. Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010. *Drug Alcohol Depend*. 2013;132(1-2):95-100.
Lankenau SE, Teti M, Silva 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):37-41.

11

Opioid Prescribing Decreasing

Total number of opioid prescriptions dispensed in the United States 2006-2019



Centers for Disease Control and Prevention [website]. <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>. Accessed January 2020.

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

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

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

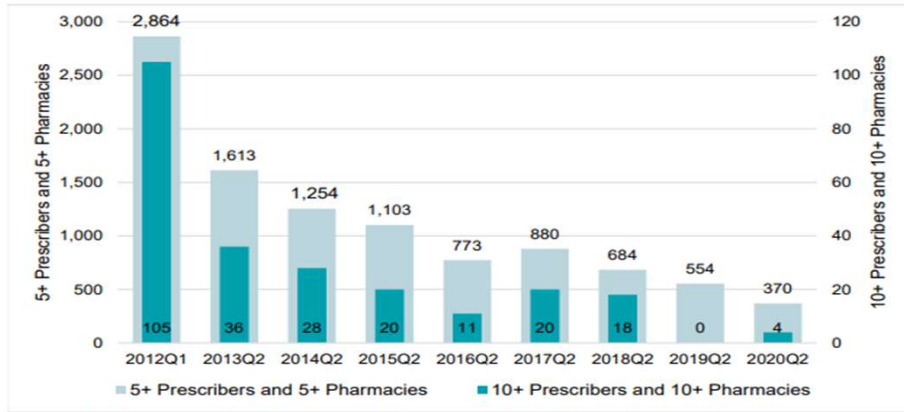
- Directly administered to patients
- Dispensed in the health care system of the Department of Corrections
- Patients under the age of 16



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

16

E-Forcse, RxAware®



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



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

17

E-Forcse, RxAware®

RxSearch > Patient Request



Patient Request

Patient Info

First Name* Last Name*

Partial Spelling 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*

09/19/2018 09/18/2020

Patient Location

Search accuracy can be improved by including the address

Zip Code

[Patient Rx Request Tutorial](#)
 Can't view the file? [Get Adobe Acrobat Reader](#)
 * Indicates Required Field



18

E-Forcse, RxAware®

Also Search

PMP Interconnect
 RxCheck
 None

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

- A Alabama
- C Colorado Connecticut
- D Delaware
- G Georgia
- I Idaho
- L Louisiana
- M Maine Massachusetts Michigan Military Health System Minnesota Mississippi
- N North Carolina
- O Ohio
- P Pennsylvania
- R Rhode Island
- S South Carolina
- T Tennessee
- V Virginia
- W Wisconsin



19

E-Forcse, RxAware®

Filled	Written	Sold	ID	Drug	QTY	Days	Prescriber	RX #	Dispenser	Refill	Daily Dose*	Pynt Type	PMP
05/15/2024	05/06/2024	05/16/2024	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ju Joc	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
04/16/2024	04/11/2024	04/17/2024	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ma Jam	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
03/19/2024	03/07/2024	03/19/2024	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ma Jam	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
02/14/2024	02/09/2024	02/20/2024	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ju Joc	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
01/17/2024	01/11/2024	01/17/2024	1	Oxycodone-Acetaminophen 10-325	112.00	28	Eb Pra	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
12/20/2023	12/15/2023	12/20/2023	1	Oxycodone-Acetaminophen 10-325	112.00	28	Eb Pra	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
11/22/2023	11/21/2023	11/22/2023	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ro Jon	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
10/26/2023	10/25/2023	10/26/2023	1	Oxycodone-Acetaminophen 10-325	108.00	27	Ju Joc	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
09/28/2023	09/28/2023	09/28/2023	1	Oxycodone-Acetaminophen 10-325	112.00	28	Ma Jam	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL
08/28/2023	08/25/2023	08/28/2023	2	Oxycodone-Acetaminophen 10-325	120.00	30	Ju Joc	[REDACTED]	Sha (0574)	0/0	60.00 MME	Comm Ins	FL



20

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



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

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 cast 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



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



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.



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

27

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

INVALID PRESCRIPTION

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



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



64B16-27.831 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



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?



I SEE THAT YOU ARE NEW TO OUR PHARMACY HOW CAN WE HELP YOU TODAY?



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 32801
Phone: (407)-826-4537 Fax: (407)-826-4538

Rx

ME 100001 DEA 1234567

Name: Jennifer Jones DOB 11/23/72 Date July 19th 2024

Address: 4000 South 2nd street Louisville, KY 40214

Diagnosis: Methadone 10 mg
G90.50

Non-Acute Pain 3 tabs P.O. TID

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

270
(two-hundred and seventy)

Michelle Smithson M.D.
Signature

Refills NR: 1 2 3 4 5



UnitedHealthcare Community Plan
Health Plan (800) 911-87726-04
Member ID: S999999999
Subscriber: JENNIFER JONES
Payer ID: 7726
Payer Name: OHPHCP
Rx ID: 610484
ACUOH 9999
Rx PCN: 9999

NO

001 Administered by UnitedHealthcare Community Plan of Ohio, Inc. ©



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

Your doctor is in Orlando however your address is Kentucky

When was your last office visit?

Does this medication help your ability to function?

Do you have insurance?

Yes, I'm on vacation and couldn't fill if before I left

I've been taking care of my mom in Orlando for the past few months

Friday

I couldn't function without it

Yes, I have Kentucky Medicaid

iCARE PHARMACY SERVICES

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			03/10/2010
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

iCARE PHARMACY SERVICES

40



Consult the provider

Profession	Medical Doctor
License Status	CLEAR/ACTIVE
Year Began 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-3):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)-826-4537 Fax: (407)-826-4538

Rx

04022523456 ME 100001 DEA 1234567

Name: Jennifer Jones DOB 11/23/72 Date July 19th 2024

Address: 4000 South 2nd street Louisville, KY 40214

Diagnosis: Methadone 10 mg
G90.50

Non-Acute Pain 3 tabs P.O. TID

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

270
(two-hundred and seventy)

Michelle Smithson M.D.
Signature

Refills NR: 1 2 3 4 5

DRIVER'S LICENSE
License No: B04-122-350
Birthdate: 11-23-1972
www.kentucky.gov

XXX, XXXX
4000 S 2ND ST
LOUISVILLE KY 40214-1957
JEFFERSON COUNTY

Jennifer Jones

UnitedHealthcare Community
Health Plan (93040) **911-87726-04**
Member ID: 999999999 Member: OHPHCP
SUBSCRIBER: JENNIFER JONES Payer ID: 7726
MFI#: 999999999
PCP Name: Michelle Smithson
DR. PROVIDER: BRONKHORST Rx # OTUM104
PCP Phone: (99)999-9999 Rx PCN: ACU04
9999

NO



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.



64B16-27.831 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

North Florida Primary Care
 Hillary Sampson, M.D.
 654 River Oaks Trail
 Jacksonville, FL 32209
 Phone: (904)-823-1110 Fax: (904)-823-1111

Rx

040295123456 DEA 1234567

Name Fabio Cash DOB: 4/2/1977 Date July 19th 2024

Address 4267 Gate Parkway, Jacksonville, FL 32209

Alprazolam 2mg

1 P.O. QID PRN Anxiety

#120
(One-hundred and Twenty)

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

Refills NR 12 Hillary Sampson M.D.
 Signature



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	Walq (2518)	FL
01/20/2023	Oxycodone 10mg	45	30	Ja Mar	Walq (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



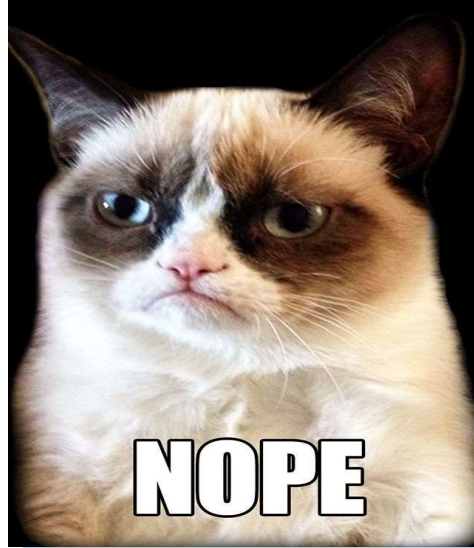
Current clinical best practices



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 Filling of Controlled Substance Prescriptions.2016.

62

The Case of Ms. Lewis

Florida Primary Care
Petra Franks, M.D.
1975 APPLE CT
JACKSONVILLE, FL 32209
PHONE: (904)-369-8490 FAX: (904)-369-8491

Rx

040225123456 DEA PF1234567

Name Hope Lewis DOB: 6/5/2001 Date July 20th 2024
Address 429 Greenery way, Jacksonville FL 32209

Cheratussin AC 100mg-10mg/5ml

Take 10ml qA-6hrs prn

420ml
(Four hundred and twenty)

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

Petra Franks M.D.
Signature

Refills NR: 2 3 4 5

Florida Primary Care
Petra Franks, M.D.
1975 APPLE CT
JACKSONVILLE, FL 32209
PHONE: (904)-369-8490 FAX: (904)-369-8491

Rx

040225123456 DEA PF1234567

Name Hope Lewis DOB: 6/5/2001 Date July 20th 2024
Address 429 Greenery way, Jacksonville FL 32209


Amoxil 500mg

Take 1 po TID #21

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

Petra Franks M.D.
Signature

Refills NR 1 2 3 4 5



The Go To PLACE FOR PHARMACY SERVICES

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

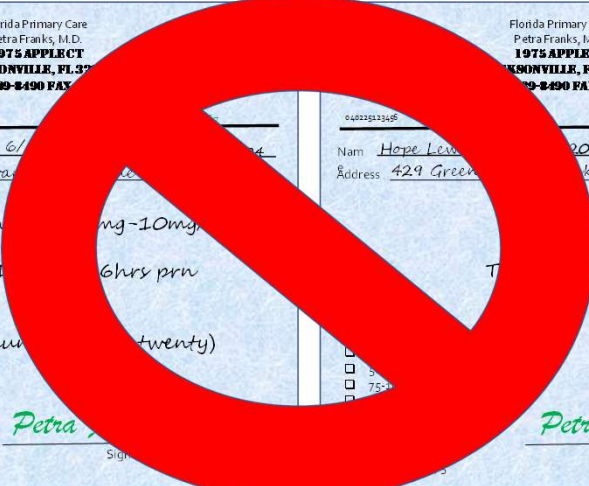
Looked up doctor in the pharmacy computer system and called that number

No record of the doctor seeing the patient



66

The Case of Ms. Lewis



Florida Primary Care
Petra Franks, M.D.
1975 APPLE CT
JACKSONVILLE, FL 32209
PHONE: (904) 309-8490 FAX: (904) 309-8491

Florida Primary Care
Petra Franks, M.D.
1975 APPLE CT
JACKSONVILLE, FL 32209
PHONE: (904) 309-8490 FAX: (904) 309-8491

DEA PF1234567

Name: Hope Lewis DOB: 6/1/1974 Name: Hope Lewis DOB: 6/1/1974 Date: July 20th 2024
Address: 429 Greenery way Jacksonville FL 32209 Address: 429 Greenery way Jacksonville FL 32209

Cheratussin 10mg-10mg 500mg
Take 1 6hrs prn TID #21

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

(Four hundred twenty)

Petra Franks Petra Franks M.D.
Signature Signature

Refills NR: 2 3 4 5



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




Excludes


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

HB 21

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





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

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 Opioids: Medications

NON-OPIOID MEDICATIONS	DESCRIPTIONS, ADDITIONAL ADVANTAGES & DISADVANTAGES
Acetaminophen (Tylenol)	Relieves mild-moderate pain and treats fevers. Does not affect the stomach, kidneys, heart, or blood. Can cause liver damage if taken in excess.
Non-steroidal Anti-inflammatory Drugs (NSAIDs): Naproxen (Aleve), Ibuprofen (Advil, Motrin), Celecoxib (Celebrex)	Relieves mild-moderate pain and reduces swelling and inflammation. Risk of stomach problems increases for people who take NSAIDs regularly. Can increase risk of bleeding.
Nerve Pain Medications: Gabapentin (Neurontin), Pregabalin (Lyrica)	Relieves mild-moderate nerve pain (burning and/or tingling pain). Can cause drowsiness, dizziness, loss of coordination, headache and constipation.
Antidepressants: Duloxetine (Cymbalta), Venlafaxine (Effexor XR)	Relieves mild-moderate chronic pain, some pain (burning and tingling pain) and headaches. Depending on medication, side effects can include drowsiness, dizziness, dryness, constipation, weight loss or gain.
Medicated Creams, Foams, Gels, Lotions, Ointments, Sprays and Patches: Lidocaine (Lidocaine), Menthol, Capsaicin, Lidocaine, Capsaicin, Compound Tincture	Can be used to relieve mild-moderate pain because medication is applied where the pain is. Medication relieves nerve pain (burning and tingling pain) by numbing or numbing the pain at the site of the pain. Topical, sprays, ointments and patches provide localized relief of pain. Do not affect the rest of the body. Can provide relief for some types of pain. A pharmacist can be consulted to meet a patient's specific needs. Side effects in the most common case are mild. Can cause skin irritation, itching or swelling on the skin.
Interventional Pain Management	Includes epidural steroid injections, spinal cord stimulation, radiofrequency ablation, and intrathecal drug delivery systems, or placement of temporary nerve blocks. Medication goes to the site of the body. Can provide relief for some types of chronic pain. Can be used in combination with other medications. Can cause complications.
Non-opioid Anesthesia	Options can be replaced with safer medications that block pain during and after surgery. A health care provider in an ambulatory care center can provide options and discuss side effects.

Non-Opioid Alternatives

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



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 \(flsenate.gov\)](https://www.flsenate.gov/bills/2022/sb312)



74

Get Involved

Pharmacists working against the Opioid Epidemic



Educate on Safe Prescribing and Disposal Practices



Substance Use Disorder Treatment

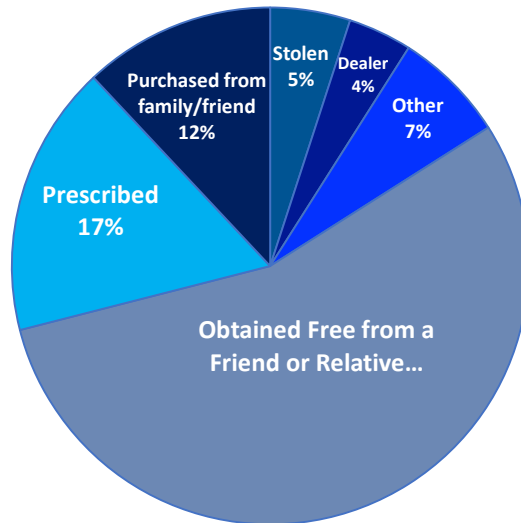


Prevent Overdose Deaths



75

Don't Let the Medicine Cabinet Become Your Communities Dealer



<http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.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.¹



Be sure to keep these **medicines out of reach** of young children. For more information on safe medicine storage visit 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 Accessed June 2024.

78

FDA Flush List

Active Ingredient	Found in Brand Names
Benzhydrocodone /Acetaminophen	Apaxa
Buprenorphine	Belbuca , Bunavail , Butrans , Suboxone , Subutex , Zubsolv
Fentanyl	Abstral , Actiq , Duragesic , Fentora , Onsolis
Diazepam	Diastat / Diastat AcuDial rectal gel
Hydrocodone	Anexsia , Hydralgia ER , Lortab , Norco , Reprexain , Vicodin , Vicoprofen , Zohydro ER
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 , Roxicet , Roxicodone , Roxycodone , Targinia 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 June 2024.

79

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 June 2024.

80

Opioid REMs Program



Opioid 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?
Opioids 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 sleepy or 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 ongoing treatment.


Risk Factors for Opioid Abuse:

- You have:
 - a history of addiction
 - a family history of addiction
- You take medicines to treat mental health problems
- You are under the age of 65 (although anyone can abuse opioid medicines)

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 opioid 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.
- Benzodiazepines (like Valium or Xanax)
- Muscle relaxants (like Soma or Flexeril)
- Sleep medicines (like Ambien or Lunesta)
- Other prescription opioid medicines




Page 1 of 2

www.fda.gov Accessed June 2024.

81

Opioid REMs Program



Opioid Analgesic REMS
Patient Counseling Guide

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 a non-opioid medication, physical therapy, exercise, rest, acupuncture, types of behavioral therapy, or patient self-help techniques.

What is naloxone?

- Naloxone is a medicine that treats opioid overdose. It is sprayed inside your nose or injected into your body.
- Use naloxone if you have it and call 911 or go to the emergency room right away if:
 - 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
- Giving naloxone to a person, even a child, who has not 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.

Where can I get naloxone?

- There are some naloxone products that are designed for people to use in their home.
- Naloxone is available in pharmacies. Ask your healthcare provider about how you can get naloxone. In some states, you may not need a prescription.
- When you get your naloxone from the pharmacy read the Patient Information on how to use naloxone and ask the pharmacist if anything is unclear.
- 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/druginfo/psopai>

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

- Your healthcare provider has prescribed _____ for you. Read the Medication Guide for this medicine, which is information provided by your pharmacy.
- Remember this other important information about your opioid 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 medicine.
- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- Visit: www.fda.gov/oc/oid 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



83

Buprenorphine

Methadone

Naltrexone








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 DIRECTORY
-  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

Rx

DEA **TD1234567**

Name Timothy Timely DOB: 7/23/97 Date July 20th 2024
Address 429 Greenery 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

Rx

DEA **TD1234567**

Name Timothy Timely DOB: 7/23/97 Date July 20th 2024
Address 429 Greenery way, Jacksonville FL 32209

Suboxone Film 8/2mg	Xanax 2 mg	
Take 1 film BID for opioid dependence		
#60 (Sixty)		
1 P.O. BID PRN for anxiety		
#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	PATIENT HAS BEEN ON THE SAME				FL	
05/21/2024	REGIMEN FOR A YEAR				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

<p>Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville, FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491</p> <p>040225123456 DEA <u>TD1234567</u></p> <p>Name <u>Timothy Timely</u> DOB: <u>7/23/97</u> Date <u>July 20th 2024</u> Address <u>429 Greenery way, Jacksonville FL 32209</u></p> <p style="border: 2px solid green; padding: 2px; display: inline-block;">Adderall 30mg</p> <p>Take 1 tablet BID for ADHD</p> <p style="text-align: center;">#60 (sixty)</p> <p><i>Thomas Dumas</i> M.D. Signature</p> <p>Refills NR 1 2 3 4 5</p>	<p>Behavioral Health Services Thomas Dumas, M.D. 839 Boogie Drive Jacksonville, FL 32209 Phone: (904)-369-8490 Fax: (904)-369-8491</p> <p>040225123456 DEA <u>TD1234567</u></p> <p>Name <u>Timothy Timely</u> DOB: <u>7/23/97</u> Date <u>July 20th 2024</u> Address <u>429 Greenery way, Jacksonville FL 32209</u></p> <p style="border: 2px solid green; padding: 2px; display: inline-block;">Suboxone Film 8/2mg Xanax 2 mg</p> <p>Take 1 film BID for opioid dependence 1 P.O. BID PRN for anxiety</p> <p style="text-align: center;">#60 (Sixty)</p> <p><i>Thomas Dumas</i> M.D. Signature</p> <p>Refills NR 1 2 3 4 5</p>
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94

The Case of Mr. Timely

Westshore ER
 William Fox, M.D.
 8200 Fake Street
 Jacksonville, FL 32209
 Phone: (904)-369-8490 Fax: (904)-369-8491

Rx

DEA **WF1234567**

Name Timothy Timely Date August 3rd 2024
 Address 429 Greenery way, Jacksonville FL 32209

Percocet 10/325mg

Take 1 tablet Q4-6 hrs prn pain

#10
(Ten)

William Fox M.D.
 Signature

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

Refills NR 1 2 3 4 5

2 weeks later

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

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

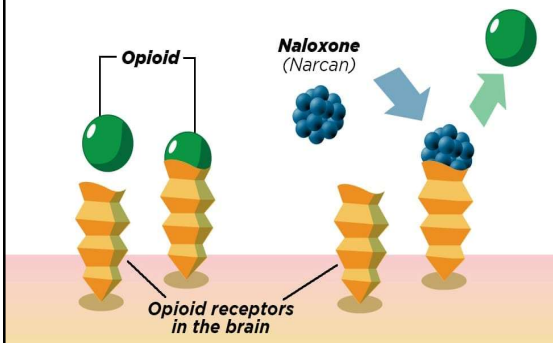


Community management of opioid overdose. WHO. 2014; 1-88
 Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95.

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



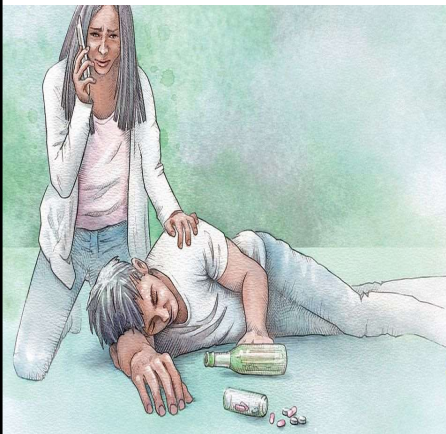
- ▲ SMALL, CONSTRICTED "PINPOINT PUPILS"
- ▲ FALLING ASLEEP OR LOSS OF CONSCIOUSNESS
- ▲ SLOW, SHALLOW BREATHING
- ▲ CHOKING OR GURGLING SOUNDS
- ▲ LIMP BODY
- ▲ PALE, BLUE, OR COLD SKIN



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

99

Responding to an Opioid Overdose



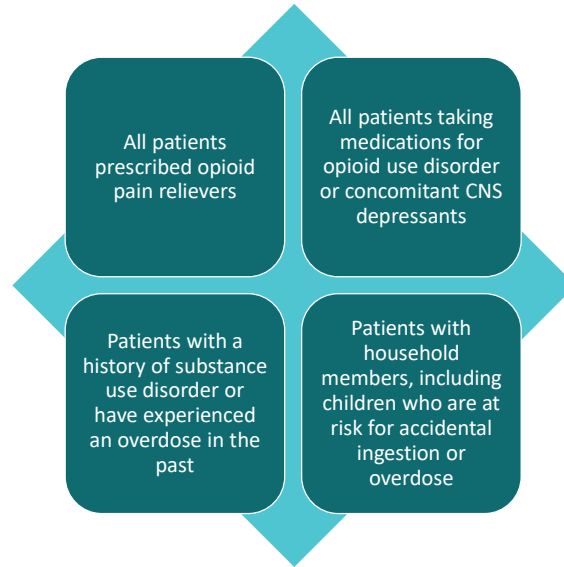
- 1 Call 911 immediately
- 2 Administer naloxone
- 3 Try to keep the person awake and breathing
- 4 Lay the person on their side to prevent choking
- 5 Stay with the person until emergency workers arrive



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

100

FDA Recommendations for Naloxone



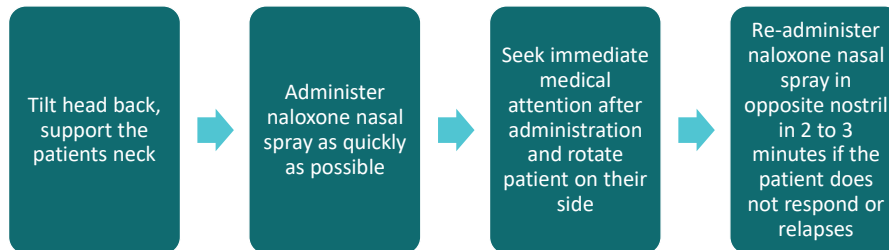
101

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

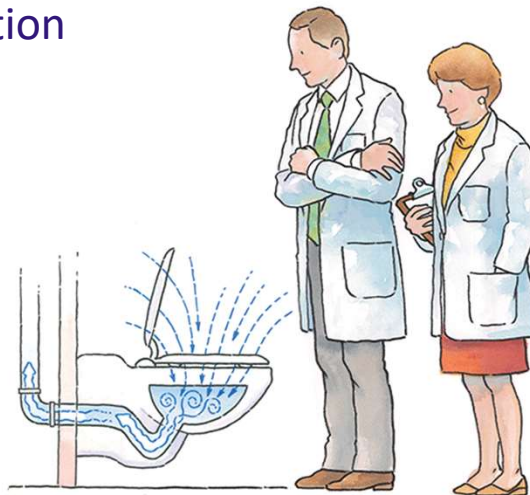
OTC Approved
March 29th 2023



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