 Controlled Substance Validation

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Citation

Martin Diaz, Claudia; Hernandez, Jessica; Neubauer, Laura; and Guizan Corrales, Eduardo, "Controlled Substance Validation" (2020). *All Publications*. 3379.  
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Controlled Substance Validation

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Disclosure

- The following authors have no relevant financial or non-financial relationships in the products described and reviewed in this presentation.
  - Claudia Martin Diaz, Pharm.D.
  - Jessica Hernandez, Pharm.D.
  - Laura Neubauer, Pharm.D.
  - Eduardo Guizan, Pharm.D.
Objectives

- Describe federal and state laws pertaining to the prescribing and dispensing of opioid controlled medications
- Discuss methods of validating a prescription for therapeutic appropriateness and approaches for the detection of prescriptions that are not medically appropriate or have been furnished by fraudulent means
- Review and assess prescriptions for appropriateness, quantity limitations and other requirements for opioids in the treatment of acute and chronic management of pain
- Discuss the purpose and function of the Florida Prescription Drug Monitoring Program (PDMP) E-FORCSE in identifying potential diversion of controlled substances (CS)
- Provide comprehensive patient education on overdose symptoms, information on available treatment resources for opioid dependence, addiction, misuse or abuse, as well as naloxone counseling (storage, disposal, potential drug interactions, side effects)
# Schedules of CS’s

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Potential for Abuse</th>
<th>Examples</th>
</tr>
</thead>
</table>
| C-I | High – Medical use currently not accepted in the US | • Heroin  
• Lysergic acid diethylamide (LSD)  
• Ecstasy |
| C-II | High – May lead to severe psychological or physical dependence | • Hydromorphone  
• Methadone  
• Meperidine  
• Oxycodone  
• Fentanyl  
• Amphetamines  
• Methylphenidate |
| C-III | Less than C-I or C-II’s – May lead to low-moderate psychological or physical dependence | • Combination products containing <15 mg of hydrocodone per dosage unit  
• Combination products containing ≤90 mg of codeine  
• Buprenorphine products  
• Ketamine  
• Anabolic steroids |
| C-IV | Low | • Benzodiazepines |
| C-V | Low | • Cough preparations containing ≤200 mg of codeine per 100 mL or per 100 g |
Background

- An average of 130 Americans die every day from an opioid overdose.

- In 2018:
  - 2 million people had an opioid use disorder.
  - Approximately 10.3 million people aged 12 or older misused opioids.

- The United States Department of Health and Human Services (HHS) developed a 5-point comprehensive strategy to address opioid abuse, dependence, and overdose.
HHS 5-point Comprehensive Strategy

1. Better addiction prevention, treatment, and recovery services
2. Better data
3. Better pain management
4. Better targeting of overdose reversing drugs
5. Better research
Florida Opioid Prescribing Rates

60.9 vs 58.7
Florida Drug Overdose Deaths

National Institute on Drug Abuse: Florida Opioid Summary
CDC Combats Opioid Crisis

- Enhanced State Opioid Overdose Surveillance (ESOOS) Program
- Captures different types of data for both fatal and nonfatal overdoses
  - 2016: 12 states were funded
  - 2017: additional 20 states and the District of Columbia were added
- Every four months, ESOOS-funded states report overdose data to CDC

www.cdc.gov/drugoverdose/data/prescribing/overdose-death-urbanicity
ESOOS Program

- Data collected via emergency department (ED) hospital billing system and synchronized surveillance data
  - Utilize standard diagnostics codes that categorize if the visit was for an overdose

- Objective is to improve the timeliness of fatal and nonfatal opioid overdose data for action and response
  - Establish an early warning system
  - Integrates data from death certificates and medical investigations
  - Shares findings with state and national stakeholders
- Identified 700 deaths involving fentanyl analogs across 10 of the ESOOS states from July to December 2016

- Reported findings on opioid overdoses treated in the EDs in 16 of the ESOOS states from July 2016 through September 2017, showed that ED visits for opioid overdoses increased 30% in all parts of the United States
History

- **1970**: Enactment of the CSA
- **1990**: Amendment to CSA allows for E-prescribing of opioids
- **2010**: ↑ in OD deaths due to ↑ prescribing
- **2010**: ↑ in OD deaths due to heroin
- **2013**: ↑ in OD deaths due to use of synthetic opioids
- **2017**: HHS enacts 5-point strategy to combat opioid epidemic
- **2018**: House Bill 21

CSA: controlled substance act; OD: overdose; HHS: Health and Human Services
Federal Controlled Substance Laws
Controlled Substance Act

- The CSA provides a mechanism for substances to be controlled
- Establishes federal requirements regarding both illicit and licit CS
- Designed to function in tandem with state controlled substance laws to make certain that pharmaceutical CS are prescribed, administered, and dispensed for a legitimate medical purpose
Controlled Substance Act

Manufacturers

Doctors

Patients

Distributors

Pharmacies

Closed System
The Drug Enforcement Administration (DEA) responsibility in regards to pharmaceutical CS:

- Prevent diversion and abuse of CS while ensuring appropriate and uninterrupted supply to meet the patient’s legitimate medical, scientific, and research needs.
Valid Prescription Requirements

- **Prescription:** an order for a medication which is dispensed to or for an ultimate user

- An Rx for a CS must be **dated** and **signed** on the date when it was issued

- **Must include:**
  - Patient’s full name and address
  - Practitioner’s full name, address, and DEA registration number
  - Medication name
  - Strength and dosage form
  - Quantity prescribed
  - Directions for use
  - Number of refills authorized
Valid Prescription Requirements

- Rx must be written in ink or typewritten and manually signed by the practitioner on the date when issued
- An Rx for a CS may only be issued by a physician, dentist, podiatrist, veterinarian, or mid-level practitioner acting in the usual course of professional practice and for a legitimate medical purpose
Pharmacist’s role in validating CS prescriptions:

- Responsible to exercise sound professional judgment when making a determination about the legitimacy of an Rx prior to dispensing medication
- Responsible for ensuring Rx has been issued by an appropriately registered practitioner
Electronic Prescriptions

- The DEA published an interim final rule for electronic Rxs for CS
- Became effective June 1st, 2010
- Provide practitioners with the option of writing Rxs for CS electronically
- Allow pharmacies to receive, dispense, and archive these electronic Rxs
C-II Substances Requirements
C-II Substances

- Require a written Rx which must be manually signed by the practitioner or an electronic Rx meeting all of the DEA’s requirements.
- There is no federal time limit within which a C-II Rx must be filled after being signed by the practitioner.
- No federal limits with respect to the quantities of medications dispensed via an Rx.
- Oral orders are only permitted in emergent situations.
- Refills are prohibited.
C-II Substances

- Up to a 90-day supply of a C-II may be dispensed under the following conditions:
  - Each Rx must be issued on a separate prescription blank
  - Must be issued for a legitimate medical purpose by an individual practicing under the course of professional practice
  - Rx must provide written instructions indicating the earliest date on which a pharmacy may fill each Rx
  - Allowed under State Laws
  - Practitioner complies fully with all requirements under the CSA and state laws
C-II Substances

- Rxs may be transmitted to the pharmacy by facsimile in order to expedite the filling of an Rx
- The original Rx must be presented to the RPh and verified against the facsimile at the time the CS is dispensed
C-II Substances

- Exceptions for C-II facsimile prescriptions:
  - C-II narcotic CS to be compounded for the direct administration to a patient by parenteral, IV, IM, SQ, or intraspinal infusion
  - C-II’s for residents of Long Term Care Facilities
  - C-II’s for a patient enrolled in a hospice program
C-II Dispensing Requirements

- Required information for Rx labels:
  - Date of filling
  - Pharmacy name and address
  - Rx number
  - Patient’s name
  - Prescriber’s name
  - Directions for use and cautionary statements
  - “CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed”
C-II Dispensing Requirements

- C-II’s may only be dispensed pursuant to a written Rx signed by the practitioner with the exception of an emergency situation.

- **Emergency dispensing:** immediate administration of the medication is necessary for proper treatment of the intended ultimate user and no alternative treatment is available.
Prescriber must provide a written and signed Rx to the pharmacy within **seven days** of Rx being phoned in and must contain "authorization for emergency dispensing" written with the date of the oral order.

Rx must be limited to the amount needed to treat the patient during the emergency.

Order must be immediately reduced to writing by the RPh and contain all information with the exception of the prescriber’s signature.
C-II Partial Dispensing

- C-II’s may be partially dispensed if the RPh is unable to supply the full quantity
  - Remaining portion may be dispensed within 72 hours of the first partial dispensing
  - RPh must notify prescribing practitioner if remaining portion cannot be filled within 72 hours
  - RPh must note quantity supplied on the front of the written Rx
CIII-V Substances Requirements
CIII-V Substances

- Rx may be received via facsimile as long as the practitioner has manually signed the Rx
- Rx may be dispensed pursuant to an oral Rx made by an individual practitioner and reduced to writing by the RPh
- May be transferred to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies on a one time basis
CIII-V Substances

- Pharmacies sharing a real-time, on-line database may transfer up to the maximum refills permitted by law.
- Transfer of CIII-V must be communicated between two licensed RPhs.
Dispensing of C-III & C-IV Refills

- C-III’s and C-IV’s may be refilled up to 5 times within 6 months after the date of issue.
- Required information to be recorded on the back of Rx:
  - RPh’s initials
  - Date the Rx was refilled
  - Amount of medication dispensed on the refill
Florida Controlled Substance Laws
Standards of Practice

- The Board of Pharmacy recognizes that it is important for the patients to be able to fill valid Rxs for CS.

- RPhs should not fear disciplinary action for dispensing CS for a legitimate medical purpose in the usual course of professional practice.

- Every patient’s situation is unique and Rxs for CS shall be reviewed accordingly.

Florida Statue 64B16-27.831
Definitions – FL Law

- **Valid Rx** – An Rx is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

- **Invalid Rx** – An Rx is invalid if the RPh knows or has reason to know that the Rx was not issued for a legitimate medical purpose.
House Bill 21

- Effective July 1st, 2018
- Florida specific
- Objective is to increase regulation, training, and reporting required when CS are prescribed and dispensed
  - E-FORCSE®*
  - Prescribing limitations

*Electronic-Florida Online Reporting of Controlled Substance Evaluation Program
## Defining Pain

<table>
<thead>
<tr>
<th>Acute Pain</th>
<th>Non-acute or Chronic Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal, predicted, physiological, and <strong>time-limited response</strong> to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness</td>
<td>• Cancer, terminal condition, palliative care or serious traumatic injury with an Injury Severity Score (ISS) ≥9</td>
</tr>
<tr>
<td>• Chronic nonmalignant pain persisting beyond usual course of disease or injury OR pain persisting &gt;90 days after surgery</td>
<td>• Requires treatment plan</td>
</tr>
<tr>
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<td>• Patients entered in CS agreement with prescriber</td>
</tr>
<tr>
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<td>• Patients must be seen at least every 3 months</td>
</tr>
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<td>• Patient may only have a single provider</td>
</tr>
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<td><strong>Footnote:</strong> House Bill No. 21: Chapter 2018-13.p1-106</td>
</tr>
</tbody>
</table>
# Application

<table>
<thead>
<tr>
<th>Acute Pain</th>
<th>Non-acute Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Limits an Rx for an opioid listed in C-II to 3 days</td>
<td>• Prescriber <em>must</em> indicate “NONACUTE PAIN” on an Rx for a C-II medication</td>
</tr>
<tr>
<td>• Limit may be increased to 7 days if determined to be medically necessary</td>
<td>• Patients treated for a traumatic injury with an ISS of ≥9 must be concurrently prescribed an emergency opioid antagonist</td>
</tr>
<tr>
<td>• Prescriber <em>must</em> have “ACUTE PAIN EXCEPTION” on the Rx</td>
<td>• If this is not received, RPh should follow standard policy and procedures and contact prescriber</td>
</tr>
<tr>
<td>• Limits the dispensing of a CII-III medication in connection to a surgical procedure to a 14 day supply</td>
<td>• Any changes should be promptly reduced to writing and properly annotated</td>
</tr>
<tr>
<td>• Limits do not apply to C-II medications for treatment of addiction</td>
<td></td>
</tr>
</tbody>
</table>

House Bill No. 21: Chapter 2018-13.p1-106
Prescription Pads Sample

Specifications for Front of Rx Pad

1. Prescriber Information
2. Prescriber Location
3. DEA Number/Nonacute Pain/Acute Pain Exception
4. Patient Information
5. Background Ink
6. Category of Licensure
7. Tracking Number
8. Security Features

Security Features May Be Printed on Front or Back of Rx Pad

- Resist erasures and reproductions
- The blank must be printed on artificial watermarked paper
- Contain blue or green background ink that resists reproduction
- Ink changes color when rubbed with a coin
- Display the words "VOID" or "ILLEGAL" if the prescription pad is copied

Dade County Pharmacy Association
Assessing for Prescription Appropriateness
Deciding for Prescription Appropriateness

- Rx looks authentic and has all the information required by law
- Perform prospective Drug Utilization Review
- Assess drug, dose and duration
- Review the patient’s medication profile in your computer
- Review the PDMP report
Legible Prescription

- A written Rx for a CS must have the quantity of the medication prescribed in both textual (one, two, three, etc) and numerical (1, 2, 3, etc) formats.

- Must be dated in one of the following ways:
  - Numerical month/day/year format (ex: 1/1/2016)
  - Abbreviated month written out (ex: Jan. 1, 2016)
  - Month written out in whole (ex: January 1, 2016)
Deciding for Prescription Appropriateness

- Speak with the prescriber
- Previous experience
  - Converse and observe the behavior of the patient
- Patient’s medical history
- Clinical appropriateness and safety
  - Quantity limitations and other requirements in the treatment of acute and chronic management of pain
Validating a Prescription
Corresponding Responsibility

- The responsibility for the proper prescribing and dispensing of CS is upon the prescribing practitioner, but a corresponding responsibility rests with the RPh who fills the Rx.
- The law further states that any individual knowingly dispensing an invalid Rx for a CS will be subject to criminal penalties and administrative sanctions.

CFR Section 1306.04
Validating a Prescription

- The process implemented by the RPh to determine that the Rx was issued for a legitimate medical purpose
- Each Rx may require a different validation process and no singular process can be applied each situation
- A concern with validity does not mean the Rx should not be filled

Florida Statue 64B16-27.831
Validating a Prescription

- When validating an Rx:
  - Neither a person or licensee must interfere with the exercise of the RPh’s independent professional judgment
  - Communication with the patient should not be overheard by others
  - If the RPh determines that concerns with validity cannot be resolved, the RPh must refuse to fill

Florida Statue 64B16-27.831
Refusal of CS Prescription

Before the refusal of an Rx, the RPh shall do the following:

- Communicate with the patient or the patient’s representative
- Contact the prescriber or the prescriber’s agent
- Access the PDMP to acquire information
Duty to Report

- If an RPh believes that a prescriber is involved in the diversion of CS, he/she must report the prescriber to the Department of Health
- This can be reported online at:
# Federal and State Requirements for CII-CV

<table>
<thead>
<tr>
<th></th>
<th>CII</th>
<th>CIII-CV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Refills</strong></td>
<td>No refills allowed</td>
<td>5 within 6 months from date written</td>
</tr>
<tr>
<td><strong>Transfer of Rx Between Pharmacies</strong></td>
<td>No transfers permitted</td>
<td>1 allowed (may transfer additional times to the maximum if within same common database)</td>
</tr>
<tr>
<td><strong>Facsimile Rx Allowed</strong></td>
<td>May be received in preparation, but original hard-copy is required</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Exceptions:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Narcotic compounded for direct administration to patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• LTCF/Hospice Patients</td>
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</table>
# Federal and State Requirements for CII-CV

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<thead>
<tr>
<th></th>
<th>CII</th>
<th>CIII-CV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electronic Rx Allowed</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Partial Fills Allowed</strong></td>
<td>Yes &lt;ul&gt;&lt;li&gt; Remainder required within 72 hrs&lt;/li&gt;&lt;li&gt; For terminally ill patients and LTCF patients, Rx is good for 60 days&lt;/li&gt;&lt;/ul&gt;</td>
<td>Yes &lt;ul&gt;&lt;li&gt; No restrictions as long as within total quantity and 6 month limitation&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
<tr>
<td><strong>Emergency Dispensing</strong></td>
<td>Limited to the amount needed to treat the patient &lt;ul&gt;&lt;li&gt; Dispensing is limited to a 72-hour supply&lt;/li&gt;&lt;/ul&gt;</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Expiration Date</strong></td>
<td>No expiration (FL law imposes 1 year expiration on all Rx)</td>
<td>6 months from date written</td>
</tr>
</tbody>
</table>
Fraudulent Prescriptions

- Usually patients tend to come at the end of the day
  - RPh is extremely busy
  - Prescriber’s office is closed
- Most drug abusers seek areas where communication and cooperation between healthcare professionals is minimal
- The RPh should become familiar with CS that are popularly abused and resold on the streets

Types of Fraudulent Prescriptions

- Quantity altered: change “10” to “100” or “10” to “40”
- Adding refills or altering the directions
- Adding an additional medication to a legal Rx
  - Changing medication: adding “ES” to Vicodin
- Individuals calling in their own Rx
  - Forging call back number and using fictitious patient or physicians name and addresses

DEA Guidelines to Prescription Fraud. Florida Board of Pharmacy.
Prescription Drug Diversion: Fraudulent Tactics Utilized in the Community Pharmacy.
Fraudulent Prescriptions: Things to Look For

- Rx looks “too good”. The prescriber’s handwriting is too legible
- Quantities, directions, or dosages differ from usual medical usage
- Rx does not comply with acceptable standard abbreviations (directions that are written out)
- Rx appears to be photocopied
- Directions are written in full with no abbreviations
- Rx is written in different color inks or written in different handwriting
Diversion Techniques and Signs by Patients

- Changes in personality and/or appearance
- Claiming multiple allergies to alternative medications
- Aggressively complaining about a need for a medication
  - Uses medical terminology with respect to their pain
- Requests specific generics or brands
- No clear diagnosis from the physician
- Frequently ask for early refills
Diversion Techniques by Prescribers

- Patients traveling long distances to see practitioner
- Practitioner prescribing excessive quantities of CS relative to the medical condition
- Multiple medications within the same category or medication cocktails being prescribed
  - Examples: Narcotic pain killer + benzodiazepine + sleeping pill + codeine containing cough syrup + carisoprodol or any other combination
- Health care professionals prescribing outside their scope of practice
Diversion Techniques by Prescribers

- Physician’s note and diagnosis are similar for every patient
  - Lack of individualization

- Practitioner ignoring signs of abuse
  - Patient’s appearance
  - Requesting for specific CS
  - Practitioner ignoring toxicology reports

- Beware of nurses and non-medical staff calling in oral Rxs
Motivation for Diversion

- Money – financial gain
- Fear
  - Stop blackmail
- Sexual favors
- Keep business going/co-independency
- Personal Use – self abuse
Pharmacist Checklist to Prevent Diversion

- Type of medication prescribed (number of CNS depressants and stimulants)
- Duplicate therapy or duplicate therapeutic classes
- Strengths, quantity, and days supply of medication prescribed
- Number of physicians the patient is seeing
- Escalating doses, quantities, and/or strengths
- Method of payment by patient
- Look for documentation in patient record
**Overview**

**What is it?**
- Electronic systems that digitally store, monitor, and analyze CS dispensing information

**What data is collected?**
- Patient info
- Prescriber info
- Dispenser info
- CII-V medications

**Who can access data?**
- Prescribers
- RPh
- Law enforcement
- State medical boards
Structure of Legislation
Data Reported to E-FORCSE®

- Prescribing practitioner name, federal DEA registration number, National Provider Identification (NPI), and date Rx written
- Date Rx was filled and the method of payment
- Name, address, telephone number and date of birth (DOB) of patient for whom the Rx was written

Florida Statute 893.055(3)(a)(1-8)
Data Reported to E-FORCSE®

- Name, national drug code, quantity, and strength of CS
- Name, federal DEA registration number, and address of the pharmacy/location from which the CS was dispensed
- Name of pharmacy or practitioner (other than an RPh) dispensing the CS and the practitioner’s NPI identifier
- Other appropriate identifying information as determined by department rule
Healthcare Professional Responsibilities

- Must report to PDMP *each time* a CS in CII-V is dispensed
  - All patients ≥16
  - Including internet and mail order pharmacies and dispensing healthcare practitioners
- Report as soon thereafter as possible but *no later than close of next business day* after Rx dispensed
  - Exceptions apply
  - Dispenser must file a *zero report* if there are no transactions to report for that day

Florida Statute 893.055(3)(a)(1-8)
Zero Reports

- [https://pmpclearinghouse.net](https://pmpclearinghouse.net)
- Confirmation email is sent to submitter
Healthcare Professional Responsibilities

- Those that never dispense CS in or into Florida are not required to report to E-FORCSE®

- Must notify E-FORCSE® in writing by submitting a “Notification of Exemption from Reporting Form”
  - Must be renewed biennially on or before February 28 in odd years

Statutory Exceptions

- Patients <16
- C-V non-opioid medications
- System is not operational
- Requestor has technological or electrical failure
  - Prescriber or dispenser *shall document the reason for not consulting* PDMP in patient’s record
  - *Shall not prescribe/dispense ≥3-day supply*
Reporting Exemptions

- All acts of administration:
  - Directly to patient
  - Hospital
  - Nursing home, assisted-care facility, or rehabilitation center
  - Ambulatory surgical center
  - Hospice
  - Intermediate care facility for the disabled

- Dispensing in the Florida Department of Corrections or ED of a licensed hospital
Emergency Suspension from Reporting

- A reporting suspension waiver will be granted for the seven day reporting period.
- Once the state of emergency has been lifted, the dispenser must report the backlog of data as soon as possible to bring reporting current.
Reporting Noncompliance

A dispenser who willfully and knowingly fails to report the dispensing of a CS medication, as required by section 893.055, F.S., commits a misdemeanor of the first degree.

Punishable by 775.082 or 775.083, F.S.
Utilizing E-FORCSE®

Patient Request

Patient Info
First Name*  Last Name*

Partial Spelling

Date of Birth*  Date of Birth Range
MM/DD/YYYY

Prescription Fill Dates
No earlier than 2 years from today

From*  To*
12/18/2017  12/18/2019

Patient Location
Search accuracy can be improved by including the address
Zip Code
An RPh must verify the identity of an individual prior to dispensing a CS medication. Proper identification is issued by a state or the Federal Government containing the person’s photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).
Assessment of Rx using E-FORCSE®

- PDMP reports are only as good as they are entered
- Potential errors may include:
  - Rx filled but not picked up yet
  - Incorrect day supply
  - Wrong date written
  - Wrong doctor
  - Patient name misspelled or multiple last names
  - Wrong DOB or address
Assessment of Rx using E-FORCSE®

- If something does not look correct in PDMP, call the pharmacy who filled the Rx or prescriber in order to verify.
  - Example: An RPh looks at the PDMP and sees the patient had an Rx for alprazolam 2 mg, #300, one tab BID.
    - Steps to take: call pharmacy who filled Rx and verify the information found on PDMP.
PDMP Checklist

- Type of medications prescribed
- Duplicate therapy
- Strengths and quantities
- Number of physicians the patient is seeing
- Number of pharmacies the patient is using
- Is the patient using urgent care centers, convenience clinics, EDs, and/or dentists to obtain CS medications?
- Are patients getting medications filled early?
- Are the doses, quantities, and/or strengths escalating?
Opioid Overdose, Prevention and Management
On average, 130 Americans die each day from an opioid overdose.

Between 1999-2017, there were ~400,000 opioid overdose deaths:

- 1990’s: increased prescribing of opioids
- 2010: rise in heroin overdose deaths
- 2013: synthetic opioid overdose deaths, specifically involving fentanyl
Pathophysiology of Overdose

- Several receptors mediate the effects of opioids
  - Mu → analgesia, euphoria, constipation, respiratory depression, miosis
  - Kappa → analgesia, diuresis, dysphoria
  - Delta → analgesia, convulsions, anxiolysis

- Opioid receptors are located in both the central and peripheral nervous system (brain, spinal cord and GI tract)

Opioid Mechanism of Action

- Potent agonism of the mu receptor by opioids results in a release of dopamine, blockade of pain transmission and a euphoric sensation via the reward pathway

- In the case of overdose, the opioid receptors located in the medulla are overwhelmed and can suppress respiratory drive to the point of cessation
Opioid Pharmacokinetics

- Normally, opioids undergo first order elimination
- When opioid receptors are saturated, elimination is converted to zero order kinetics and small dose increases can change plasma concentration immensely
Risk Factors for Overdose

- Individuals who are dependent on opioids for chronic pain
- Taking increasing doses of opioids for pain management
- High-dose opioids (> 50 MME/d)
- Concomitant severe medical or psychiatric conditions (depression, HIV, lung/liver disease)
- Combining opioids with alcohol or other sedatives
- Male gender
- Younger age
- Household members taking opioids
- History of injection drug use

Morphine Milligram Equivalents

High-dose opioids (> 50 MME/d) increase a patient's risk of overdose.
Naloxone
Mechanism of Action

- Naloxone is a pure opioid antagonist that competes and displaces opioids at opioid receptor sites
- Has stronger affinity than opioids at all opioid receptor subtypes, but most notably at the mu receptor
- Specifically designed to only reverse overdose – while it still binds to opioid receptors, it will not produce a “high” or have any opioid-like effects
- Naloxone has no effect if opioids are not present

Naloxone Administration

- Naloxone is available to be administered via 2 routes:
  - Intranasal
    - A. Narcan® nasal spray
    - B. Naloxone nasal spray with atomizer
  - Intramuscular
    - C. Evzio® auto-injector
    - D. Naloxone injectable – IM or SC
# Naloxone Dosing

<table>
<thead>
<tr>
<th>Products</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narcan® Nasal Spray</td>
<td>4 mg/0.1 mL</td>
</tr>
<tr>
<td>Naloxone Nasal Spray with Atomizer</td>
<td>2 mg/2 mL</td>
</tr>
<tr>
<td>Evzio® Auto-injector</td>
<td>2 mg/0.4 mL</td>
</tr>
<tr>
<td>Naloxone for injection</td>
<td>0.4 mg/1 mL</td>
</tr>
</tbody>
</table>
Naloxone (Narcan®) Nasal Spray

- Requires no assembly, very simple to use
- Peel, Place, Press
  - Peel back the tab to remove the device from the packaging
  - Hold nasal spray with your thumb on the bottom, and your middle and index fingers on either side of the nozzle
  - Tilt the person’s head back, support their head and place the tip of the nozzle into 1 nostril until your fingers touch the patient’s nose
  - Press the plunger firmly to administer the full dose and call 911
  - Repeat with the other nostril if the person does not respond in 2-3 minutes

Naloxone Nasal Spray

- Requires assembly
- Pop off the yellow caps from either end of the syringe
- Screw on the nasal atomizer to the tip of the syringe
- Remove the colored cap from the naloxone and insert into the barrel of the syringe, gently screwing them together
- Insert the white cone into the nostril and give a short, strong push on the end of the naloxone to administer
- **One half of the naloxone capsule should be administered into each nostril**
- Repeat the above if the patient does not respond in 3 minutes

Naloxone (IM)

- Administering injectable naloxone (either IM or SC) requires assembly
- First, remove the cap from the naloxone vial and uncover the needle
- Insert the needle into the rubber stopper
- Invert the vial to withdrawal the full contents (1 mL) into the syringe
- Inject naloxone into either the deltoid or quadricep muscle
- Naloxone can be injected through the clothing!
- Repeat the dose if the patient does not respond within 3-5 minutes

Naloxone (Evzio®)

- No assembly and very simple to use
- The device is equipped with a voice instruction system to guide the user through the entire administration process
- Steps for use:
  - The auto-injector should be pulled from the outer case
  - Firmly remove the red safety guard (the needle is housed within the black base)
  - Place the black end of the device against the middle of the outer thigh, press firmly and hold in place for 5 seconds (the needle will retract into the device when the dose is given)
  - **Can be administered through clothing**
  - If no response in 2-3 minutes, repeat the dose using a second auto-injector
- Note: the Evzio® device makes a distinct clicking/hissing sound on administration – this is normal and indicates the device is working properly

Storage and Disposal

Storage

- Naloxone should be stored at room temperature in its original packaging
- Should be kept away from children/pets, but always in a place that is quickly and easily accessible
- Do not assemble naloxone until ready to administer, when applicable

Disposal

- For intranasal dosage forms, the used naloxone can be discarded with other solid waste
- For injectable dosage forms, the used naloxone should be discarded of in a sharps container (this can be an empty laundry detergent bottle or thick/hard plastic container)

Drug Interactions and Side Effects

➢ DDI’s
  ✓ Due to its action as an opioid antagonist, naloxone will have an interaction with any drug considered an opioid

➢ Side effects
  ✓ Sudden opioid withdrawal symptoms:

✓ Body aches
✓ Diarrhea
✓ Tachycardia
✓ Fever
✓ Runny nose
✓ Sneezing
✓ Goose bumps
✓ Sweating
✓ Yawning
✓ Nausea/vomiting
✓ Nervousness
✓ Restlessness
✓ Shivering
✓ Abdominal cramps
✓ Weakness
✓ Hypertension

Who Should be Given a Prescription for Naloxone?

- Title XXXII, Ch. 456.44 of Florida Pharmacy Law states:
  - EMERGENCY OPIOID ANTAGONIST.—For the treatment of pain related to a traumatic injury with an **Injury Severity Score of 9 or greater**, a prescriber who prescribes a Schedule II controlled substance listed in s. 893.03 or 21 U.S.C. s. 812 **must concurrently prescribe an emergency opioid antagonist**, as defined in s. 381.887(1).

- Patients who are considered to be “high risk” for opioid overdose:
  - History of overdose or substance abuse
  - High opioid doses (> 50 MME/d)
  - Concurrent benzodiazepine use
  - Sleep apnea
  - Pregnancy
  - Renal/hepatic disease
  - > 65 years old
  - Concomitant mental health conditions

Recognizing an Overdose

- The “opioid overdose triad” is a combination of 3 signs and symptoms that can be used to identify an opioid overdose
  - Pinpoint pupils
  - Unconsciousness
  - Respiratory depression (slow, shallow breathing)
- Other signs to look for include:
  - Skin, lips and fingernails will be a bluish/purple color
  - Choking sounds, or a snore-like gurgling noise
  - Vomiting
  - Slowed heart rate
  - Body is limp
- The combination of opioids with alcohol and other CNS depressants increases the risk of death due to an overdose

How to Tell the Difference

- It can sometimes be unclear whether a person is overdosing or is just extremely high.
- Always err on the side of caution and respond as if the person is experiencing an overdose.

<table>
<thead>
<tr>
<th>High</th>
<th>Overdosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pinpoint pupils</td>
<td>• Pinpoint pupils</td>
</tr>
<tr>
<td>• Muscles are droopy/limp</td>
<td>• Loss of consciousness</td>
</tr>
<tr>
<td>• “Nodding out”</td>
<td>• Awake but unable to speak</td>
</tr>
<tr>
<td>• Slurred speech</td>
<td>• Skin/nail/lip color changes</td>
</tr>
<tr>
<td>• <strong>Might seem disoriented, but</strong></td>
<td>• <strong>Unresponsive</strong></td>
</tr>
<tr>
<td>will respond to outside stimulus (noises,</td>
<td></td>
</tr>
<tr>
<td>agitation)</td>
<td></td>
</tr>
</tbody>
</table>

- Whether or not the patient is responsive will help to determine if the patient is high versus overdosing.

Responding to an Overdose

- **Call 911**
- **Perform CPR**
- **Administer naloxone**
- **Stay until help arrives**
Responding to an Overdose

1. Call 911
   - Opioid overdoses will still require professional medical assistance even if naloxone helps

2. Support the patient’s breathing with CPR
   - Ensure a clear airway
   - Place one hand on the patient’s chin, tilt head back and pinch the nose closed
   - Place mouth over patient’s mouth to make a seal and give 2 slow breaths – the patient’s chest should rise
   - Give one breath every 5 seconds

Responding to an Overdose

3. Administer naloxone when signs of an overdose are present
   - Naloxone should be given to restore respiratory drive

4. Stay until help arrives
   - You can expect naloxone to work within 3-5 minutes
   - Duration of action of naloxone is 30-90 minutes
   - Patients should be placed on their side
   - Do not slap or forcefully stimulate patients as it may cause harm
   - Patients should not be placed in cold water, injected with speed to wake them up or be forced to vomit the ingested drug(s)

Avoiding Accidental Overdoses

According to the World Health Organization, several measures can be taken to avoid opioid overdose on a global scale:

- Increasing the availability of opioid dependence treatment, including for those dependent on prescription opioids
- Reduce irrational or inappropriate prescribing of opioids
- Closely monitoring opioid prescribing and dispensing

Patient education for avoiding accidental overdoses

- Never adjust your own dose – speak to your doctor if your pain is uncontrolled
- If a dose is missed, do not take extra medication to make up for the missed dose
- Do not mix with other medications such as benzodiazepines, antidepressants, cocaine) and/or alcohol

The Pharmacist’s Role

According to the 2019 Florida statutes, Title XXIX, chapter 381.887:

“An authorized health care practitioner may prescribe and dispense an emergency opioid antagonist to a patient or caregiver for use in accordance with this section, and pharmacists may dispense an emergency opioid antagonist pursuant to such a prescription or pursuant to a non-patient-specific standing order for an auto-injection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use”
STATE OF FLORIDA
DEPARTMENT OF HEALTH
STATEWIDE STANDING ORDER FOR NALOXONE

As authorized by Section 381.887, Florida Statutes, and directed by Executive Order Number 17-146, most recently extended by Executive Order 19-36, this Florida statewide Standing Order for Naloxone is issued.

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

The pharmacy must maintain a copy of the Standing Order for Naloxone if dispensing naloxone pursuant to the order.

Incorporated in this Standing Order for Naloxone is the expectation that the SAMHSA Opioid Overdose Prevention Toolkit Five Essential Steps for First Responders be followed.

Approved Options for Intranasal or Auto-Injector Administration:

<table>
<thead>
<tr>
<th>Intranasal</th>
<th>Auto-Injector</th>
<th>Intranasal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naloxone 2mg/2ml prefilled syringe, #2 syringes</td>
<td>Naloxone 0.4 mg or</td>
<td>Narcan Nasal Spray 4mg, #2</td>
</tr>
<tr>
<td>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose.</td>
<td>Naloxone 2 mg</td>
<td>SIG: Administer a single spray intranasally into one nostril. Call 911.</td>
</tr>
<tr>
<td>Call 911. May repeat x 1. Mucosal Atomization Device (MAD) #2</td>
<td>#1 twin pack</td>
<td>Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</td>
</tr>
<tr>
<td>SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.</td>
<td>SIG: Administer one auto-injector upon signs of opioid overdose to adult or pediatric patients into outer thigh, through clothing, if necessary. Call 911. May repeat x 1 in 2 to 3 minutes. No kit is required. Product is commercially available.</td>
<td></td>
</tr>
</tbody>
</table>

Executed this 25th day of February, 2019.

Jeffrey P. Burgoon, M.D., Ph.D.
DE-88050
Deputy Secretary for Children’s Medical Services
Florida Department of Health
Treatment Resources for Substance Abuse
Florida’s State Opioid Response Project (SOR) is administered through the Office of Substance Abuse and Mental Health (SAMH) in the Florida Department of Children and Families.

The SAMH Program is the legislatively appointed state authority for substance abuse, mental health, and methadone designation.

https://www.myflfamilies.com/service-programs/samh/
Follow the “Get Help” link to find local treatment programs in your area.

Find Local Services By County

If you or someone you know is in need of substance abuse and/or mental health services, our local managing entities can help you locate available programs. Please choose your county from the drop-down list below for the managing entity contact in your area.

County: Dade

Substance Abuse & Mental Health

Your Local Provider of Services

South Florida Behavioral Health Network

Telephone: 888-248-3111
Treatment Resources

https://www.samhsa.gov/
Take Home Points

- According to state law, C-II Rxs must be filled within 1 year.
- C-II Rxs may be faxed to the pharmacy to expedite the filling of a Rx, however the original Rx must be presented at time of dispensing.
- House Bill 21 limits quantity of CS that can be dispensed and requires practitioners to indicate the type of pain which correlates with the day supply:
  - 3 day supply: “acute pain”
  - 7 day supply: “acute pain exception”
  - >7 days: “nonacute pain”
- It is the standard of practice for the Florida Board of Pharmacy to dispense control substance to patients with a valid Rx for a legitimate medical purpose.
Take Home Points

- RPhs should take all necessary steps when validating an Rx and refuse to fill it if professional judgment concerns cannot be resolved as there is a corresponding responsibility when dispensing such prescriptions.

- RPh must check E-FORCSE® for each new Rx dispensed no later than close of next business day.

- Dispensers must notify E-FORCSE® by submitting a Notification of Exemption from Reporting form if they will not dispense CS.

- Patients with Rxs for opioids at doses ≥50 MME/d are at higher risk for overdose – this calculation should be well understood.

- Naloxone should be dispensed to any patient who could possibly be experiencing an overdose – it will not have any adverse effects if it is given and not truly needed.
Questions

- T/F: The main purpose of House Bill 21 is to limit acute pain to seven days
  - False: House Bill 21 limits Rxs according to type of pain; for acute pain the limit is a 3 day supply. In order to get a 7 day supply, the prescriber must indicate “acute pain exception”

- T/F: If a prescriber does not include the required information on an Rx for a C-II CS, the RPh is legally allowed to confirm with the prescriber and write it on the Rx
  - True

- T/F: SAMHSA is a government based helpline that provides information for Opioid Treatment Programs nationwide
  - True

- T/F: The dose for Evzio® is 0.4 to 2 mg IV, IM, or SQ every 2-3 minutes
  - False: Evzio® is the auto-injector formulation that administers 2 mg per 0.4 mL

- T/F: All formulations of naloxone can be safely disposed of by flushing them down the toilet
  - False: For intranasal dosage forms, used naloxone can be discarded with other solid waste; for injectable dosage forms, used naloxone should be discarded in a sharps container

- T/F: RPhs are allowed to dispense a 3-day supply of a CS if the PDMP was not consulted
  - True
Thank You!
Controlled Substance Validation

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Eduardo Guizan, Pharm.D.
Baptist Hospital of Miami