Management of Controlled Substances Dispensing 2018: FOCUS on Health Quality

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Objectives

- Summarize compliant pharmacist licensure requirements as per 64B16-27.831 of the Florida Administrative Code and other regulations governing the dispensing of controlled substances
- Differentiate a “valid” vs. “invalid” prescription order for a controlled substance drug -including the appropriate therapeutic doses for prescribed controlled substances
- Describe processes that foster regulatory compliance when validating a prescription order

Speakers Disclosure

- Dr. Mikhael and Mr. Tomaka do not have a vested interest or an affiliation with any corporation or organization offering financial support or grant monies for this seminar
- Dr. Mikhael and Mr. Tomaka do not have an affiliation with any organization whose philosophy could potentially bias this presentation

Speakers

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Affiliations

- FSHP and Central Florida Society
- Consultant Pharmacy Services
- Clinical Consultant Pharmacist
- Outpatient - Ambulatory Facilities

The information here is solely for educational purposes.

The content of this presentation provides a general overview of the regulatory requirements.

Pharmacists and Technicians should review state and federal regulatory statutes for a complete description of compliance requirements.

Our discussion does not constitute legal, risk, or accreditation advice.

No warranty is made, expressed or implied, with respect to this presentation and any liability resulting from any use or reliance on this event is disclaimed.

Special Acknowledgement

Douglas J. Tam, Pharm.D. Candidate 2019  
University of Florida College of Pharmacy

Students ROCK!
Objectives

Recall processes for evaluating the legitimate medical purposes for the controlled substance prescriptions
Recognize and describe the appropriate use of the Florida Prescription Drug Monitoring Program Database EFORSCE at the presentation’s conclusion
Identify proper disposal of unused controlled substances

Objectives

Evaluate methods for properly addressing and resolving problems recognized during Drug Utilization review including, interactions, side effects, dosing concerns
Explain resources for opioid physical dependence, addiction, misuse, and abuse

Opioid Regulatory Madness?
June 2018: US House Passes 12 Bills Combating Opioid Crisis
H.R. 4275 Empowering Pharmacists in the Fight Against Opioid Abuse Act
H.R. 5197 Alternatives to Opioids (ALTO) Act
H.R. 5327 Comprehensive Opioid Recovery Centers Act
H.R. 5041 Safe Disposal of Unused Medication Act
H.R. 5473 Better Pain Management Through Better Data Act

Opioid Regulatory Madness?
June 2018: US House Passes 12 Bills Combating Opioid Crisis
H.R. 5009 Jessie’s Law
H.R. 5812 Creating Opportunities that Necessitate New & Enhanced Connections that Improve Opioid Navigation Strategies Act
H.R. 4284 Indexing Narcotics, Fentanyl and Opioids (INFO) Act
H.R. 5483 Special Registration for Telemedicine Clarification Act
H.R. 5353 Eliminating Opioid Related Infectious Diseases Act
H.R. 5582 Abuse Deterrent Access Act of 2018

FL Controlled Substances What’s New?
CHAPTER 2018-13
Committee Substitute for House Bill No. 21
- Signed by the FL Governor on March 19, 2018
- Effective July 1, 2018
- Addresses opioid abuse in FL
- Supplements forthcoming Federal mandates

CS/CS/HB 21
- Establishes prescribing limits
- Requires continuing education on controlled substance prescribing
- Maintains current CE requirement for pharmacists
- Expands required use of Florida’s Prescription Drug Monitoring Program, EFORSCE
HB 21: Prescribing Limits

**Acute Pain**
- Prescribing practitioner may prescribe or dispense up to a 3-day supply of a Schedule II opioid to alleviate acute pain
  - If the physician determines more than a three-day supply is needed based on professional judgement
  - Documents the justification for deviating from the 3-day supply limit in the patient’s medical record

HB 21: Acute Pain

"Acute pain" is the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness

HB 21: Acute or not...

"Acute pain" does not include pain related to cancer, terminal conditions, pain treated with palliative care, or traumatic injuries with an Injury Severity Score of 9 or greater

An Injury Severity Score ranges from 1 to 75
The "score" is a method for describing trauma patients with multiple injuries and evaluating emergency care

HB 21: Traumatic Pain

Injury Severity Score (ISS)
- Anatomical scoring system that provides an overall score for patients with multiple injuries
- Each injury is assigned an "Abbreviated Injury Scale" (AIS) score allocated to one of six body regions
- Head, Face, Chest, Abdomen, Extremities (including Pelvis), External
### Injury Severity Score (ISS)

**ISS = sum of 3 highest AIS**

<table>
<thead>
<tr>
<th>AIS Code</th>
<th>AIS Score</th>
<th>Injury Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Head</td>
<td>High</td>
</tr>
<tr>
<td>2</td>
<td>Face</td>
<td>Moderate</td>
</tr>
<tr>
<td>3</td>
<td>Neck</td>
<td>Severe</td>
</tr>
<tr>
<td>4</td>
<td>Thorax</td>
<td>Critical</td>
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<tr>
<td>5</td>
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</tr>
<tr>
<td>6</td>
<td>Extremity</td>
<td>Fractional sever</td>
</tr>
<tr>
<td>7</td>
<td>Upper extremity</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Lower extremity</td>
<td>9</td>
</tr>
<tr>
<td>9</td>
<td>Unspecified</td>
<td>1</td>
</tr>
</tbody>
</table>

Injury Score of 9 or greater is Traumatic.

**Sample Injury Severity Score Calculation**

Injury = (3, 4, 1) + (9, 3, 2) + (8, 3, 1) = 20

**Krongdai Unhasuta, RN. Ed. D. Trauma Specialist.**

**Trauma Scoring**

https://www.slideshare.net/krongdai/trauma-scoring

### AIS: Body region

<table>
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### CS/C S/HB 21

**Prescriptions for Non-acute Pain**

If a Schedule II opioid is prescribed for the treatment of pain other than acute pain, the prescriber must indicate "Non-acute Pain" on the prescription.

- **Non-acute Pain**
  - Cancer
  - Terminal condition
  - Palliative care pain
  - Traumatic injury with an Injury Severity Score of 9 or greater

### CS/C S/HB 21

**Regulatory Compliant Prescriptions must contain Pain Condition “notation” otherwise Rx is for “Acute Pain” with 3 day supply limitation**

- **Acute Pain**
- **Acute Pain Exception**
- **Non Acute Pain**

### Concurrent Opioid Antagonist

For the treatment of pain related to a traumatic injury with an injury severity score of 9 or greater, a prescriber issuing a schedule II controlled substance must concurrently prescribe an emergency opioid antagonist.

**HB 21 Rx summary Impacting the Pharmacist**

- Prescriptions for Schedule II Opioids for the treatment of Acute Pain may not exceed a 3 day supply.
- A 7 day supply for acute pain may be prescribed if all of the following conditions are met:
  - More than a 3 day supply is needed based on the professional judgement of the prescriber
  - The prescriber documents "ACUTE PAIN EXCEPTION" on the prescription
  - The prescriber documents in the medical records the acute medical condition and lack of alternative treatment options that justify deviation from the day supply limit

- Chronic Non-Acute Pain Prescribing*
- Adds to existing prescriber requirements for patient chart documentation when treating chronic non-acute pain
- Prescriptions for schedule II opioid for the treatment of pain other than acute pain (i.e. chronic pain, or pain that is excluded from the definition of acute pain), must indicate "NON-ACUTE PAIN" on the prescription*

*Florida Statute 456.9-44 Controlled Substance prescribing

CS/CS/HB 21 pharmacist are....

- Required to become familiar with changes to certain prescribing limits on controlled substances
- Required to become familiar with emerging rules adopted by prescribing practitioners that establish guidelines for use of controlled substances for treatment of acute pain
- Required to report to the Prescription Drug Monitoring Program (PDMP) system when dispensing any controlled substances Schedules II, III, IV, and V drug to a patient.

Exceptions - schedule V controlled substances that are non-opioids
- prescriptions dispensed to patients under the age of 16

Pharmacist Corresponding Responsibility

The DEA spells out a “corresponding responsibility” of prescribers and pharmacists. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Appropriate Pain Management

- Rationale for therapeutic selection
- Documented medical condition
- Regulatory compliant

What Makes A Controlled Substances Prescription Valid?

- Valid Prescription
- Based on a practitioner-patient relationship
- Issued for a legitimate medical purpose

What Makes A Controlled Substances Prescription Valid?

- Trust
- Honesty
- Appropriateness

Green Flags
Red Flags

- Circumstances that cause suspicion about the validity of the prescription
- We must act upon the red flags we observe

If pharmacist is convinced that providing the controlled substances Rx to the patient is **NOT** in the best interest of the patient, document the process and file at the pharmacy!

If the pharmacist is convinced that the controlled substances Rx is not valid or illegal, there may be a requirement to report the issue to regulatory authorities.

Kenneth R. Baker, BS Pharm, ID *Refusal To Fill Prescriptions* Drug Topics, June 22, 2018

Valid CS Prescription

- Date prescription was issued
- Prescriber’s signature
- Patient’s full name and address
- Medication name & strength
- Dosage form
- Quantity prescribed
- Directions for use
- Prescriber’s name, address, and DEA registration number


Valid CS Prescription

- Pharmacist communication with prescriber
- Bona-fide medical condition, diagnosis
- Pain management contract with prescriber
- Established provider patient relationship
- Pharmacist-Patient relationship

AWARx® is available to all Florida licensees. For more information, visit FloridaPMP.com or call 1-877-719-3120.

E-FORCSE = Electronic Florida Online Reporting of Controlled Substances Evaluation Program

Now known as: AWARx®

E-FORCSE PDMP AWARx® platform is now available at: https://florida.pmpaware.net

Valid CS Prescription

- Consult the Prescription Drug Monitoring Program (PDMP) FL E-FORCSE

E-FORCSE®, Florida Prescription Drug Monitoring Program
4052 Bald Cypress Way
Bldg C-16
Tallahassee, FL 32309
(877) 719-3120

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FL PDMP

- E-FORCSE® AWARx® requires:
  - Every individual register as a separate user, using their email address as their username within the system
  - A user can register as a designee (referred to as a “Prescriber Delegate - Unlicensed” or “Pharmacist Delegate - Unlicensed” in PDMP AWARx®
  - Delegate role is designed to allow the user to generate reports on the behalf of another, current user

AWARx® is available to all Florida licensees. For more information, visit FloridaPMP.com or call 1-877-719-3120.
How Do I Register for E-FORCSE?

• Open a browser window https://Florida.pmpaware.net
• Click “Create and Account”.
• Enter an email address and password.
• Select User Role
• Enter personal and employer information.
• Click “Submit your Registration”

E-FORCSE™ Delegate/Designee

• Pharmacists designating a “delegate” have E-Force subscription and rights
• Pharmacists can delegate access rights to Registered Pharmacy Technicians
• Delegate must be directly supervised
• Appointed to act as an agent of a prescriber or dispenser for the purposes of requesting or receiving information from E-FORCSE
• Delegate must complete education and additional requirements as specified on the E-FORCSE site: http://www.floridahealth.gov/statistics-and-data/e-force

FL PDMP Log On

Delegate Assignment

Patient Request

FL PDMP AWARxE™ template

FL PDMP Patient Request

Clicking the Partial Spelling boxes for either first or last name allows the option to use only part of a patient’s name to perform a search

Use when searching hyphenated names or names that are abbreviated “Will” vs. “William”
Patient searches may include a zip code BUT it is recommended that searches be made without zip code.

Four main sections: Patient Information, Prescriptions, Prescribers, and Dispensers.

Patient Advisory Report

MME (Milligram Morphine Equivalents)

Prescribers table displays the information for all prescribers who issued a prescription to the patient within the search period used.

Dispensers table displays the information for all dispensers who filled a prescription to the patient within the search period used.
FL PDMP “Multiple” Patients

Multiple Patients Found
Why do we have this?
You identified multiple patients who match the criteria you provided. You have the following options:
- Refine your search by providing additional search information.
- Select any patient group to run a report.
- If you believe more than one group identifies your patient, select them to run a report.

**Patient 1202**
Name: DOB: Gender: Address:
John Doe 1990-01-01 Male 1123 Hot St. Wichita, KS 67209

**Patient 1203**
Name: DOB: Gender: Address:
Jane Smith 1990-01-01 Female 1123 Hot St. Wichita, KS 67209

Select a patient listed OR

FL PDMP Partial Search

If entered search criteria cannot identify a single patient record, the user receives a message that multiple patients have been identified

Refine their search criteria and run the report
-or-
select one or more of the patient records identified and run the report

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Drug Diversion Prevention Tool Proactive Utilization Review

The Pharmacist is the health care provider who:

- Evaluates appropriate drug dosing
- Reviews excessive utilization
- Evaluates drug-drug interactions
- Addresses potential side effects
- Maintains active communication with patient and prescriber

Drug Diversion Prevention Tool Proactive Utilization Review

The Pharmacist is the health care provider who:

Fosters a system that provides consistent, people-centered language when addressing drugs

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Diversion Prevention

In 2015, 3.8 million Americans reported misusing prescription drugs within the last month, and deaths from prescription opioids have more than quadrupled since 1999

About half of the people who reported misusing prescription drugs in 2015 received them from a friend or relative

GAO Highlights October 2017 United States Government Accountability Office

Diversion Prevention

Safe Disposal of Unused Medication Act of 2018 (proposed)

- “Ensuring that unused prescription opioids are properly disposed of is critical to saving lives and combating the opioid crisis” Senator Maggie Hassan (NH)
- Senator Susan Collins (ME) “The disposal of unused prescription drugs is key to making sure they do not fall into the wrong hands”

An important step in preventing drug diversion includes educating consumers about the dangers of leaving unused controlled prescription medication in the home

OPIOID RISK MITIGATION

Provider Mandate
Patients with signs or symptoms of abuse must be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility.

Pharmacist Corresponding Responsibility
- Communication with other providers
- Evidence/behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, patient shall be discharged, all testing and actions documented in the medical record.

OPIOID Addiction Treatment Resources
- US government resource
- Substance Abuse and Mental Health Services Administration
- Guidelines for program and facilities certification
- Directory of local treatment facilities

OPIOID Risk Mitigation

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References

- Department of Health and Human Services, Substance Abuse and Mental Health Services Administration: 1600 Polk St, Nashville, MD 38107
  https://www.congress.gov/115/bills/hr5041/BILLS-115hr5041ih.pdf