

Validation and Counseling Prescriptions for Controlled Substances and Opioids

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Bob Parrado, BPharm, RPh
Parrado Pharmacy Consultants, Inc.

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Disclosure

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

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LEARNING OBJECTIVES FOR PHARMACISTS

Upon completion of this activity, the Pharmacist and will be able to:

- ▶ Describe how to ensure access to controlled substances (CS) for all patients with a valid prescription.
- ▶ Examine the Prescription Drug Monitoring Program's database
- ▶ Compare the prescriptions for appropriate therapeutic value
- ▶ Locate prescriptions that are not based on a legitimate medical purpose
- ▶ Discuss the laws and rules related to prescribing and dispensing of CS

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LEARNING OBJECTIVES FOR PHARMACISTS "continued"

- ▶ Discuss the proper patient storage and disposal of CS
- ▶ Summarize protocols for addressing and resolving problems recognized during DUR
- ▶ Illustrate education on F.S. 381.887 emergency treatment for suspected opioid overdoses and the Surgeon General's Statewide Standing Order for Naloxone
- ▶ Illustrate counseling points for patients with opioid prescriptions
- ▶ Recall available treatment resources for opioid dependence, addiction, abuse and misuse

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LEARNING OBJECTIVES FOR PHARMACY TECHNICIANS

Upon completion of this activity the pharmacy technician will be able to:

- ▶ Use the Prescription Drug Monitoring Program's Database
- ▶ Describe prescriptions for appropriate and accurate information
- ▶ Recognize the laws and rules related to the prescribing and dispensing of controlled substances

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Prescription Drug Abuse... Is it a Problem?

- Opioid abuse is a nationwide epidemic¹
- Every 19 minutes someone in the United States dies from an "un-intended" overdose²
- 95 people die daily in the U.S.
- Half of all opioid deaths involve a prescription opioid⁴

¹NABP Video titled "Red Flags" available at <https://www.nabp.net/news/new-educational-video-for-pharmacists-addresses-prescription-drug-abuse>
²Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, CDC Grand Rounds: Prescription Drug Overdoses—a US Epidemic. MMWR 2012; 61(11):19-24
⁴Centers for Disease Control and Prevention, Injury Prevention & Control, Opioid Overdose available at <http://www.cdc.gov/drugoverdose/>

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Are there people that really need pain medications?

- Over **116 Million** Americans have pain from chronic pain conditions⁵
- Millions more experience acute pain conditions
- Pain that occurs suddenly and/or acutely is a symptom
- Chronic pain is considered a disease
- Untreated pain burdens the economy and the health care system

1. Institute of Medicine, *Relieving Pain in America*, June 2011, accessed 8/22/2016
<http://www.nationalacademies.org/pain/relievingpain/Report%20Final%2011/RelievingPaininAmericaABlueprintforTransformingPreventionCare.aspx>
 5. Dept of Veterans Affairs, *Pain in the VA: Vital Signs Toolkit*, October 2000, available at http://www.va.gov/PAINMANAGEMENT/docs/Pain_Al_the_Sign_Vital_Sign_Toolkit.pdf

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Quotas on Controlled Substance Purchases

- Are you having a problem in your pharmacy being able to acquire enough medication to take care of your patients?
- Is there really a quota that is mandated by DEA, DOH or the Board of Pharmacy?
- Has your wholesaler "cut you off" because of your purchases?
- How can you defend your purchases?

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Wholesalers Due Diligence of Purchasers

Section 499.0121(15), Florida Statutes

- (b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions.
- **A wholesale distributor must assess orders for greater than 7500 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable.**
- In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures.

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How do you know if the patient really has pain?

- Many patients and physicians are complaining to both State and Federal Legislators that they cannot access their legally prescribed medications.
- Does the drug and the quantity of medication prescribed seem to match the patient's needs?
- Are there any "**Red Flags**" that alert you that the prescription may not be for a legitimate medical purpose?

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What is a "Red Flag" ?

Anything that causes you concern that there is a problem with the prescription.

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Red Flags on Controlled Substance Prescriptions

Anything that causes you concern that the prescription may not have been issued for a **legitimate medical purpose!**

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64B16-27.810 Prospective Drug Use Review, FAC

- (1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:
- (a) Over-utilization or under-utilization;
 - (b) Therapeutic duplication;
 - (c) Drug-disease contraindications;
 - (d) Drug-drug interactions;
 - (e) Incorrect drug dosage or duration of drug treatment;
 - (f) Drug-allergy interactions;
 - (g) Clinical abuse/misuse

Rule 64B16-27.810 Prospective Drug Use Review, Florida Administrative Code, accessed 3/22/2016, available at <http://www.frules.org/gateway/rukeno.asp?rid=64B16-27.810>

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What makes a prescription valid under federal law?

21 CFR §1306.04(a)⁷ a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 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.

Drug Enforcement Administration, Title 21, Code of Federal Regulation § 1306.04, accessed 3/22/2016, available at www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol9/pdf/CFR-2011-title21-vol9-sec1306-04.pdf

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Definition of a Controlled Substance Prescription Section 893.02(22), Florida Statutes.

Section 893.02(22), "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a "state other than Florida", but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness.

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State of Florida Definition of a Controlled Substance Prescription Continued

However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. *A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, ...*

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Controlled Substance Prescribing- Section 456.44, Florida Statutes

Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, **for the treatment of chronic nonmalignant pain**, must:

- (a) Designate himself or herself as a **controlled substance prescribing practitioner** on the physician's practitioner profile.

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Controlled Substance Prescribing- Section 456.44, Florida Statutes

- (e) "**Chronic nonmalignant pain**" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than **90 days** after surgery.

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Controlled Substance Prescribing Practitioner

This requirement is only applicable to those physicians that are treating patients for chronic nonmalignant pain. Therefore, physicians that are not treating patients for chronic nonmalignant pain are not required to register and may continue prescribing controlled substances for other diagnoses.

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Electronic Prescribing for Medicinal Drugs Section 456.43, Florida Statutes

- (1) Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.
- (2) Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care.

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Written Prescriptions for Medicine Drugs (Legible Prescription Act) Section 456.42, F.S.

- (1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug **must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription:**

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Written Prescriptions for Medicine Drugs
(Legible Prescription Act) Section 456.42, F.S.
Continued

A written prescription...
must contain the name of the prescribing practitioner,
the name and strength of the drug prescribed, the
quantity of the drug prescribed, and the directions for
use of the drug; must be dated; and must be signed by
the prescribing practitioner on the day when issued.

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Written Prescriptions for Medicine Drugs
(Legible Prescription Act) Section 456.42, F.S.
Continued

(2) A written prescription for a controlled substance
listed in chapter 893 must have the quantity of the
drug prescribed in both textual and numerical formats,
must be dated in numerical, month/day/year format,
or with the abbreviated month written out, or the
month written out in whole,....

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Written Prescriptions for Medicine Drugs
(Legible Prescription Act) Section 456.42, F.S.
Continued

and must be either written on a standardized
counterfeit-proof prescription pad produced by a
vendor approved by the department or electronically
prescribed as that term is used in s. 408.0611, F.S.

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CS RX's Covid 19 Rule Exception

- ▶ On January 31, 2020, Secretary of Health and Human Services Alex Azar declared a public health emergency in response to COVID-19. Following this announcement, DEA worked in consultation with HHS to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation. (Effective 3/31/2020) DEA-registered practitioners may continue this telemedicine practice for as long as the designation is in effect, if all required conditions are met:

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Covid 19 Rule continued

- ▶ The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
- ▶ • The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system.
- ▶ • The practitioner is acting in accordance with applicable Federal and State law.

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Covid 19 Rule continued

- ▶ Provided the practitioner satisfies these requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available adhering to DEA regulations, including issuing a prescription electronically or by calling in a prescription to the pharmacy.

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Covid 19 Rule continued Emergency C-2

- ▶ Prescriber can call in a C-2:
- ▶ If for an immediate need and cannot get a written prescription to the patient:
- ▶ Has **15 days** to get a prescription to the pharmacy.
- ▶ Can be written, EPCS, scan or photograph of Rx

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Covid 19 Rule continued

- ▶ It is the responsibility of the practitioner to ensure that, whichever method the practitioner uses, the prescription contains all of the required information outlined in 21 CFR 1306.05 and 1306.11(d), including the statement that the prescription is "Authorization for Emergency Dispensing." As a condition of this exception, the practitioners who choose to send this specific type of prescription to the pharmacy via facsimile, photograph, or scan must maintain the original paper prescription in the patient file.

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Prescriptions for Obesity Drugs

(6488-9.012 Allopathic Physicians & 64815-14.008 Osteopathic Physicians)

Prescriptions or orders for any drug or synthetic compound for the purpose of assisting in weight loss **must be in writing** and signed by the prescribing physician. **Initial prescriptions or orders of this type shall not be called into a pharmacy by the physician** or by an agent of the physician.

Each physician who is prescribing, ordering or providing weight loss enhancers to patients must assure that such patients undergo an in-person re-evaluation within 2 to 4 weeks of receiving a prescription, order or dosage. The re-evaluation shall include the elements of the initial evaluation **and an assessment of the medical effects of the treatment being provided. Any patient that continues on a drug or synthetic compound assisted weight loss program shall be re-evaluated at least once every 3 months.**

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New DEA: 21 U.S.C.A. § 829. Prescriptions Schedule II Partial Fills

- **Effective: July 22, 2016**
- A prescription for a controlled substance in schedule II may be partially filled if--
 - It is not prohibited by State law;
 - The partial fill is requested by the patient or the practitioner that wrote the prescription; and
 - The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
 - Shall be filled not later than 30 days after the date on which the prescription is written.
- Emergency situations: [72 hour supply; Section 893.04, (1) (f), F.S.]
 - The remaining portions of a partially filled prescription for a controlled substance in schedule II--
 - May be filled; and Shall be filled not later than 72 hours after the prescription is issued.

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Patient Access To Opioids Being Limited

- ▶ Despite the shifting nature of the opioid epidemic, government efforts to stop it continue to focus on punishing doctors who overprescribe and reducing patient access to opioids.
- ▶ New CDC Guidelines for Prescribing Opioids for Chronic Pain
- ▶ Guideline suggests 3 days for most patients, up to 7 days for some and more than 1 week of therapy in rare cases
- ▶ Manufacturer production quotas were decreased for 2017 because of these guidelines and decreased again for 2018
- ▶ Prescribers are being urged to try non opiates initially, NSAIDS etc

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New Board Rule Revises 64B16-27.831 for Dispensing Controlled Substance Prescriptions

- When validating no one can interfere with your professional judgment
- Communication with patient must not be overheard by others
- If concerns with the validity cannot be resolved, the Pharmacist shall refuse to fill or dispense the prescription.

Florida Administrative Code Rule 64B16-27.831 available at <https://www.flrules.org/gateway/RuleInfo.asp?rule=64B16-27.831>

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New Board Rule Revises 64B16-27.831 for Dispensing Controlled Substance Prescriptions⁸

- Before refusing to dispense a controlled substance prescription based solely upon a concern with the validity of the prescription the pharmacist must attempt to resolve concerns by
 1. Communicating with patient or their agent
 2. Communicating with prescriber
- In lieu of 1 and 2 but not both, the PDMP may be used to acquire information relevant to pharmacist's concern
- Can refuse to fill due to patient's refusal to cooperate with pharmacist

⁸Florida Administrative Code Rule 64B16-27.831 available at <https://www.frules.org/gateway/RulesNo.asp?id=64B16-27.831>

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New Board Rule Revision of 64B16-27.831 on Dispensing Controlled Substance Prescriptions

- Duty to report a prescriber to the Department of Health if you have a concern they may be involved in diversion
- Electronic prescriptions for controlled substances in schedules II through V are valid

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64B16-27.831 "SOP" for Dispensing Controlled Substance Prescriptions

- A prescription is valid when based on a practitioner-patient relationship & issued for a legitimate medical purpose
- If the prescription is not issued for a legitimate medical purpose it is not valid
- Validating means the process implemented by the pharmacist to determine the legitimate medical purpose (must resolve all the **red flags** before dispensing)

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What are Potential "Red Flags"?

Examples: Not all inclusive

- Unusual behavior of patient (nervous, overly friendly, aggressive, threatening)
- Cannot afford insurance (financial hardship)... but....
- Pays Cash (Large sums of cash.. Hundreds or Thousands of dollars)
- Has insurance but does not want to use insurance for controlled substance purchases
- One person presenting prescription's for controlled substances for multiple patients

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And Then More Potential "Red Flags"

- Multiple patients presenting from same prescriber for same or like prescriptions
- Multiple patients presenting at same time from same prescriber for same meds
- Multiple patients presenting at your pharmacy from distant home addresses
- Multiple patients presenting with Florida ID Card

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More Potential "Red Flags"

- Street names (blues, oxys, zanny bars for Xanax 2mg, Dans for Soma, Stop signs for Opana ER)
- Known drugs of abuse (Oxycodone, hydromorphone, alprazolam, fentanyl, carisoprodol)
- Cocktails ("Trinity"-Hydrocodone-alprazolam-carisoprodol & "Holy Trinity" oxycodone-alprazolam-carisoprodol)

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More Potential "Red Flags"

- Only controlled substances on profile
- Large quantities of medications prescribed...hundreds... thousands
- Patient is visiting multiple prescribers (doctor shopping?)
- Patient is visiting multiple pharmacies (pharmacy hopping?)
- Geography (distance between patient home, physician office and pharmacy)

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What Do You Do If You ID a Potential "Red Flag"?

- What is your responsibility?
- Do you know the patient?
- Do you know the prescriber?
- Have you visited the prescriber?
- Have you accessed the PDMP?

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What is YOUR responsibility?

- To verify that you are dispensing a valid and legally prescribed medication to a patient with a legitimate medical need.
- To verify that the medication is appropriate for the medical need of the patient.
- To act in the best interest of the patient.

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Assessment

▶ True or False:

A valid prescription is defined as a prescription that follows all regulations for prescriptions. Verifying legitimate medical purposes for each prescription is not always necessary for controlled substances.

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Do YOU know the PATIENT?

- Regular patient? New Patient?
- What is his/her diagnosis?
- Has he/she been on pain meds before...how do you know?
- Has he/she developed a tolerance to the dose you are being asked to dispense?

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Do YOU know the PRESCRIBER?

- Is the prescriber in your community?
- Is the prescriber associated with a pain management practice?
- Is the prescriber associated with a well known medical center/hospital/emergency room?
- Why is the patient visiting this prescriber?
- Does this prescriber appear to be "pattern prescribing"?

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Have YOU visited the prescriber's office?

- Have you visited the prescribers office?
- Is it in a "forsaken" part of the community?
- Is the prescriber in a group practice?
- Do all the prescribers in this practice prescribe in the same manner?
- Is the only medical equipment in the office a "bic" pen??
- Are there large quantities of patients milling about in the parking lot??

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Does the prescriber's office resemble a pill mill?

A "pill mill" is a doctor's office, clinic, or health care facility that routinely conspires in the prescribing and dispensing of controlled substances outside the scope of the prevailing standards of medical practice in the community or violates the laws of the state of Florida regarding the prescribing or dispensing of controlled prescription drugs.

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Pill Mills Tip-Offs

- Non-traditional medical office locations
- No insurance accepted
- Armed Security guard at front door
- Out of state license plates in parking lot
- Parking lot loitering
- Long lines inside and outside
- Lack of medical equipment
- Treatment options limited to pills only

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More Pill Mills Tip-Offs

- Angry dog behind counter
- Affiliation with specific pharmacies
- Cash Only Signs in waiting room
- Cash Only Signs on the FRONT DOOR

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Have you accessed the PDMP?

- Pharmacists may access the PDMP to alleviate **red flag** concerns
- 3 million prescription records are uploaded on a monthly basis
- As of January 1, 2018 All Dispensers Must Report By End of Next Business Day
- HB 21: Mandatory Utilization Coming

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Authority for Access to the E-FORCSE Database Information

- Section 893.0551, FS authorizes direct access by a pharmacy, prescriber, dispenser licensed by the Department of Health or their designee
- "Designee" means a person preferably a licensed or certified health care professional, appointed to act as an agent of a prescriber or dispenser for the purposes of requesting or receiving information from the PDMP.
- Enrollment and use of the database is not mandatory prior to prescribing or dispensing a controlled substance

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Overview of the Designee Process

- Credentialed and registered prescriber or dispenser selects a licensed or registered health care professional established under Chapter 456 or if necessary, another appropriate person in their practice to act on their behalf as a designee.
- Designee must register and be linked to a prescriber or dispenser Master Account holder
- Designee must be directly supervised by the linked prescriber or dispenser.

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New AWARxE Platform

My Dashboard

Patient Alerts
PATIENT ALERTS
No Patient Alerts Received

Recent Requests

Patient Full Name	DOB	Status	Request Date	Designee
Adam Smith	01/01/1900	Verified	01/01/2017 2:58PM	Test Name
Adam Smith	01/01/1900	Verified	01/01/2017 2:58PM	Test Name
Adam Smith	01/01/1900	Verified	01/01/2017 2:58PM	Test Name
Adam Smith	01/01/1900	Verified	01/01/2017 2:58PM	Test Name
Adam Smith	01/01/1900	Verified	01/01/2017 2:58PM	Test Name

Delegates

Designee Name	Status	Request Date
Adam Smith	Verified	01/01/2017 2:58PM
Adam Smith	Verified	01/01/2017 2:58PM
Adam Smith	Verified	01/01/2017 2:58PM
Adam Smith	Verified	01/01/2017 2:58PM
Adam Smith	Verified	01/01/2017 2:58PM

PMP Announcements
01/01/2017
Lorem ipsum dolor sit amet, consetetur elipsum...

Quick Links
Dashboard of Dashboard
Sample Link
Sample Link
Sample Link

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Patient Report Patient Report

Linked Records

Name	DOB	Age	Gender	Address
Patient Name	01/01/1900	1	Female	632 West Road Patient Care, Wichita, KS 67205
Patient Name	01/01/1900	2	Female	632 West Road Patient Care, Wichita, KS 67205
Patient Name	01/01/1900	3	Female	632 West Road Patient Care, Wichita, KS 67205

Report Criteria

Patient Name	Last Name	DOB
Patient Name	Patient Name	01/01/1900

Prescriptions

Summary
Total Prescriptions: 4
Prescriptions: 4
Private Pay: 0
Active Daily AMH: 0

Patient	DOB	Request Date	Request Time	Requester	Requester Role	Requester Type	Requester ID	Requester Name	Requester Address	Requester City	Requester State	Requester Zip	Requester Phone	Requester Email	Requester Fax	Requester F10	Requester F20	Requester F30	Requester F40	Requester F50	Requester F60	Requester F70	Requester F80	Requester F90	Requester F100	
08/18/2017	1900	08/18/2017	08:00	0001	DR	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001	0001

Dispensaries

Dispensary	Address	City	State	Zip	Phone
0001	0001	0001	0001	0001	0001
0002	0002	0002	0002	0002	0002
0003	0003	0003	0003	0003	0003
0004	0004	0004	0004	0004	0004

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Data Integrity Reduces Inadvertent Red Flags

<p>Dispenser Reporting</p> <ul style="list-style-type: none"> • Accuracy is important • Correct spelling of patient's first and last name • Complete addresses • Extraneous notes in reporting fields • Edit and void changes 	<p>Why it is important?</p> <ul style="list-style-type: none"> ✓ Sound clinical decisions ✓ Determines the blending of the patient's records ✓ Expedites patient search results ✓ Creates multiple profiles ✓ Accurately reflects dispenser's records when information is edited or prescriptions are not picked up
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E-FORCSE Patient Information: Security and Privacy

- Section 893.0551, F.S., any person who willfully and knowingly violates this section of law by sharing confidential protected health information commits a felony of the third degree
- Felony convictions related to Chapter 893, F.S. can result in licensure non-renewal
- Board of Pharmacy sanctions have included \$10,000 fine, laws and rules, ethics, no PDM for 1 year

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Assessment Question

Who can access information on the PDMP?

- A. Pharmacist
- B. Pharmacy Technician
- C. Designated person
- D. All the above
- E. A & C

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Role Of Pharmacists In This Opioid Crisis

- ▶ First contact with patients receiving opioid prescriptions
- ▶ Knowledge of the opioid crisis problem
- ▶ Have you checked the PDMP
- ▶ Counseling strategies
- ▶ Early intervention
- ▶ Disposal bags available in your pharmacy??
- ▶ Literature available in your pharmacy??
- ▶ Who would you refer a patient to??

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Discussion Assessment

- ▶ What are some common protocols and methods that are used in your practice to
 - ▶ Verify if a prescription has a legitimate medical purpose
 - ▶ Resolving discrepancies recognized during DUR

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Assessment Question

- ▶ M.M. has just been dispensed a controlled substance to manage his pain after a long dental procedure. He has never taken a controlled substance before this visit. Which of the following should be discussed in his patient counseling session? Select all that apply:
 - A. Storage
 - B. Lending it to another person who may need it in your household if you do not want to dispose it
 - C. Disposal
 - D. How to use the medication safely
 - E. Signs and symptoms of using too much medication

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Opiate Dosing Comparison
Morphine Equivalent Dosing
(100 to 120mg MS is lethal dose to opiate naïve patient)

- ▶ Codeine in mg. X 0.15 = MED
- ▶ Hydrocodone in mg X 1 = MED
- ▶ Oxycodone in mg X 1.5 = MED
- ▶ Oxymorphone in mg X 3 = MED
- ▶ Methadone in mg (1-20) X 4 = MED (Inc with dose 4-8-10-12X every 20mg)
- ▶ Hydromorphone in mg X 4 = MED
- ▶ Fentanyl in total mcg/d X2.4 = MED (100 X stronger than MS)
- ▶ Sufentanil 1000 X stronger than MS
- ▶ Carfentanil 10,000 X stronger than MS

CDC, 2017

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Assessment Question

How much stronger is oxycodone than morphine?

- A. Equal potency to morphine
- B. Twice as strong as morphine
- C. 1.5 times as strong as morphine

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Patient Counseling on Opioids

- ▶ Pharmacists are the first healthcare practitioners interacting with a patients first exposure to an opioid
- ▶ Pharmacist initiated counseling for patients with opioid prescriptions should include but not limited to: dosing, storage, security, side effects, interactions and proper disposal of unused opioids
- ▶ First opportunity to address the potential dangers of opioids

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Proper Disposal of Unused Controlled Substances

- ▶ Seven Steps for safer drug disposal – Florida Department of Health
- ▶ Keep the medicines in the original container. This will help identify the contents if they are accidentally ingested.
- ▶ Mark out your name and prescription number for safety.
- ▶ For pills: add some water or soda to start dissolving them.
- ▶ For liquids: add something inedible like cat litter, dirt or cayenne pepper.
- ▶ Close the lid and secure with duct or packing tape.
- ▶ Place the bottle(s) inside an opaque (non see-through) container like a coffee can or plastic laundry bottle.
- ▶ Tape that container closed.
- ▶ Hide the container in the trash.

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Proper Disposal of Unused Controlled Substances

- ▶ Drop off disposal sites are available in the community
- ▶ County Sheriff websites
- ▶ DEA Drug Takeback Days
- ▶ Professional disposal companies; eg: Stericycle
- ▶ FDA website suggestions
- ▶ Disposal bags

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Naloxone Standing Order

- ▶ 381.887(3) 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 autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use.

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Naloxone Standing Order

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

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5 Essential Steps for First Responders

- ▶ **Step 1 C: all for help** (Dial 911)
- ▶ **Step 2: Check for signs of opioid overdose:** extreme sleepiness, shallow breathing, fingernails or lips turning blue, extremely small pinpoint pupils, slow heartbeat and/or low blood pressure, listen for "death rattle", an exhaled breath with labored sound coming from the throat...patient is near death...needs emergency CPR.
- ▶ **Step 3:** Support the persons breathing...clear airway, tilt head back
- ▶ **Step 4:** Administer naloxone (may take more than 1 dose)
- ▶ **Step 5:** Monitor the person's response (Naloxone will work for 30 to 90 minutes depending on level of od)

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Naloxone Standing Order

- ▶ Pharmacy must have a standing order with a physician
- ▶ Must maintain a copy of the standing order if dispensing naloxone

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Treatment Strategies (Overdose)

- ▶ Naloxone (Narcan)
- ▶ Availability of Naloxone for first responders
- ▶ Availability of Naloxone for patients & care givers
- ▶ **This is not long term treatment: life saving only**
- ▶ Gets you to the 3 legged stool

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Treatment Strategies Opioid Dependence

- ▶ 3 legged stool
- ▶ MAT (Medication Assisted Treatment)
- ▶ Recovery Support
- ▶ Psychosocial services

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MAT

- ▶ 3 medications currently being used in MAT
- ▶ Methadone
- ▶ Buprenorphine
- ▶ Naltrexone
- ▶ Treatment is more effective with long term therapy (up to 2 years)
- ▶ Vivitrol (injectable naltrexone monthly)
- ▶ Probuphine (implantable buprenorphine 6 months)

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Available Treatment Resources

- ▶ SAMSHA Toll Free Treatment Referral Helpline
- ▶ 1-800-662-HELP (4357)
- ▶ Behavioral Health Treatment Services Locator
- ▶ www.findtreatment.samsha.gov
- ▶ DACCO
- ▶ Gracepoint
- ▶ ACTS
- ▶ County Drug Task Force Coalitions: Hillsborough County Anti Drug Alliance (HCADA), Pasco County Alliance for Substance Abuse (ASAP)

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Assessment Question

What is MAT?

- A. Rug that goes under your prescription verification terminal
- B. Medication Assisted Treatment
- C. Part of an opioid dependence program
- D. B and C

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Assessment Question

Which of the following is accurate regarding opioid treatment strategies? Select the best answer

- A. Naloxone is used for occasional and sometimes long term care for chronic opioid users. It is a valuable resource for preventative care
- B. Usually, the three legged stool is initial treatment followed by Naloxone treatment
- C. Naloxone is a life-saving last resort that should result in a myriad of long term treatment options including MAT, therapy, and rehabilitation
- D. None of the above is true

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Assessment Question

Which of the following is true regarding Naloxone? Select all that apply

- A. A standing order is mandatory for dispensing
- B. A standing order is mandatory for dispensing but does not necessarily have to be on hand
- C. A standing order is only necessary when Naloxone is used for long term treatment
- D. A standing order is mandatory for dispensing and must be on hand at all times
- E. None of the above are true

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Before Dispensing a Controlled Substance What must YOU do?

- Resolve any **red flags** that are present on the prescription!!
- Can all **red flags** be resolved??
- If you can resolve the **red flag**...document what you did to resolve it!!!!
- Where will you document the resolution?

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How can YOU Resolve These Red Flags? Let's Try!!

- Known drugs of abuse (Oxycodone, hydromorphone, alprazolam, fentanyl, carisoprodol)
- Cocktails (Trinity-Hydrocodone-alprazolam-carisoprodol & Holy Trinity oxycodone-alprazolam-carisoprodol)
- Unusual behavior of patient (nervous, overly friendly, aggressive, threatening)

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Are these Resolvable?

- Geography (distance between patient home, physician office and pharmacy)
- Cannot afford insurance (financial hardship)... but.....
- Pay Cash (Large sums of cash.. Hundreds or Thousands of dollars)
- Has insurance but does not want to use insurance for Controlled Substances

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How about these?

- Street names (blues, oxys, zanny bars for Xanax 2mg, Dans for Soma, Stop signs for Opana ER)
- Multiple prescribers (Doctor shopping??)
- Only controlled substances on profile
- One person presenting prescriptions for controlled substances for multiple patients
- Multiple patients presenting from same prescriber for same or like prescriptions

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Verifying a Prescription

- What must you do to verify a prescription?
- Who do you speak to?
- Why would you ask for a diagnosis?
- Why would you ask for an MRI? Are you qualified to read an MRI?
- What if the office tells you to "quit bothering me and just fill the damn prescription"
- Can a patient resolve a "**red flag**"?

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Assessment Discussion

Briefly give examples of how you ensure safe access to controlled substances (CS) for all patients with a valid prescription in your practice

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Were they all Resolvable?

- What did you do with the "Red Flags" that were resolved??
- Document then FILL THE SCRIPT!!!!
- There are truly patients in need of legally prescribed pain medications.
- What did you do with the "Red Flags" that you could not resolve??

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Now that you have resolved the Red Flags Now What?

- You have resolved the red flags and documented the resolution
- Do you have the medication in stock to be able to fill the prescription?
- Are you willing to fill the prescription?
- Is it too much trouble to fill that script?
- Are you being pressured to not fill the pain scripts?

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What is YOUR duty to YOUR PATIENT?

- To dispense a valid and legally prescribed medication.
- Have you done your due diligence?
- In your professional judgment is the medication appropriate?
- Have you resolved the **red flags**?
- If So.....YOU ARE A HEALTH CARE PROVIDER!

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SO PROVIDE

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QUESTIONS?

Bob Parrado, BPharm., RPh
 Parrado Pharmacy Consultants, Inc.
bobparrado1@hotmail.com
 Cell (813) 361-0491

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