Schedule II Medications: Laws and Regulations

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DISCLOSURE DECLARATION

• The following declare they have no relevant financial interest in relation to this activity:
  • Charissa Kam, presenter
  • Tara Haworth, presenter

• Off-label uses of medications will be disclosed during the presentation

• Brand names, kept to a minimum, are used when necessary to differentiate products
LEARNING OBJECTIVES

1. Discuss federal and state laws pertaining to scheduled II (C-II) medications
2. Define requirements for C-II medication prescriptions
3. Review advanced nurse practitioners (APRNs) and physicians assistants (PAs) authority to prescribe C-II medications
4. Recognize recent changes in laws and regulations of controlled medications that affect practitioners
FAST FACTS

• The United States has 5% of the world’s population & consumes 75% of the world’s prescription drugs

• Deaths from prescription opioids—like oxycodone, hydrocodone, and methadone—have more than QUADRUPLED since 1999

• Nearly half of all opioid overdose deaths involve a prescription opioid


CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016.
RISK FACTORS FOR ABUSE

Risk Factors for Prescription Opioid Pain Reliever Abuse and Overdose

- Obtaining overlapping prescriptions from multiple providers and pharmacies.
- Taking high daily dosages of prescription opioid pain relievers.
- Having mental illness or a history of alcohol or other substance abuse.
- Living in rural areas and having low income.

WHAT ABOUT PEDIATRIC PATIENTS?

- Marijuana (56.6%)
- Pain Relievers (22.5%)
- Inhalants (9.7%)
- Tranquilizers (3.2%)
- Hallucinogens (3.2%)
- Stimulants (3.0%)
- Cocaine (0.8%)
- Sedatives (0.8%)
- Heroin (0.1%)

2.9 Million Initiates of Illicit Drugs
• In 2013, 2 million Americans ≥ 12 years of age abused or were dependent on opioids

• 2.6 per 100,000 persons in the U.S. ages 15-24 died of a prescription opioid overdose
CONTROLLED SUBSTANCES (CS)

- Government Regulation
  - Establish controls to prevent
    - Abuse
    - Trafficking
    - Diversion
  - Ensure availability for medical and scientific use
    - Accessible to patients who need them
FEDERAL ENFORCEMENT AUTHORITY

• Drug Enforcement Administration (DEA)
  • Established 1973
  • To enforce federal drug laws
    • Tasked with combating drug smuggling and use within the US
  • Lead agency for domestic enforcement of the Controlled Substances Act
CONTROLLED SUBSTANCES

- Tightly regulated due to abuse potential or risk
- Placed in Schedules according to abuse potential by the DEA
- Schedule I: Highest abuse potential
- Schedule IV: Lowest abuse potential
SCHEDULES OF CS

• Schedule I
  • High abuse potential
  • No safe, accepted medical use

• Schedule II
  • High abuse potential
  • Safe and accepted medical use

• Schedule III, IV, V
  • Less risk of abuse potential than the class above
  • Safe and accepted medical use

Controlled Substance Schedules. Drug Enforcement Administration website
SCHEDULE II MEDICATIONS

- High abuse risk but also safe and accepted medical uses in the United States
- 1981: Texas Law requires doctors to write all prescriptions for Schedule II drugs on special three-part (triplicate) form
- 1999: Triplicate prescription was replaced by official prescription form which are issued by the Texas Department of Public Safety (DPS) to prescribers
UPDATES

• 2016: Official prescription forms are now issued by the Texas State Board of Pharmacy (TSBP)

• 2018: Pharmacists will be required to search the prescription monitoring database, AWAR_XE, prior to dispensing CS
  • Must enter dispensing information into AWAR_XE within 1 business day of dispensing CS
FEDERAL VS. STATE REGULATION

• Must comply with both federal and state laws and regulations
• When laws or regulations differ, the *more* stringent rule applies

Controlled Substance Schedules. Drug Enforcement Administration website.
FACT OR FICTION?

Most pediatric nonmedical opioid users obtain opioid medications for free from acquaintances and strangers.

FICTION
FEDERAL TENETS OF LAWFUL PRESCRIBING

- Issued by a registered practitioner
- For a legitimate medical purpose
- In the usual course of professional practice

Federal Law CFR 1306.04 (a)
PRESCRIBING AND DISPENSING CS

• Corresponding responsibility of proper prescribing and dispensing between the prescribing practitioner and the pharmacist who fills and dispenses the prescription

Federal Law CFR 1306.04 (a)
A practitioner may not:

Prescribe, dispense, deliver or administer a controlled substance or cause a controlled substance to be administered under the practitioners direction and supervision except for valid medical purpose and in the usual course of medical practice.

Sec 481.071(a)
TEXAS CONTROLLED SUBSTANCES ACT

- A pharmacist may not:
  - Dispense or deliver a controlled substance except under a valid prescription and in the course of professional practice
  - Dispense a controlled substance if they know/should have known that the prescription was issued without a patient-practitioner relationship

Sec 481.071(a)
TEXAS DANGEROUS DRUG ACT

• Pharmacist requested to dispense a dangerous drug under a prescription issued by a practitioner shall determine, in the exercise of their professional judgment, that the prescription is valid.

• Pharmacist may not dispense a dangerous drug if they knows/should have known that the prescription was issued without a valid patient-practitioner relationship.

Sec. 483.021 (a)
FACT OR FICTION?

Only 11% of pediatric nonmedical opioid users endorse using opioids solely to “get high.”

FACT

Frese W. Pediatrics in Review Apr 2011, 32 (4) e44-e52
A prescriber may, directly or by standing order, prescribe an opioid antagonist to:

- A person at risk of experiencing an opioid-related drug overdose
- A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose

Sec. 483.102 (a)
TEXAS DANGEROUS DRUG ACT

- A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:
  - Dispensing or failing to dispense the opioid antagonist
  - If the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from eventual administration of the opioid antagonist

Sec. 483.103 (c)
TEXAS PHARMACY ACT

• Pharmacist shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription.

• Pharmacist may not dispense a prescription drug if the pharmacist knows/should know that the prescription was issued on the bases of and Internet-based or telephonic consultation without a valid practitioner-patient relationship.

Sec. 562.056(a)

Hydrocodone combination products schedule II. Texas Medical Association website.
FEDERAL AND STATE LAW

• Common Thread
  • Prescription must be for legitimate medical use
  • Valid physician-patient relationship must exist
  • Physician and pharmacist have corresponding responsibility to determine prescription is valid
Enough prescription painkillers were prescribed in 2010 to medicate every American adult every 4 hours for one month.

CRIMINAL OFFENSES

• Felony charge (effective 9/1/2011)
  • Person obtaining a prescription for a controlled substance that is not medically necessary
    • Doctor Shopping
  • Person registered under the CSA or working for a registrant to knowingly take controlled substances
    • For personal use
    • To divert for unlawful use by another person

Sec. 481.1289 & 481.1285
NEWS FLASH!
PRESCRIPTION DRUG MONITORING

• AWARXE
  • Online monitoring program launched September 1, 2016

http://www.dps.texas.gov/director_staff/public_information/pr080212.htm
Texas Prescription Monitoring Program

The Texas Prescription Monitoring Program (PMP) collects and monitors prescription data for all Schedule II, III, IV and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. The PMP also provides a venue for monitoring patient prescription history for practitioners and the ordering of Schedule II Texas Official Prescription Forms. Click here for more information about the PMP.

Prescription Monitoring Program FAQs

YouTube Introduction Video

AWARxE/CLEARINGHOUSE

AWARxE – Provides a venue for practitioners to query patient reports of controlled substance prescriptions.

AWARxE FAQs

PMP Clearinghouse – Dispenser portal for reporting to the prescription monitoring program.

Clearinghouse FAQs

Dispenser Data Submission Guide

Registration Manual

Quick Reference Guide - Making a Request in PMP AWARxE

User Support Manual

OFFICIAL PRESCRIPTION FORM ORDER

Official CII Prescription Forms – For more information regarding the ordering of official CII prescription pads.

Ordering Official CII Prescription Forms

CII Prescription Form FAQs

IMPORTANT LINKS

Texas Children’s Hospital
My Dashboard

Patient Alerts
No patient alerts received.

Recent Requests
No Requests found.

Supervisors
No Supervisors found.

PMP Announcements
No Announcements Available

Quick Links
- Ordering Official CII Prescription Forms
- Texas State Board of Pharmacy
- Texas Board of Nursing
- Texas Medical Board
- Texas State Board of Dental Examiners
- Drug Enforcement Administration
- Texas Optometry Board
- Texas State Board of Podiatric Medical
More than 50% of surveyed 12th graders report fewer than five occasions of lifetime nonmedical opioid use.

FACT OR FICTION?

FACT
ELECTRONIC PRESCRIPTION FOR CS

• Federal Law 21 CFR 75(61).16236
  • Effective June 1, 2010 the CFR was revised to:
    • Provide practitioners with the option of writing prescriptions for CSs electronically following existing rules
    • Permit pharmacies to receive, dispense, and archive these electronic prescriptions
    • Provide pharmacies, hospitals, and practitioners with the ability to use modern technology for CS prescriptions while maintaining the closed system of controls on CSs
ELECTRONIC PRESCRIPTION FOR CS

• Federal Law 21 CFR 1306.08
  • A practitioner may sign and transmit e-prescriptions if all of the following requirements are met:
    • Must comply with all other requirements for issuing CS prescriptions
    • Must use an application that meets specific requirements (in Part 1311)
    • Must comply with requirements for electronic orders and prescriptions (in Part 1311)
ELECTRONIC PRESCRIPTION FOR CS

• Federal Law 21 CFR 1311.102
  • Practitioner responsibilities rapid reporting of identified breaches
  • Same responsibilities when issuing e-prescriptions for CSs as when issuing a paper or oral prescription including issuing prescriptions only for a legitimate medical purpose and in the usual course of professional practice
  • The prescription must conform in all essential respects to the law and regulation
E-PRESCRIBING C-II PRESCRIPTIONS

- DEA issued rules in 2010 allowing electronic transmission of CS prescriptions (EPCS)
  - Requirement for the certification of both the prescriber software system and pharmacy software system by an independent third party auditor
- Texas DPS adopted the same requirements and updated their rules October 2013, to allow C-II CS to be transmitted electronically
E-PRESCRIBING C-II PRESCRIPTIONS

- March 1, 2014, Texas DPS concluded beta testing of electronic transmission of C-II drugs with a small number of prescribing physicians and pharmacies
- Purpose of the pilot was to ensure that C-II prescriptions were reported accurately to the Texas Prescription Monitoring Program (PMP)
- List of pharmacies and providers with EPCS capabilities
FACT OR FICTION?

Almost half of children ages 10 to 18 years report using an opioid during their lifetimes for medical and nonmedical purposes.

FACT
PREScribing cs in Texas

1. Evaluation of patient with medical history and physical exam
2. Written treatment plan
3. Informing patient of risks and benefits of plan and treatment options
4. Obtaining patient agreement for compliance with treatment plan
5. Periodic reviews of the patient and modification of treatment plan

6. Referring for further evaluation or treatment when necessary

7. Documenting rational for treatment plan and controlled substance prescriptions in medical records
C-II PRACTITIONER RESPONSIBILITIES

• Federal and State requirements:
  • Practitioner’s name, address, DEA #
  • Patient's name, address and age or date of birth
  • Controlled substance prescribed
  • Quantity of controlled substance prescribed, written numerically and as a word
  • Intended use or diagnosis
    • If not deemed detrimental to the patient's well-being
C-II PRACTITIONER RESPONSIBILITIES

• Federal and State requirements:
  • Date written (cannot be post-dated)
  • Preference for brand, if necessary
  • Prescriber signature

• APRN/PAs
  • Must use the official prescription forms issued with their name, address, phone number, DPS and DEA numbers, and the delegating physician's name and DPS number
  • Official prescription order form must be signed by the requesting ARPN/PA, and by the delegating physician

Controlled Substances. Texas Medical Board Website. Prescription Forms. Texas Department of Public Safety website.
OFFICIAL PRESCRIPTION FORMS

Controlled Substances. Texas Medical Board Website.
Prescription Forms. Texas Department of Public Safety website.
OFFICIAL PRESCRIPTION FORM ORDERING

- TSBP now distributes official prescription pads
Texas Prescription Monitoring Program

The Texas Prescription Monitoring Program (PMP) collects and monitors prescription data for all Schedule II, III, IV and V controlled substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state. The PMP also provides a venue for monitoring patient prescription history for practitioners and the ordering of Schedule II Texas Official Prescription Forms. Click here for more information about the PMP.

AWARx/CLEARINGHOUSE

AWARxE – Prescribers and dispensers register here to query patient reports of controlled substance prescriptions.

PMP/CLEARINGHOUSE – Dispenser portal for reporting to the prescription monitoring program.

OFFICIAL PRESCRIPTION FORM ORDER

For more information regarding the ordering of official CII prescription pads.

IMPORTANT LINKS
SECURITY FEATURES

• Control number
  • Unique number for each prescription form that must be reported in the record when a C-II prescription is filled

• Pantograph
  • Scanning and copying produce a VOID on the face of the prescription

• Thermochromatic ink
  • Applying heat or vigorously rubbing the thumbprint, on the back of the prescription, will cause the check mark symbol to disappear

• State of Texas or Texas Department of Public Safety seal
  • Appears as a watermark on the face of the prescription
QUIZ

According to Federal and State Law, can the following be changed on C-II prescriptions?

a. Name of the patient?
b. Address of patient?
c. Name of the drug?
d. Strength of the drug?
e. Name of the prescribing physician?
f. Date of the prescription?
MODIFICATIONS TO C-II PRESCRIPTIONS

• Federal and State Law
  • May NOT be changed
    1. Name of the patient
    2. Name of the drug
    3. Name of the prescribing physician
    4. Date of the prescription
  • Any other item may be changed if the pharmacist
    1. Contacts prescribing physician for verbal permission
    2. Documents change, name of authorizer, initial of pharmacist
C-II PRESCRIPTION: QUANTITY

- Amount or duration that can be prescribed at one time
  - Federal Regulations
    - No limit
  - State specific
    - Texas: 90 day supply

Controlled Drugs. Texas State Board of Pharmacy Website.
C-II PRESCRIPTION: EXPIRATION

- Length of time a C-II prescription is valid
  - Federal Regulations
    - No limit
  - State specific
    - Texas: 21 days
Medical users of opioids report similar rates of abuse of prescription drugs, specifically opioids

FICTION
EMERGENCY DISPENSING

• Appropriate when:
  • Immediate administration of the C-II is necessary for proper treatment
  • No appropriate alternatives are available, including drugs in lower schedules or non-controlled drugs
  • Not reasonably possible for practitioner to provide a written prescription before dispensing

21 CFR 290.10
EMERGENCY DISPENSING (CONT.)

• Appropriate when:
  • A pharmacist may dispense a C-II medication after receiving an oral authorization if:
    • Quantity is limited to the emergency period only
  • Prescription shall be reduced to writing with all the required information except the signature of the practitioner
  • Pharmacist makes a reasonable attempt to make sure the oral authorization came from a registered practitioner

21 CFR 290.10
EMERGENCY DISPENSING (CONT.)

- Appropriate when:
  - A pharmacist *MUST* receive the written prescription within 7 days from an oral authorization
    - The prescription should include:
      - A Notation: “Authorization for Emergency Dispensing”
      - Date of oral authorization
  - If the information is not received within 7 days, the pharmacist is required to report this missing information to the DEA.

21 CFR 290.10
PRESCRIPTIVE AUTHORITY

• Must be delegated by a physician through a written document prescribed by law
  • Prescriptive Authority Agreement (PAA)
• Limitations apply to prescribing CS
PRESCRIPTIVE AUTHORITY OF C-IIS

- Ordering and prescribing may be delegated to APRN/PAs who are:
  - To patients on discharge from the hospital, IF the prescription is filled at the hospital’s pharmacy
  - As part of the plan of care for the treatment of a patient who:
    - Treating terminally ill patients who are cared for through hospice
    - Facility-based in a hospital and treating patients in that hospital’s emergency department
    - Facility-based in a hospital and treating patients admitted for an intended length of ≥ 24 hours
DELEGATING PHYSICIAN CONSULTATION

- Duration of prescription, including refills can not exceed 90 days
- APRNs/PAs must consult with the delegating physician for refills of a prescription for controlled substances after the initial 90 day supply
- Also required when prescribing controlled substances for children under the age of two years
- In both cases, the consultation must be documented in the patient’s medical record
SITE AND DISTANCE RESTRICTIONS

• Eliminated with implementation of Senate Bill 406
  • November 1, 2013

• Physicians may delegate prescriptive authority to APRN/PAs in any location in Texas
MODIFYING REGISTRATION

• To indicate you have authority to prescribe C-II medications
  • Fax or mail modification form to DPS
    Fax: (512) 424-5799
    Controlled Substances Registrations
    MSC-0438 PO Box 4087
    Austin, TX 78773-0438
Which prescription opioid is abused most and used for nonmedical purposes in Texas?

Hydrocodone
PRESCRIPTION ABUSE

• Hydrocodone continues to be the most prevalent prescription opioid used for nonmedical purposes in Texas

• Ingredient in the “Houston Cocktail” or “Holy Trinity,” along with alprazolam and carisoprodol.
HYDROCODONE COMBINATION PRODUCTS

• Moved to schedule II October 6, 2014

• Prohibits ARPN/PAs authority to prescribe these drugs outside of a hospital or hospice setting
  • May need to update delegated prescriptive authority agreements

• Can no longer be called into pharmacies
  • Except in emergencies

• Official prescription pads must be used
  • Obtained from the Texas State Board of Pharmacy (TSBP)
  • Triplicate prescription pads issued by DPS prior to September 1, 2016, are still valid
December 2013, meeting, the Texas Medical Board (TMB) reviewed Section 157.0511 (b)(2) of the Medical Practices Act that reads:

- The prescription, including a refill of the prescription, is for a period not to exceed 90 days

TMB determined that this section means that “an APRN/PA may issue prescriptions for a total of 90-days’ supply of a CS including refills.”
• TMB stated that the intent of the section is to allow 90-days’ supply and not to limit the patient to one refill
• APRN/PA can issue a prescription with more than one refill provided the total quantity does not exceed more than a 90-day supply
• Further discussions with staff of the Medical Board have also resulted in the interpretation that essentially a CS prescription issued by an APRN/PA, expires 90-days after issuance
Recently contracted with various insurance companies for third party processing of prescriptions

Many patients experience significant barriers to access of opioid analgesics upon discharge from TCH

TCH Outpatient Pharmacy – 3rd Floor Clinical Care Center

Any patient seen or treated in a Texas Children’s Ambulatory Clinic, Office, or Surgery Area who are given a prescription for an opioid analgesic

Any patient discharged from the inpatient setting at TCH, the Pavilion for Women, or the TCH Emergency Center who are given a prescription for an opioid analgesic
QUESTIONS?

THANK YOU!