Pharmacists’ Responsibilities when Dispensing Controlled Substance Prescriptions

Gay Dodson, R.Ph.
Executive Director/Secretary

Houston DEA Pharmacy Diversion Awareness Conference
September 8 & 9, 2012
Goals

Discuss state and federal laws and rules regarding dispensing responsibilities.

Identify resources and tools available to assist pharmacists in making dispensing decisions.

Answer your questions.
Board of Pharmacy Members

Jeanne D. Waggener, R.Ph. – President, Waco
Alice G. Mendoza, R.Ph. – Vice-President, Kingsville
Dennis F. Wiesner, R.Ph. – Treasurer, Austin
Buford T. Abeldt, Sr., R.Ph. – Lufkin
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L. Suzan Kedron – Dallas
Phyllis A. Stine – Abilene
Joyce Tipton, R.Ph., MBA – Houston
Charles F. Wetherbee – Boerne
Federal Law
CFR 1306.04(a)

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.
An order purporting to be a prescription issued not in the usual course of professional treatment is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829); and

The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
State Laws
Texas Controlled Substances Act
Sec. 481.071(a)

A practitioner may not prescribe, dispense, deliver, or administer a controlled substance or cause a controlled substance to be administered under the practitioner's direction and supervision except for a **valid medical purpose and in the course of medical practice.**
Sec. 481.074(a)

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 the pharmacist knows or should have known that the prescription was issued without a **valid patient-practitioner relationship.**
Effective Date: 9/1/2011.

It is now a felony:

- For a person to obtain a prescription for a controlled substance that is not medically necessary (Doctor Shopping).

- For a person registered under the Controlled Substances Act or working for a registrant to knowingly take controlled substances:
  - For his/her own use; or
  - To divert for unlawful use by another person.
Texas Dangerous Drug Act
Sec. 483.021(a)

A pharmacist who is requested to dispense a dangerous drug under a prescription issued by a practitioner shall determine, in the exercise of the pharmacists professional judgment, that the prescription is a valid prescription.

A pharmacist may not dispense a dangerous drug if the pharmacist knows or should have known that the prescription was issued without a valid patient-practitioner relationship.
Texas Pharmacy Act
Pharmacy Act – Sec. 562.056(a)

Before dispensing a prescription, a pharmacist shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription.

A pharmacist may not dispense a prescription drug if the pharmacist knows or should know that the prescription was issued on the basis of an Internet-based or telephonic consultation without a valid practitioner-patient relationship.
Federal and State Laws – Common Theme

- A valid physician-patient relationship must exist.
- The prescription must be issued for a valid medical need.
- The prescription must be therapeutic for the patient’s condition.
- The physician and the pharmacists have a corresponding responsibility to determine the prescription is valid.
Texas Pharmacy Rules
§291.29 Professional Responsibility of Pharmacists

a) R.Ph.s shall exercise sound professional judgment with respect to the accuracy and authenticity of any Rx dispensed. If the R.Ph. questions the accuracy or authenticity of a Rx, the R.Ph. shall verify the order with the Dr. prior to dispensing.
§291.29 Professional Responsibility of Pharmacists (cont.)

b) A R.Ph. shall make every reasonable effort to ensure that any Rx, regardless of the means of transmission, has been issued for a legitimate medical purpose by a Dr. in the course of medical practice.
§291.29 Professional Responsibility of Pharmacists (cont.)

b) (cont.) A R.Ph. **shall not dispense** a Rx **if the R.Ph. knows or should have known** that the order **was issued without a valid pre-existing patient-Dr. relationship** as defined by the Texas Medical Board in 22 TAC §190.8 or without a valid Rx.
§291.29 Professional Responsibility of Pharmacists (cont.)

b)

1) A Rx may not be dispensed by means of the Internet unless pursuant to a valid Rx issued for a legitimate medical purpose in the course of medical practice by a Dr. who has conducted at least one in-person medical evaluation of the patient.
§291.29 Professional Responsibility of Pharmacists (cont.)

2) A Rx may not be dispensed if the R.Ph. has reason to suspect that the Rx was authorized without a valid patient-Dr. relationship or otherwise in violation of the Dr.’s standard of practice including that the Dr.:

A. did not establish a diagnosis;
B. prescribed drugs that were not necessary for the patient due to a lack of a valid medical need or the lack of a therapeutic purpose for the Rx; or
C. issued the Rx outside the usual course of medical practice.
Reasons to suspect that a Rx may have been authorized in the absence of a valid patient-Dr. relationship, or in violation of the Dr.'s standard of practice, include:

1) the number of Rxs issued daily by the Dr.;
2) a disproportionate number of patients of the Dr. receive controlled substances;
3) the manner in which the Rxs are authorized by the Dr. or received by the pharmacy.
§291.29 Professional Responsibility of Pharmacists (cont.)

4) the geographical distance between the Dr. and the patient or between the pharmacy and the patient;

5) knowledge by the RPh that the prescription was issued solely based on answers to a questionnaire;

6) knowledge by the RPh that the pharmacy he/she works for is otherwise associated with an Internet site that markets Rx drugs to the public without requiring a valid Rx from the patients Dr.; or
§291.29 Professional Responsibility of Pharmacists (cont.)

7) knowledge by the RPh that the patient has exhibited doctor-shopping or pharmacy-shopping tendencies.
§291.29 Professional Responsibility of Pharmacists (cont.)

d) A R.Ph. shall ensure that Rxs for the treatment of chronic pain have been issued in accordance with the guidelines set forth by the Texas Medical Board in 22 TAC §170.3 (relating to Guidelines), prior to dispensing the Rxs.
§291.29 Professional Responsibility of Pharmacists (cont.)

e) A Rx may not be dispensed if issued by a Dr. practicing at a pain management clinic that is not in compliance with the rules of the Texas Medical Board in 22 TAC §§195.1 - 195.4 (relating to Pain Management Clinics).
TSBP Website
www.tsbp.state.tx.us
Change of Address and Employment

Change of Pharmacist-in-Charge (pdf)

Updates, News & Notices

Newsletter - Fall 2011

Board Meeting Information February 14 - 15, 2012

New Fees Effective December 1, 2011

Recent Disciplinary Notifications

Are You AWARxE

Certified Pain Management Clinics (pdf)

Pharmacists Authorized to Sign Prescriptions When Performing Drug Therapy Management Under Protocol

Contact Information

William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street
Austin, Tx 78701

Directory of Email Addresses
Driving & Parking Directions

Phone: (512) 305-8000
Fax: (512) 305-8082
Licensing: (512) 305-8075 (fax)
Open Records: (512) 305-8008 (fax)
Complaints: (800) 821-3205*

* voice mail for complaint referrals
Information Regarding Controlled Substances

- Texas Medical Board Guidelines for Pain Management (Texas Administrative Code 170.3)
- Items that can be changed on a Schedule II Prescription (pdf)
- Issuance of Official Prescription Forms (pdf)
- Illegal Official Prescription Forms (pdf)
- Controlled Substances Registration Search and Verification System
- Electronic Prescriptions for Controlled Substances - Questions and Answers for Pharmacies
- Rx Patrol
(a) The Texas Medical Board will use these guidelines to assess a physician's treatment of pain.

(1) Evaluation of the patient:

(A) A physician is responsible for obtaining a medical history and a physical examination that includes a problem-focused exam specific to the chief presenting complaint of the patient.

(B) The medical record shall document the medical history and physical examination. In the case of chronic pain, the medical record should document:

(i) the nature and intensity of the pain,

(ii) current and past treatments for pain,

(iii) underlying or coexisting diseases and conditions,

(iv) the effect of the pain on physical and psychological function,

(v) any history and potential for substance abuse, and

(vi) the presence of one or more recognized medical indications for the use of a dangerous or scheduled drug.

(2) Treatment plan for chronic pain. The physician is responsible for a written treatment plan that is documented in the medical records. The medical record should include:

(A) How the medication relates to the chief presenting complaint of chronic pain,

(B) dosage and frequency of any drugs prescribed,

(C) further testing and diagnostic evaluations to be ordered,

(D) other treatments that are planned or considered,

(E) periodic reviews planned, and

(F) objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function.

(3) Informed consent. It is the physician's responsibility to discuss the risks and benefits of the use of controlled substances for the treatment of chronic pain with the patient, persons designated by the patient, or with a surrogate or guardian if the patient is without medical decision-making capacity. This discussion should be documented by either a written signed document maintained in the records or a contemporaneous notation in the record.
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...
Prescriber Responsibilities

- Conducting and documenting a patient evaluation to include obtaining a medical history and performing a physical exam
- Diagnosing the patient based on the exam and any associated diagnostic tests
- Informing the patient of the risks and benefits of the plan and treatment options
- Obtaining patient’s agreement for compliance with the plan
Prescriber Responsibilities (cont.)

- Conducting periodic reviews of the patient in view of the circumstances and documenting progress or change
- Referring the patient for further evaluation or treatment to other practitioners and obtaining consultation from other practitioners
- Documenting rationale for the treatment plan and prescriptions for controlled substances
Pain Management Clinics

Effective Date: 9/1/09

S.B. 911 (Williams/Hamilton) amended the Texas Medical Practices Act to require pain management clinics to be certified by the Texas Medical Board.

The Medical Board adopted rules that became effective on November 30, 2009.
Medical Board is posting the names of registered Pain Management Clinics on their Web-Site.

Go to www.tmb.state.tx.us
- Select “Pain Management Registration Info.”
Physician Licensure Credentialing
Seminar Sept. 21

TMB Legislative Update (PDF)

Electronic Death Registration

Pain Management Clinic Registration Info

Prescriptive Delegation Online Registration

Recent Press Releases

Buy TMB data online!

Our mission is to protect and enhance the public’s health, safety and welfare by establishing and maintaining standards of excellence used in regulating the practice of medicine and ensuring quality health care for the citizens of Texas through licensure, discipline and education.

Customer Service E-mail: verficic@tmb.state.tx.us
Customer Service: (800) 248-4062 or (512) 305-7030 (outside Texas)
Customer Service Hours: Monday through Friday 8am-5pm
Pain Management Clinic Registration

Effective September 1, 2010, a pain management clinic may not operate in Texas without obtaining a certificate from the Texas Medical Board (TMB).

Please visit Chapter 195 for the complete regulations.

Application

To apply for the pain management clinic certification, please download and fill out the form below.

Pain Management Clinic Registration form (PDF)

To withdraw a pending application or cancel certification, please download and fill out the form below.

Pain Management Clinic Certification Withdrawal/Cancellation form (PDF)

Please mail or fax the completed form to the following address:

Texas Medical Board
P.O. Box 2029 MC 240
Austin, TX 78768

(fax) 512-463-9416

Please check the spreadsheet below to confirm registration.

List of Pain Management Clinic Certificates

Pain management clinic registration information is updated regularly:

PM-Reg-Spreadsheet-For-Web-06-29-2011.xls

List of Pain Management Clinics with Disciplinary Action

Frequently Asked Questions:

What is a “pain management clinic”?
<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
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Note: This list is in alphabetical order by last name of the clinic's registered physician owner. You can use Ctrl+F to search for an individual. Hold down Ctrl and F at the same time.

On April 8, 2011, the Board of Pharmacy suspended with Notice and Opportunity to Respond (NO) the license of Victor Cheung, M.D., ER Physician, and the Board of Pharmacy has ordered the suspension of the license to practice medicine of Victor Cheung, M.D., ER Physician, who is the owner of the sub-organization named Illustration. The Board of Pharmacy considers this a complaint against the owner of the sub-organization named Illustration and further disciplinary proceedings are pending.

Texas State Board of Pharmacy 9/8-9/2012
Pain Management Clinic Registration

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Please visit Chapter 195 for the complete regulations.

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List of Pain Management Clinics with Disciplinary Action

Frequently Asked Questions:

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Pain Management Clinics with Disciplinary Action

Click on PDF's below to read Board Orders regarding the certificates of registered pain clinics.

- Houston Pain & Rehab Clinic – PMC00140 - 4/25/2011
- Winrock Medical Clinic – PMC00118 - 4/25/2011
- South Houston Treatment Center, LLC – PMC00298 - 4/16/2011
- Alliance Medical – aka Alliance Treatment Center, LLC – PMC00297 - 4/16/2011
- North Houston Wellness and Weight Loss Center – PMC00259 - 4/8/2011
- UMAT Clinic – PMC00105 - 2/22/2011
- IMFD Clinic – PMC00104 - 2/22/2011
- Oaks Medical – PMC00103 - 2/22/2011
- Preferred Medical – PMC00102 - 2/22/2011
- Spring Wellness Center – PMC00146 - 2/4/2011
- Spring Wellness Center – PMC00146 - 1/11/2011
- Better Life Pain Clinic – PMC00046
TSBP Emergency Suspension Action

TSBP is now posting the results of Emergency Suspension Actions on the Website.

Go to www.tsbp.state.tx.us

Click on – Recent Disciplinary Notifications.
The Texas State Board of Pharmacy is the state agency responsible for the licensure and discipline of Texas pharmacists and pharmacies. Look here for information about the Board’s mission, Compact with Texans, policies and guidelines, members, staff, public information reports, statutes, meeting agendas, calendar of events and more.

Pharmacy Professional Resources
- Pharmacy Technicians & Trainees
- Pharmacists & Pharmacist Applicants
- Pharmacists
- Pharmacist Interns
- Texas Pharmacy Rules & Laws
- Renew License/Registration
- Change of Address and Employment
- Online Submission

Consumer Resources
- Consumer Information Index
Details about prescription medicines, prescriptions, pharmacists, pharmacies, and the role and functions of the Board.

- Complaint Process
How to file a complaint concerning a pharmacist or pharmacy that is licensed by the Board. Complaints must be in writing.

- License & Registration Verifications
Search and review public records related to Board licenses & registrations.

Job Openings at TSBP
Look here for the latest job positions.

Contact Information
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street
Austin, TX 78701
Directory of Email Addresses
Driving & Parking Directions
Phone: (512) 305-8000
Fax: (512) 305-8082
Licensing: (512) 305-8075(fax)
Recent Disciplinary Notifications

December 1, 2011
Board temporarily suspends pharmacist license of Joy P. Coleman-Looney, R.Ph.

August 3, 2011
Board temporarily suspends pharmacist license of Bright Onemboji Wokocha, R.Ph.
Board temporarily suspends pharmacy license of Adhright Pharmacy, Incorporated
Board temporarily suspends pharmacy license of Richmond Professional Pharmacy

July 13, 2011
Board temporarily suspends pharmacist licenses of Shantae Shaggard, R.Ph.
Board temporarily suspends pharmacy license for River’s Edge Pharmacy

May 9, 2011
Board Temporarily Suspends pharmacist license of Hetty Osaro Umeh, R.Ph.
Board Temporarily suspends pharmacy license for Medsure RX

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Home - Privacy Policy - Questions/Comments - Site Map - Contact
Open Records Policy - Accessibility - Compliant with Section 508
The Texas State Board of Pharmacy is the state agency responsible for the licensure and discipline of Texas pharmacists and pharmacies. Look here for information about the Board’s mission, Compact with Texans, policies and guidelines, members, staff, public information reports, statutes, meeting agendas, calendar of events and more.
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Updates, News & Notices

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333 Guadalupe Street
Austin, Tx 78701
Directory of Email Addresses
Driving & Parking Directions

Phone: (512) 305-8000
Fax: (512) 305-8082
Licensing: (512) 305-8075 (fax)
Open Records: (512) 305-8008 (fax)
Complaints: (800) 821-3205*

* voice mail for complaint referrals
Texas State Board of Pharmacy

DEA has scheduled another National Prescription Drug Take Back Day on Saturday, October 29, 2011, from 10:00 am to 2:00 pm, to provide a venue for persons who want to dispose of unwanted and unused prescription drugs.

Drug Disposal - National Take-Back Initiative
www.deadiversion.usdoj.gov
Department of Justice Drug Enforcement Administration
Office of Diversion Control

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Texas State Board of Pharmacy

TSP is seeking a highly motivated individual to perform advanced administrative support work for the Division of Professional Services.

http://www.tsbp.state.tx.us/files_pdf/12_002.pdf
www.tsbp.state.tx.us

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