

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.



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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.**



CFR 1306.04(a) (cont.)

- 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.**



CFR 1306.04(a) (cont.)

- 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 practitioners 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.**

Criminal Offenses

Sec. 481.1289 & 481.1285

- 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 pharmacist's 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.)

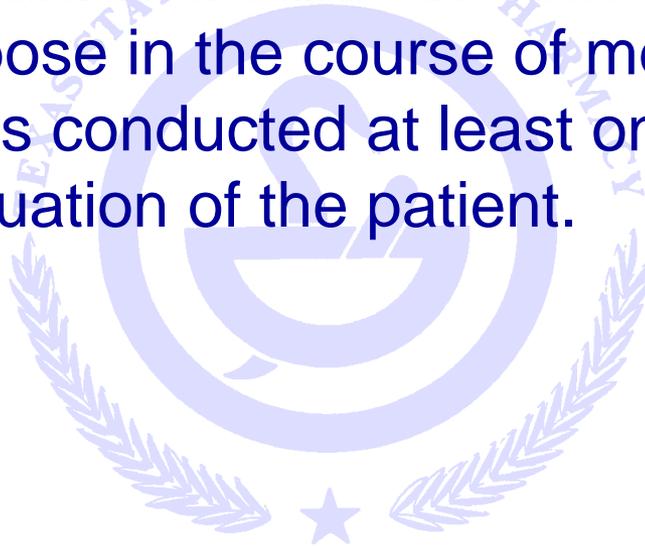
- b) (cont.) A R.Ph. shall not dispense a Rx if the R.Ph. knows or should have known that the order was issued without a valid pre-existing patient-Dr. relationship as defined by the Texas Medical Board in 22 TAC §190.8 or without a valid Rx.



§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.

§291.29 Professional Responsibility of Pharmacists

- c) 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).



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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](#)

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TITLE 22

EXAMINING BOARDS

PART 9

TEXAS MEDICAL BOARD

CHAPTER 170

PAIN MANAGEMENT

RULE §170.3

Guidelines

(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

TITLE 22 EXAMINING BOARDS
PART 9 TEXAS MEDICAL BOARD
CHAPTER 170 PAIN MANAGEMENT
RULE §170.3 **Guidelines**

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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.

Pain Management Clinics (cont.)

- 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.”





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

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

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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"?

A	B	C	D	E	F	G	H	I	J	
Management Certificate #	Clinic Name	Clinic City	Certificate Issue Date	Certificate Expiration Date	Certificate Current status	Current status date	License #	Last Name	First Name	
*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.										
86	PMC00251	NORMANDY MEDICAL, PA	HOUSTON	9/20/2010	11/30/2012	AC	9/20/2010	E9598	Davis	Carl
87	PMC00252	AT YOUR BEST FAMILY PRACTICE	HOUSTON	9/20/2010		CR - Canceled by Request	2/23/2011	E9598	Davis	Carl
88	PMC00130	ADULT MEDICINE & PAIN MANAGEMENT CENTER	PEARLAND	8/27/2010	8/31/2012	AC	8/27/2010	G1370	DeLeon	George
89	PMC00322	Adult Medicine & Pain Management Center (Location #2)	Sweeny	12/2/2010	2/28/2013	AC	12/3/2010	G1370	DeLeon	George
90	PMC00202	ADVOCATE PAIN MANAGEMENT CENTER - LOCATION 1	BELLAIRE	8/31/2010		CR - Canceled by Request	1/31/2011	L9171	Dent	David
91	PMC00203	ADVOCATE PAIN MANAGEMENT CENTER - LOCATION 2	PASADENA	8/31/2010	8/31/2012	AC	8/31/2010	L9171	Dent	David
92	PMC00350	Advocate Pain Management Center	Houston	1/27/2011	2/28/2013	AC	1/27/2011	L9171	Dent	David
93	PMC00179	MARK A DIRNBERGER	ARLINGTON	8/31/2010	8/31/2012	AC	8/31/2010	L5305	DIRNBERGER	MARK
94	PMC00069	CLINICA LATINA	HOUSTON	8/5/2010	8/31/2012	AC	8/5/2010	K0289	Dumas	Carlos
NA - Not Active (Canceled by Board)										
95	PMC00259	NORTH HOUSTON WELLNESS & WEIGHT LOSS CENTER	HOUSTON	9/20/2010			4/8/2011	L4351	Dumas	Natascha
96	PMC00199	PRECISION PAIN CONSULTANTS	AUSTIN	8/31/2010	8/31/2012	AC	8/31/2010	M5138	Dumitrescu	Mihnea
97	PMC00279	ESA ANESTHESIA, LLP - LOCATION 1	DALLAS	10/15/2010	11/30/2012	AC	10/15/2010	H0319	EAMES	BRADLEY
98	PMC00280	ESA ANESTHESIA, LLP - LOCATION 2	DALLAS	10/15/2010	11/30/2012	AC	10/15/2010	H0319	EAMES	BRADLEY
99	PMC00281	ESA ANESTHESIA, LLP - LOCATION 3	ARLINGTON	10/15/2010	11/30/2012	AC	10/15/2010	H0319	EAMES	BRADLEY
100	PMC00189	INTERVENTIONAL NEUROLOGY	HOUSTON	8/31/2010	8/31/2012	AC	8/31/2010	G9451	Edmondson	Everton
101	PMC00194	PRIMECARE MEDICAL ASSOCIATES	HOUSTON	8/31/2010	8/31/2012	AC	8/31/2010	K0729	Egbunike	Augustine
102	PMC00183	RIVER CITY ANESTHESIA AND PAIN MANAGEMENT	SAN ANTONIO	8/31/2010	8/31/2012	AC	8/31/2010	G6069	Ellis	Jay
103	PMC00153	CPR MEDICAL GROUP	HOUSTON	8/27/2010	8/31/2012	AC	8/27/2010	H5705	EVANS	DONNIE
104	PMC00154	HOLLAND MEDICAL GROUP	HOUSTON	8/27/2010	8/31/2012	AC	8/27/2010	H5705	EVANS	DONNIE
105	PMC00209	ELIZABETH EVERSULL, MD	PLANO	8/31/2010	8/31/2012	AC	8/31/2010	L5328	Eversull	Elizabeth
106	PMC00331	Wellness and Care Group of Texas Location # 1	Grand Saline	12/2/2010	2/28/2013	AC	12/3/2010	M6127	Farhat	Niaz
107	PMC00332	Wellness and Care Group of Texas Location # 2	Center	12/2/2010	2/28/2013	AC	12/3/2010	M6127	Farhat	Niaz
108	PMC00081	DEFINITIVE INTERVENTIONAL SPINE CENTER	SPRING	8/12/2010	8/31/2012	AC	8/12/2010	K8150	FILLEY	MARK
109	PMC00093	SAM A FINO, MD - Location 1	DALLAS	8/19/2010	8/31/2012	AC	8/19/2010	J2004	FINO	SAMEER
110	PMC00094	SAM A FINO, MD - Location 2	KILGORE	8/19/2010	8/31/2012	AC	8/19/2010	J2004	FINO	SAMEER
111	PMC00008	FIROZ MEDICAL GROUP, PA	WILLS POINT	3/11/2010	5/31/2012	AC	3/11/2010	K9527	FIROZ	MUSTAFA
112	PMC00294	Deborah Fisher, MD PA	Sherman	11/1/2010	11/30/2012	AC	11/1/2010	L9195	Fisher	Deborah
113	PMC00198	JERRY L FRANZ, MD, PA	IRVING	8/31/2010	8/31/2012	AC	8/31/2010	E1580	Franz	Jerry
CR - Canceled										

On April 8, 2011, the Board ordered the Surrender with Natascha Tov management clinic certificate Loss Center. The Board accepted the surrender of the clinic's pain management certificate and further disciplinary proceedings.



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Frequently Asked Questions:

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Pain Management Clinics with Disciplinary Action

Click on PDFs 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](#) - 4/15/2011
- [Alliance Medical – aka Alliance Treatment Center, LLC – PMC00297](#) - 4/15/2011
- [North Houston Wellness and Weight Loss Center – PMC00259](#) - 4/8/2011
- [UMAT Clinic – PMC00105](#) - 2/22/2011
- [IMED 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.
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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 Omemgboji Wokocha, R.Ph.](#)

[Board temporarily suspends pharmacy license of Adbright Pharmacy, Incorporated](#)

[Board temporarily suspends pharmacy license of Richmond Professional Pharmacy](#)

July 13, 2011

[Board temporarily suspends pharmacist license of Shantae Shepard, 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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DEA has scheduled another National Prescription Drug Take Back Day on Saturday, October 29, 2011, from 10:00 am - 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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TSBP 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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