

NOTICE OF INSPECTION
 Texas State Board of Pharmacy
 333 Guadalupe Street, Suite 3-600
 Austin, Texas 78701-3942
 (512) 305-8000

| | | |
|--------------------|---------------|----------------------------|
| Name of Individual | Title | R.Ph. Lic. # Expires |
| Name of Facility | | |
| Address | | |
| City/State | Zip | Phone # |
| , TX | | () |
| DEA Registration # | Expires | DPS Registration # Expires |
| Date | Time of Entry | |

PURPOSE OF INSPECTION

(1) Complaint
 (2) Routine
 (3) Preceptor
 (4) Follow-up to Warning Notice
 (7) New Pharmacy
 (8) Change/Owner
 (15) Pre-Inspection
 (17) Follow-up to Complaint
 (18) Follow-up to Theft/Loss Report
 (12) Other _____

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent _____ has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the _____ for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Witnesses:

Signature

Signature

Signature

TEXAS PHARMACY ACT
(Occupations Code, Subtitle J)

CHAPTER 554. BOARD POWERS AND DUTIES; RULEMAKING AUTHORITY
SUBCHAPTER A. POWERS AND DUTIES

Sec. 554.001. General Powers and Duties of Board.

- XXX
- (c) The board may:
- XXX
- (2) inspect a facility licensed under this subtitle for compliance with this subtitle.
- XXX

CHAPTER 556. ADMINISTRATIVE INSPECTIONS AND WARRANTS
SUBCHAPTER A. GENERAL PROVISIONS

Sec. 556.001. Definition. In this chapter, "facility" means a place:

- (1) for which an application has been made for a pharmacy license under this subtitle;
- (2) at which a pharmacy licensed under this subtitle is located;
- (3) at which a pharmacy is being operated in violation of this subtitle; or
- (4) where the practice of pharmacy occurs.

SUBCHAPTER B. INSPECTIONS

Sec. 556.051. Authorization To Enter and Inspect. The board or a representative of the board may enter and inspect a facility relative to the following:

- (1) drug storage and security;
- (2) equipment;
- (3) components used in compounding, finished and unfinished products, containers, and labeling of any item;
- (4) sanitary conditions; or
- (5) records, reports, or other documents required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws.

Sec. 556.052. Requirements Before Entry and Inspection.

- (a) Before an entry and inspection of the facility, the person authorized to represent the board must:
- (1) state the purpose for the inspection; and
 - (2) present to the owner, pharmacist, or agent in charge of the facility:
 - (A) appropriate credentials; and
 - (B) written notice of the authority for the inspection.
- (b) If an inspection is required by or is supported by an administrative inspection warrant, the warrant is the notice for purposes of Subsection (a)(2)(B).

Sec. 556.053. Extent of Inspection. Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

- (1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;
- (2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in compounding, finished and unfinished products, or records; or
- (3) perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.

Sec. 556.054. Limitation on Inspection. Unless the owner, pharmacist, or agent in charge of a facility consents in writing, an inspection of the facility authorized by this chapter may not extend to:

- (1) financial data;
- (2) sales data, other than shipment data; or
- (3) pricing data.

XXX

SUBCHAPTER C. WARRANTS

Sec. 556.101. Warrant Not Required. A warrant is not required under this chapter to:

- (1) inspect books or records under an administrative subpoena issued under this subtitle; or
- (2) enter a facility or conduct an administrative inspection of a facility if:
 - (A) the owner, pharmacist, or agent in charge of the facility consents to the inspection;
 - (B) the situation presents imminent danger to the public health and safety;
 - (C) the situation involves inspection of a conveyance, if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant; or
 - (D) any other exceptional situation or emergency exists involving an act of God or natural disaster in which time or opportunity to apply for a warrant is lacking.

XXX

TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: **A** **B** **C (BEDS _____)** **D**

Name of Pharmacy _____
 Pharmacist in Charge _____
 Personnel _____

TSBP License # _____
 Lic _____ Exp _____
 Lic _____ Exp _____
 Lic _____ Exp _____
 Lic _____ Exp _____
 Lic _____ Exp _____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline.
 √ items in Column Two receive a Warning Notice (W/N).

For an explanation of specific violations noted, refer to remarks section of inspection report.

| R/L | W/N | |
|-----|-----|--|
| | 1 | Licenses not posted |
| | 2 | Insufficient Equipment |
| | 3 | Orderly/Clean |
| | 4 | Balance Failed |
| | 5 | Equipment Inspection |
| | 6 | Inadequate Library |
| | 7 | Improper security |
| | 8 | Environment |
| | 9 | Delinquent licenses/certifications |
| 36 | | No notification of substitution |
| 90 | | No complaint notification |
| 38 | | Area for non sterile compounding |
| 43 | | Records for non sterile compounding |
| 47 | | Out of date/mislabeled drug stock |
| 48 | | Improper drug storage |
| 53 | | Illegal possession of C/S |
| 57 | | Corresponding Responsibility |
| 59 | | Improper drug destruction |
| 61 | | Improper supervision of supportive personnel |
| 62 | | Aiding and abetting |
| 65 | | Improper registration procedures |
| 66 | | Grey Market diversion/Samples |
| 76 | | No PIC |
| 34 | | Notification Violation |
| 79 | | Nametags |
| 60 | | Improper documentation of training |
| 92 | | Improper automated dispensing procedures |

| R/L | W/N | |
|-----|-----|--|
| | | Date of last inventory |
| | 15 | No PIC inventory |
| | 69 | No annual inventory |
| | 68 | No change of ownership inventory |
| | 31 | Closed Phcy/Change of owner improper |
| | 17 | Incomplete inventory |
| | 18 | Records not available |
| | 46 | Improper distribution |
| | 54 | Improper prepackaging procedures |
| | 24 | Theft/Loss not reported |
| | 30 | Invoices not dated/initialed |
| | 86 | Absence of RPh pick up records |
| | 19 | Rx lacks proper information |
| | 25 | No documentation of refill authorization |
| | 32 | Rx label is incorrect |
| | 40 | Non emergency C-II Rx |
| | 26 | C II Rx noncompliance |
| | 37 | Illegal dispensing |
| | 45 | Improper dispensing/labeling |
| | 44 | Refill CIII-V over 5x/6mo |
| | 55 | Refill prn past one year |
| | 78 | Counseling area |
| | 80 | No counseling by RPh |
| | 56 | Improper transfer of Rx |
| | 50 | Out of state verbal Rx for C/S |
| | 49 | Substitution noncompliance |
| | 33 | Rx records not in numerical order |

| R/L | W/N | |
|-----|-----|--|
| | 10 | Rxs not separated |
| | 35 | Invoices not separated |
| | 67 | No written information |
| | 21 | Computer records incomplete |
| | 22 | Computer system noncompliance |
| | 82 | PMR Incomplete |
| | 83 | PMR Absent |
| | 84 | No drug regimen review |
| | 16 | No perpetual inventory |
| | 27 | Improper inpatient records |
| | 51 | Improper ER dispensing |
| | 75 | Improper absence of RPh procedures |
| | 70 | No P&P manual |
| | 71 | Incomplete P&P manual |
| | 72 | Improper procedures for IV preparation |
| | 81 | Area for preparation of sterile products |
| | 85 | Patient Care Guidelines incomplete |
| | 87 | Quality Control/Assurance |
| | 88 | Cytotoxic/Biohazardous Procedures |
| | 89 | Refrigerator Temperature Log |
| | 28 | No provision log |
| | 29 | Incomplete provision log |
| | 52 | Improper provision/dispensing in Class D |
| | 63 | Prohibited drugs in Class D pharmacy |
| | 64 | Violation of limited formulary |
| | 91 | RPh visits/contact documentation |
| | 73 | Formulary not complete |

