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- Review the responsibilities of the pharmacist-in-charge.
- Review recent changes to the rules for Class A pharmacies.
- Review the most common deficiencies found during inspections of pharmacies.



- | | |
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- To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.



- Texas Pharmacy Act, Occupations Code, §§ 551 – 566, 568 – 569
- Texas Pharmacy Rules
 - Chapter 281. Administrative Practice and Procedure
 - Chapter 283. Licensing Requirements for Pharmacists
 - Chapter 291. Pharmacies
 - Chapter 295. Pharmacists
 - Chapter 297. Pharmacy Technicians and Pharmacy Technician Trainees
 - Chapter 303. Destruction of Dangerous Drugs and Controlled Substances
 - Chapter 309. Generic Substitution
 - Chapter 311. Code of Conduct
- Texas Controlled Substances Act and Rules
- Texas Dangerous Drug Act
- Texas Food, Drug and Cosmetic Act



- Each Class A (Community) Pharmacy shall have
 - One PIC who is employed on a full-time basis, for only one Class A pharmacy:
 - unless the pharmacies are not open to provide pharmacy services simultaneously; or
 - during an emergency, up to two Class A pharmacies open simultaneously if the pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a period of 30 consecutive days.



Responsibilities of the PIC



- Pharmacy technicians and pharmacy technician trainees must be registered **BEFORE** they begin work in the pharmacy.
- In addition, pharmacy technicians must renew that registration every 2-years and **CANNOT** work with a delinquent registration.
- Note: Pharmacy technician trainee registrations expire after 2-years and cannot be renewed.



- Pharmacy technicians and pharmacy technician trainees shall complete initial training as outlined by the pharmacist-in-charge in a training manual.
- This training may not be transferred to another pharmacy unless:
 - the pharmacies are under common ownership and control and have a common training program; and
 - the pharmacist-in-charge of each pharmacy in which the pharmacy technician or pharmacy technician trainee works certifies that the pharmacy technician or pharmacy technician trainee is competent to perform the duties assigned in that pharmacy.



- The pharmacist-in-charge shall assure the continuing competency of pharmacy technicians and pharmacy technician trainees through in-service education and training to supplement initial training.
- The pharmacist-in-charge shall document the completion of the training program and certify the competency of pharmacy technicians and pharmacy technician trainees completing the training.



- A written record of initial and in-service training of pharmacy technicians/trainees shall be maintained and contain the following information:
 - name of the person receiving the training;
 - date(s) of the training;
 - general description of the topics covered;
 - a statement that certifies that the pharmacy technician/trainee is competent to perform the duties assigned;
 - name of the person supervising the training; and
 - signature of the pharmacy technician/trainee and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training of pharmacy technicians/trainees.



- Pharmacy technician/trainee training shall be outlined in a training manual.
- Such training manual shall, at a minimum, contain the following:
 - written procedures and guidelines for the use and supervision of pharmacy technicians/trainees. Such procedures and guidelines shall:
 - specify the manner in which the pharmacist responsible for the supervision of pharmacy technicians and pharmacy technician trainees will supervise such personnel and verify the accuracy and completeness of all acts, tasks, and functions performed by such personnel; and
 - specify duties which may and may not be performed by pharmacy technicians and pharmacy technician trainees;



- instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians/trainees in the pharmacy:
 - Orientation;
 - Job descriptions;
 - Communication techniques;
 - Laws and rules;
 - Security and safety;
 - Prescription drugs:
 - Basic pharmaceutical nomenclature;
 - Dosage forms;



- Drug orders:
 - Prescribers;
 - Directions for use;
 - Commonly-used abbreviations and symbols;
 - Number of dosage units;
 - Strengths and systems of measurement;
 - Routes of administration;
 - Frequency of administration; and
 - Interpreting directions for use;



- Drug order preparation:
 - Creating or updating patient medication records;
 - Entering drug order information into the computer or typing the label in a manual system;
 - Selecting the correct stock bottle;
 - Accurately counting or pouring the appropriate quantity of drug product;
 - Selecting the proper container;
 - Affixing the prescription label;
 - Affixing auxiliary labels, if indicated; and
 - Preparing the finished product for inspection and final check by pharmacists;



- Other functions;
- Drug product prepackaging;
- Written policy and guidelines for use of and supervision of pharmacy technicians and pharmacy technician trainees;
- Confidential patient medication records; and
- Pharmacy technicians/trainees compounding non-sterile shall meet the training and education requirements specified in §291.131 (regarding Pharmacies Compounding Non-sterile Preparations)



- Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.
 - Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.
- Class A Pharmacies may not sell, purchase, trade or possess prescription drug samples.



Chapter 303 outlines the requirements for the destruction of dangerous drugs and controlled substances.

DEA changes effective: October 9, 2014.

Authorizes certain DEA registrants, including pharmacies to become authorized collectors (Note: this will require modification of the DEA registration to obtain authorization to be a collector).

Authorizes pharmacies to operate collection receptacles at long-term care facilities.



- Prescription drugs and devices shall be stored within the prescription department or a locked storage area.
- All drugs shall be stored at the proper temperatures as defined in the USP/NF.
- The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.
- The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.



- §291.34 regarding Records
 - Every record must be kept by the pharmacy for at least 2 years from the date of the record and be available to the Texas State Board of Pharmacy within 72 hours if requested.
 - Records of Schedule II controlled substances shall be maintained separately.
 - Records of Schedule III – V controlled substances shall be maintained separately or readily retrievable from all other records of the pharmacy.



- Inventory Records
 - The PIC is responsible for taking an initial inventory on the opening day of business; however, the PIC may delegate this to another individual.
 - The inventory must include all controlled substances.



- Change of PIC
 - When a change of PIC occurs, the required inventory must be taken on the date of the change. The inventory must include all controlled substances.
 - The PIC must notify the Board that a change of PIC has occurred and that the inventory was taken.
 - This information must be reported to the Board within 10 days.



- An annual inventory must be taken on May 1 of each year or on the pharmacy’s general physical inventory date. The inventory may be taken within 4 days of the specified inventory date and must include all controlled substances.
- The inventory must be signed by the PIC and notarized within 3 working days of completing the inventory.



- Inventories must be filed separately from all other records in the pharmacy and be available for inspection by the Board for 2 years.



- Each pharmacist while on duty shall be responsible for the security of the prescription department.
- The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access.
- If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured.
- The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is closed.



- The theft or significant loss of any controlled substance by a pharmacy must be reported in writing to the Board immediately upon discovery. This information may be submitted on a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.
- In addition, a pharmacy shall report in writing to the Board immediately upon discovery, the theft or significant loss of any dangerous (non-controlled) drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.



- The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.
- The pharmacy shall maintain a backup copy of information stored in the data processing system to assure that data is not lost due to system failure.
- A pharmacy that changes or discontinues the use of a data processing system must transfer the records of dispensing to the new data processing system or purge the records of dispensing to a printout which contains the same information required on the daily printout.



- A pharmacy must open and be in operation with a sufficient number of transactions within 6 months of the issuance of the pharmacy's license.
- Inspections
 - The Texas Pharmacy Act, Chapter 556, authorizes the Board to enter and inspect pharmacies.
 - The Board agent will state the purpose of the inspection, present appropriate credentials, and a written notice of the authority for inspection.
 - It is grounds for discipline of a pharmacist's license for obstructing a Board agent in the lawful performance of duties of enforcing the Act.



- Consulting with the owner concerning and adherence to the policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction
- Inspecting medications in the automated dispensing system, at least monthly, for expiration date, misbranding, physical integrity, security, and accountability
- Assigning, discontinuing, or changing personnel access to the automated pharmacy dispensing system



- Ensuring that pharmacy technicians/trainees, performing any services in connection with an automated dispensing system have been properly trained on the use of the system and can demonstrate comprehensive knowledge of the written policies and procedures for operation of the system
- Ensuring that the automated dispensing system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation



- When a pharmacy closes, the pharmacist-in-charge (PIC) shall forward to the Board, within 10 days, the following items:
 - written notice of the closing which includes the actual date of closing;
 - pharmacy license;
 - statement attesting that the required inventory has been conducted and the manner by which the drugs possessed by the pharmacy were transferred or disposed; and
 - location of all records belonging to the pharmacy (e.g., if prescription records were transferred to another pharmacy, give name and address of pharmacy).





Effective Date: December 7, 2014.

Patient counseling must be provided to new and existing patients of a pharmacy with each new prescription drug order.

A new prescription drug order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year.



Written information may now be provided to the patient in an electronic format, such as by e-mail, if:

- The patient or patient's agent requests the information in an electronic format; and
- The pharmacy documents the request.



- **Eliminated** the requirement for a pharmacy to:
 - Offer counseling on a refill prescription; and
 - Post a sign that said *"Do you have questions about your prescription? Ask the pharmacist."*



- Effective Date: December 7, 2014.
- Updated the transfer regulations to allow for the:
- Electronic transfer of records;
 - Electronic transfer of multiple or bulk prescription records between two pharmacies; and
 - Match DEA's regulations.





Grounds for Discipline

- Effective Date: December 7, 2015
- It is a ground for discipline of a pharmacist or pharmacy technician if the individual exhibits abusive, intimidating, or threatening behavior toward a board member or employee during the performance of a member’s or employee’s lawful duties.



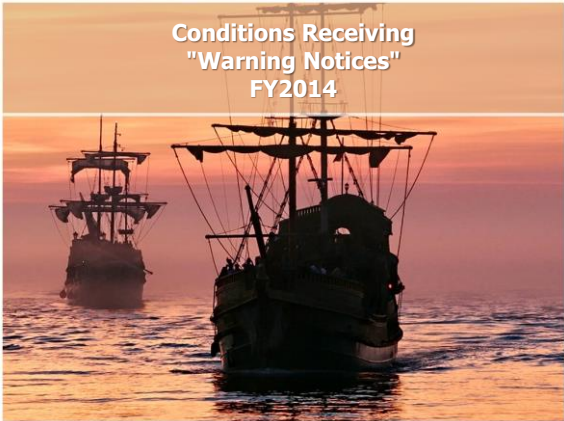
Pharmacist-in-Charge

- Effective Date: December 7, 2015
- A pharmacist-in-charge (PIC) of a Class A Pharmacy may not also be the PIC of a:
 - Class B Pharmacy; or
 - Class C Pharmacy in a hospital with 101 beds or more.



Administration of Immunizations and Vaccines

- Effective Date: December 7, 2015
- Before preparing an immunization/vaccine and between each patient contact:
 - Pharmacist must:
 - cleanse their hands with an alcohol-based waterless antiseptic hand rub; or
 - wash their hands with soap and water.
 - If gloves are worn, pharmacists must change gloves between patients.



Number of Inspections

Class	FY2014	% of FY2014 Inspections
Class A Pharmacies	1,181	69%
Class A-S	4	<1%
Class B Pharmacies	3	<1%
Class C Pharmacies	447	26%
Class C-S	4	<1%
Class D Pharmacies	57	3%
Class F Pharmacies	5	<1%
Class G Pharmacies	5	<1%
Totals	1,706	100%

Warning Notices

Class	# Pharmacies Receiving WN	% Receiving WN
Class A	537	61%
Class A-S	3	<1%
Class B	0	N/A
Class C	316	36%
Class C-S	4	<1%
Class D	18	2%
Class F	2	<1%
Class G	0	N/A
Totals	880	100%

Most Common Warning Notices
(All Classes of Pharmacy)

Violation	Number of WN Issued*	% of Total WN
Sterile Product	855	29%
Pharmacy Technician	398	14%
Records	273	9%
Drug Stock/Environment	272	9%
Prescriptions	160	5%
Inventory	156	5%
OBRA	152	5%

* One pharmacy may receive multiple Warning Notice violations.

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Sterile Product		855
No/Incomplete QA/QC	140	
No/Incomplete P&P Manual	128	
No/Inadequate Preparation Area	370	
IV Preparation	196	
No DUR	14	
Cytotoxic/Bio Procedures	7	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Pharmacy Technicians		398
No/Incomplete Training	367	
No/Improper Supervision	10	
Improper Registration	16	
No Name Tags	5	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Records		273
Records Not Available	90	
Absence of R.Ph. Record	15	
Rx Not Separated	7	
Rx Records Not Numerical Order	5	
Improper Transfer of RX copies	5	
Invoices Not Separated/Retrievable	52	
Records for Non-Sterile Compounds	77	
No Written Information on RX	22	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Drug Stock/Environment		272
Improper Environment	101	
Out-of-Date Drug Stock	83	
Security	36	
Unsanitary	30	
Improper Drug Storage	16	
Area for Non-Sterile Compounding	2	
Violation of Limited Formulary	4	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Prescriptions		160
Lack Proper Information	77	
Prescription Label Incorrect	68	
Official Rx Non-Compliance	15	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
Inventory		156
No Annual Inventory	47	
No Change of Ownership Inventory	6	
No Change of PIC Inventory	32	
Incomplete Inventory	68	
No Perpetual inventory (Class C)	2	
Improper Drug Destruction	1	

Most Common Warning Notices
(All Classes of Pharmacy) cont.

Condition	Number of WN Issued	Total
OBRA		152
Written Information Not Provided	22	
No Patient Counseling	117	
PMR Absent or Incomplete	13	

Violations NOT Resulting
in Warning Notices

- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



- Pharmacy is not able to produce 2 consecutive annual inventories.
- PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



- Egregious Conditions
 - Dispensing CII's pursuant to prescriptions not issued on an Official Form;
 - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
 - Pharmacy closed and did not notify TSBP of closing;
 - Operating without a PIC for an extended period of time (i.e., 3 months or more).

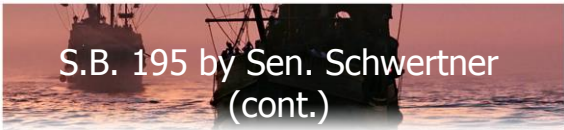


- Continuing threat – For example:
 - Impaired pharmacist on duty; or
 - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to “*cease and desist*” sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an Emergency Temporary Suspension Hearing.





- Effective Date: 6/20/2015 for some provisions and 9/1/2016 for others.
- This bill:
 - Allows the Board, on or after 6/20/2015 to:
 - Adopt rules to implement the PMP and certain other provisions related to prescriptions in the Controlled Substances Act.
 - Sign a contract with a vendor to operate the PMP.
 - Call a meeting of the Prescription Monitoring Work Group.



- On 9/1/2016:
 - The Board will establish a program to fund the Prescription Monitoring Program (PMP) though a surcharge on the license fees of persons authorized to access the PMP.
 - **The PMP is transferred from the DPS to TSBP.**
 - The Controlled Substance Registration program is abolished.



- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow the Board to inspect financial records relating to the operation of a pharmacy only in the course of an investigation of a specific complaint.
 - Require a pharmacy to file an application to change location at least 30-days prior to the move.



- Amends the Pharmacy Act to:
 - Eliminate the Generic Substitution Sign and modify the requirement for the Complaint Notification to allow electronic posting..
 - Specify that a pharmacy license may not be renewed if it has expired for 91 days or more.



- Amends the Pharmacy Act for Class E Pharmacies to:
 - Allow the Board to discipline the pharmacy if it has been disciplined in their state.
 - Prohibit a person from owning the pharmacy if their R.Ph. license was revoked, suspended, restricted, surrendered in another state.
 - Require the pharmacy to have a Texas licensed pharmacist serve as the PIC for the Texas license.



- Effective Date: 9/1/2015.
- The bill allows the substitution of interchangeable biological products.
- Interchangeable biological products are those rated equivalent by FDA (Orange Book and the Purple Book).



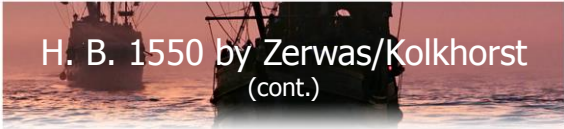
- The bill specifies that not later than the 3rd business day after dispensing the R.Ph. must “communicate” to the prescribing Dr. the name of the product provided and the manufacturer or NDC number.
- The bill outlines several methods to notify the prescriber.



- Notification is not required if:
 - There is no interchangeable biological product approved by FDA; or
 - A refill prescription is not changed from the product dispensed on the prior dispensing.
- The notification section of the bill expires on 9/1/2019.



- Effective Date: 9/1/2015.
- This bill amends the Pharmacy Act to:
 - Allow a R.Ph.s to administer epinephrine, using an auto-injector, to a patient in an emergency situation.
 - Specify a R.Ph. may not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.



- This bill amends the Pharmacy Act to:
 - Specify that a R.Ph. who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.





- Texas Pharmacy Act, Sec. 551.005. Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.



- August 2015.
 - TSBP prepares a Self-Evaluation Report.
- October 2015 – March 2016.
 - Sunset staff reviews the agency.
- Late March 2016.
 - Sunset’s confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset’s formal request for agency written response.



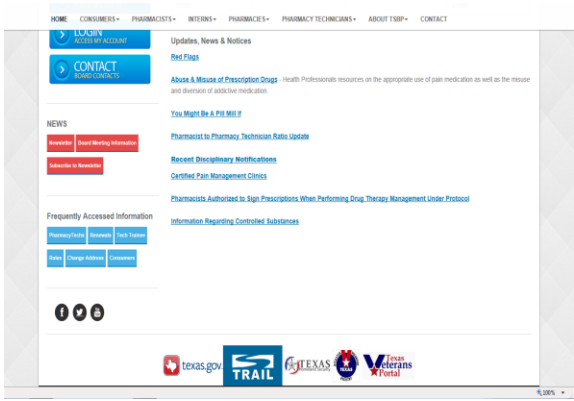
- April 2016.
 - Sunset staff report published.
- May 2016.
 - Sunset Commission holds a public hearing to receive public comment on the agency.
- Summer 2016.
 - Commission decisions are issued.
- January – May 2017.
 - 2017 Legislative Session



TSBP Website

www.pharmacy.texas.gov







- For more specific information on these requirements, refer to the Board Rules located on the TSBP website:

www.pharmacy.texas.gov



Final Reminders (Part I)

- If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.
- If you would like a copy of today's presentation slides, they are currently posted in your Lifelong Learning Account.

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Final Reminders (Part II)

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