TSBP Rules FAQ

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TSBP Rules Frequently Asked Questions

1. What amount of time is a pharmacy allowed to operate without a pharmacist-in-charge (PIC)?

Pharmacies that fail to employ a PIC are not in compliance with TSBP Rules and are subject to potential disciplinary action by TSBP. Any change of PIC must be reported per §291.3(e)(2).

2. What are acceptable delivery locations for dispensed prescriptions?

Other than prescription delivery at a pharmacy's licensed location, §291.9 provides where prescription delivery is allowed.

*Note: USPS regulations permit the mailing of controlled substances provided the mailing is not outwardly dangerous and will not cause injury to a person's life or health, and if packaging standards are met as stated in the Pharmacist's DEA Manual, including that the outside wrapper or container is free of markings that would indicate the nature of the contents.

3. During planned or unplanned leave of more than 30 days, what is the responsibility of the PIC? Is a change of PIC required?

The PIC has responsibility for the practice of pharmacy and operation at the pharmacy for which he or she is the PIC, including any and all times that the PIC is not present at the pharmacy. Because the PIC is responsible for the legal operation of the pharmacy, each PIC of a pharmacy must evaluate whether to remain PIC during periods of planned or unplanned absences that will require or necessitate absence from the pharmacy greater than 30 days.

4. What required pharmacy records can be maintained in a location other than the pharmacy's licensed location?

For any class of pharmacy, drug invoices and financial data records are permitted to be maintained at a central location, provided notification has been made to DEA for drug invoices and financial data records related to controlled substances. See §1304.04 of Title 21 CFR for specific federal regulations.

5. How do I maintain record of original prescription drug orders received as e-RXs, i.e., electronically transmitted prescription drug order?

TSBP Staff encourages not printing out an e-RX, but maintain the record as a digital image in compliance with 291.34(b)(6).

6. What is the pharmacist-to-technician ratio in a Class A (Community Pharmacy) setting? Are student pharmacist-interns included in the ratio?

Per §291.32(d)(3)(A), the ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:6, provided the pharmacist is on-site and a maximum of three are technician trainees. Per §291.32(d)(3)(B), which is based on §568.006 of the Act and therefore not subject to removal from the rules, a Class A pharmacy may have a ratio of 1:5 provided certain specified conditions set forth in TSBP rule are met.

When not under the supervision of a preceptor, a pharmacist-intern may function as a pharmacy technician and is not counted as a pharmacy technician in the ratio of pharmacists to pharmacy technicians. Per §283.5, the ratio of pharmacists to pharmacist-interns shall be 1:1 when performing pharmacy technician duties.

7. What duties are allowed by a pharmacy technician or pharmacy technician trainee?

Persons registered as a pharmacy technician or as a pharmacy technician trainee may perform non-judgmental technical duties associated with the preparation and distribution of prescription drugs. For these specific listed duties, see list in 291.32(d)(2)(C).

In addition to non-judgmental technical duties associated with the preparation and distribution of prescription drugs, pharmacy technicians (but not pharmacy technician trainees) are allowed delegation of certain additional duties set forth in 291.32(d)(2)(D) for Class A (Community Pharmacy). For a pharmacy setting other than a Class A (Community Pharmacy), additional dut(ies) allowed by a pharmacy technician are set forth in 291.55(b)(2)(A); 291.121(c)(4)(D); 291.129(d)(10); and 291.153(c)(4)(B)(iv).

8. Can I fill a prescription from a US territory?

Prescriptions authorized by practitioners licensed in U.S. Territories, i.e., Puerto Rico, U.S. Virgin Islands, American Samoa, Guam, Northern Mariana Islands, are considered the same as prescriptions that are issued by practitioners in another state. §291.34(b)(2)(B) and §291.31(45). See the Quick Reference Guide.

9. What additional information is needed on a drug order issued by an advanced practice nurse or physician assistant (collectively, MLP)? Can a MLP issue a prescription for a Schedule II controlled substance? Can a MLP issue a prescription for a Schedule III, IV or V controlled substance with refills?

The address and telephone number of the clinic where the prescription drug order was carried out or signed as well as the name of the supervising practitioner. Additionally, if the prescription is for a controlled substance, the

DEA number of both the MLP <u>and</u> the supervising practitioner. §291.34(b)(7)(A)(iii) and (xi)

Texas Medical Board Rule §193.6(c) allows for a MLP to write a prescription for a CII limited to a hospice patient in hospice care, or to a hospitalized patient or emergency room patient dispensed by the in-house hospital pharmacy.

See following FAQ for MLP prescription refill limits, and http://www.pharmacy.texas.gov/files-pdf/9Information-on-Controlled Substance-prescriptions-from Advanced Practice Registered Nurses and Physician Assistants.pdf.

10. Is there a day-supply limitation on a prescription?

Regarding the treatment of acute pain with an opioid, practitioners are limited to issuing prescriptions that do not exceed a 10-day supply.

Regarding non-opioid, not acute pain:

- C-II controlled substances, §315.3 provides that a practitioner may issue multiple written prescriptions authorizing a patient to receive up to a 90day supply of a C-II provided certain requirements of the same rule are met;
- CIII, IV or V controlled substances and dangerous drugs, there is no daysupply limitation for a prescription issued by a physician. Texas Medical Board Rule §193.6(b) limits physician assistants from prescribing greater than 90 days' supply of CIII, IV, or V controlled substances, to include refills.

Excessive quantities of a controlled substance could be a prescription red flag factor indicating an invalid or fraudulent prescription drug order.

11. Is a pharmacy allowed to distribute drugs to another pharmacy or a practitioner? What about prescriptions issued for "office use"?

§291.34(h) addresses allowable circumstances in which a pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, such as the requirement that in a 12-month period, the total number of dosage units distributed by a pharmacy may not exceed 5% of all controlled substances dispensed and distributed by the pharmacy. Dangerous drugs, in reasonable quantities, can be distributed to another pharmacy or a practitioner, and the record keeping requirements for distributions are set forth in §291.34(i).

No, a prescription cannot be dispensed for "office use." Though Texas law allows compounded drug preparations to be distributed to a practitioner for office use (see Section 562.151, et seq, of the Act), such action may not be allowed by federal law.

Other than compounded preparations, a pharmacy should adhere to drug

distribution procedures to provide a prescriber's office with prescription drugs, per §291.34(h).

12. What is required for an outpatient prescription dispensed by a Class C (Institutional Pharmacy)? Upon dispensing, how must an outpatient prescription be labeled for the patient?

Per §291.75(b)(2), outpatient prescriptions must have the elements listed in §291.34(b)(7), which are the same elements required to dispense a prescription by a Class A (Community Pharmacy).

§291.74(f)(6) states that discharge prescriptions must be dispensed and labeled in accordance with §291.33, except that certain medications packaged in unit-of-use containers that are administered to the patient during the hospitalization may be provided to the patient upon discharge provided the pharmacy receives a discharge order and the product bears a label containing the name of the patient; name and strength of the medication; name of the prescribing or attending practitioner; directions for use; duration of therapy; and name and telephone number of the pharmacy.

13. What programs are recognized pharmacist certification programs by TSBP?

TSBP does not endorse any particular certification program acknowledged by TSBP in §295.12. TSBP recommends contacting your local, state, or national pharmacy association, or any of the Texas College of Pharmacy continuing education departments to identify TSBP-approved providers of pharmacist certificate programs.

14. Can an employee perform pharmacy technician duties if they have already submitted payment to TSBP for required fees?

No, not until a registration number is issued. Search by first and last name to determine issuance of the registration on TSBP's website at https://www.pharmacy.texas.gov/dbsearch/tech search.asp.

15. Is a PO Box allowed as a patient address on a prescription? Is there an age requirement for a person to pick up a prescription from the pharmacy?

TSBP rules do not prohibit use of a PO Box for the patient's address on a prescription, and there is no specific age requirement to pick up a dispensed prescription for a dangerous drug or for a controlled substance. Texas Controlled Substances Act §481.074(a)(5) requires that a pharmacist know the person accepting delivery or require identification of the person taking possession of the controlled substance. An exception to identification upon delivery is allowed when an emergency exists and the controlled substance is needed for the well-being of the patient, as set forth in §481.074(n). When delivering to any person other than the patient, exercise common-sense and consider any potential for misuse and possible diversion-risks.

16. A single official prescription form contains two drug orders, one for a CII controlled substance and another for a non-CII drug. Is the pharmacist allowed to dispense both prescription drug orders?

Yes, a CII controlled substance and another drug may be written together on an official prescription form. Due to prescription filing requirements, a direct image must be maintained separately for each category of prescription in the pharmacy's prescription records per §291.34(b)(6)(D) and (E).

17. What do I need to know about telemedicine as a pharmacist or pharmacy?

Information about telemedicine can be found on TSBP's website at http://www.pharmacy.texas.gov/files_pdf/Telemedicine_FAQ.pdf

18. How do I remove employees from my pharmacy license?

Reporting a change of employment for technicians or staff pharmacists can be accessed online on TSBP's website at https://www.pharmacy.texas.gov/changeaddress.asp

19. As a controlled substance registrant, how do I destroy dangerous drugs and controlled substances?

For dangerous drugs destruction, a TSBP licensed pharmacist is authorized to destroy stock dangerous drugs owned by a licensed pharmacy if such dangerous drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements per §303.2.

For controlled substance destruction, a link regarding information about drug destruction can be found by clicking on the link titled, "Drug Disposal Information," on TSBP's website at

http://www.pharmacy.texas.gov/controlledsubstances.asp, which is linked to DEA's website at https://www.deadiversion.usdoj.gov/drug_disposal/index.html

20. How do I report a Theft or Loss of drugs to TSBP? Where do I locate a DEA 106 form?

The theft or significant loss of any controlled substance or dangerous drug stock by a pharmacy must be reported in writing to TSBP immediately upon discovery per §291.3(f). This information may be submitted by email to <a href="https://dx.ncbi.org/linear.ncbi.org/linea

A link regarding locating an online DEA 106 form can be found by clicking on the link titled, "Drug Enforcement Agency (DEA)," on TSBP's website at

http://www.pharmacy.texas.gov/infocies/, which is linked to DEA's website at https://www.deadiversion.usdoj.gov/index.html

21. Can I refill a prescription if the prescriber died or if the prescriber lost his/her practice license or DEA registration, i.e., surrender, revocation, or expiration?

TSBP considers best pharmacy practice in this scenario as if prescription is an emergency refill. Hence, §481.074(*l*) provides a pharmacist exercise professional judgment in refilling a prescription for a CIII, IV, or V controlled substance without the authorization of the prescribing practitioner provided that the failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering. If the pharmacist determines in his/her professional judgment this condition is met, then there are certain requirements and limitations to the amount dispensed and record-keeping that is further specified.

TSBP considers best pharmacy practice for refilling of dangerous drugs in this scenario of prescriber death or loss of practice license to consider other available means to obtain a prescription by a prescriber, and the same scenario of whether the failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering. In which case, TSBP encourages the dispensing pharmacist to dispense not greater than a thirty-day supply, document and inform the patient as stated in $\S481.074(l)(5)$.

22. What can be modified on a prescription drug order? Is the existing prescription still valid?

A pharmacist, using professional discretion and without prescriber authorization or notification, may correct a patient's name (such as a misspelling or valid name change); add the patient's address to the prescription when missing; and correct obvious issuance date errors (such as the prior year when a new year has just begun).

All other additions/modifications to a prescription require prescriber authorization and documentation of the clarification, thereby creating a new prescription drug order with all required elements. These additions/modifications are the below-listed items:

- a missing required element of a prescription per §291.34(b)(7);
- instructions regarding the earliest date a pharmacy may fill a multiple issuance prescription;
- if a controlled substance, per §315.8 a pharmacist may change or add the dosage form, drug strength, drug quantity (including showing as alpha and numeric), and directions for use.

As with any prescription element, TSBP cautions considering prescription red flag factors to identify fraudulent prescriptions, such as when certain elements lack adherence to usual medical usage or common recording.

23. Can I transfer an electronic prescription for a controlled substance (EPCS) to another pharmacy?

Per §291.34(g), refill dispensing of a prescription for a controlled substance in Schedule III, IV, or V, is permissible between pharmacies on a one-time basis only, and pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Regarding initial dispensing of a previously unfilled EPCS, if both pharmacies (originating and receiving) have the capability to forward and receive the EPCS utilizing an electronic sharing program, e.g., SureScripts® or other software, then the pharmacies may engage in electronically forwarding the EPCS for all Schedules (including Schedule II). Without such capability, best practice is to contact the prescriber in order to retract the EPCS and resend per the patient's request. Please note that TSBP is notable to comment on whether a pharmacy sharing a real-time, on-line database would be considered forwarding an EPCS for initial dispensing, and TSBP recommends contacting your local DEA field office.

24. Does a partial fill count as a refill on a prescription?

DEA Pharmacist's Manual (2020 Edition) in Section VIII-Dispensing Requirements, Partial Dispensing, provides the following: "A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued."

A link regarding the DEA Pharmacist's Manual can be found by clicking on the link titled, "DEA Pharmacist's Manual," on TSBP's website at http://www.pharmacy.texas.gov/rules/

25. May I dispense a CII prescription drug order that has been faxed to the pharmacy?

A pharmacist, using professional discretion, may dispense a CII received via facsimile for a patient in a long-term care facility or for a patient enrolled in hospice care per federal law.

https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306 11.htm

Alternatively, following conditions of the Texas Controlled Substances Act §481.0755, a faxed controlled substance prescription can be dispensed pursuant to §315.7.