

# TSBP Rules FAQ

*Click on a question to jump to the answer:*

What amount of time is a pharmacy allowed to operate without a pharmacist-in-charge (PIC)? .....	3
What are acceptable delivery locations for dispensed prescriptions? .....	3
During planned or unplanned leave of more than 30 days, what is the responsibility of the PIC? Is a change of PIC required? .....	3
Upon a change of PIC, what drugs are required to be inventoried? .....	3
What required pharmacy records can be maintained in a location other than the pharmacy's licensed location? .....	3
What drug inventories must be notarized? .....	4
What is the pharmacist-to-technician ratio in a Class A (Community Pharmacy) setting? Are student pharmacist-interns included in the ratio? .....	4
What are the operational requirements when a pharmacist is not onsite at the pharmacy? .....	4
What are acceptable reference library formats for a pharmacy? .....	4
Can the prescriber's signature be stamped on the prescription drug order? .....	5
Can I fill a prescription from a US territory? .....	5
If a prescription drug order has been issued by an advanced practice nurse or physician assistant (collectively, MLP), what additional information is the drug order required to contain? .....	5
Is a pharmacy allowed to distribute drugs to another pharmacy or a practitioner? .....	5
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? .....	5
What is required for a Class D (Clinic Pharmacy) to expand its formulary? .....	6
For license renewal, how many hours of continuing education are required for a pharmacist engaged in sterile compounding? .....	6
Can a pharmacy dispense and deliver drugs for office use by a practitioner? .....	6
What programs are recognized pharmacist certification programs by TSBP? .....	6
What is drug therapy management (DTM) by a pharmacist? .....	6
Can an employee perform pharmacy technician duties if they have already submitted payment to TSBP for required fees? .....	7
Is there a day-supply limitation on a prescription? .....	7
Is there an age requirement for a person to pick up a prescription from the pharmacy? .....	7
Is a physician assistant allowed to write a prescription for a CII? .....	8

Is a PO Box allowed for the patient address? .....8

Is a pharmacist allowed to dispense a prescription written on an official prescription form for a drug other than a CII? .....8

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? .....8

Can a physician assistant write for refills? .....8

What do I need to know about telemedicine as a pharmacist or pharmacy? .....9

How do I remove employees from my pharmacy license? .....9

As a controlled substance registrant, how do I destroy dangerous drugs and controlled substances? .....9

Where do I locate a DEA 106 form? .....9

May 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? ..... 10

What can be modified on a prescription drug order? Is the existing prescription still valid? .....10

Can I accept a fax for a CII controlled substance? ..... 11

Can I transfer an electronic prescription for a controlled substance (EPCS) to another pharmacy? .....11

Does a partial fill count as a refill on a prescription? ..... 12

How do I report a theft or loss of drugs to TSBP? .....12

## TSBP Rules Frequently Asked Questions

### **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\(e\)\(2\)](#).

### **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.

### **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.

### **Upon a change of PIC, what drugs are required to be inventoried?**

Per [§291.17\(g\)](#), an inventory taken at a change of PIC must include all stocks of all controlled substances (including any out-of-date drugs).

### **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.

### **What drug inventories must be notarized?**

Inventories conducted as annual, change-of-ownership, and closing are required to be notarized within three days after the day the inventory is completed, excluding Saturdays, Sundays, and federal holidays. [§291.17](#)

### **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 1:4, provided the pharmacist is on-site and at least one of the four is a pharmacy technician. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:3. Per [§291.32\(d\)\(3\)\(B\)](#), a Class A pharmacy may have a ratio of 1:5 provided certain specified conditions set forth in TSBP rule are met.

A pharmacist-intern functioning as a pharmacy technician 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.

### **What are the operational requirements when a pharmacist is not onsite at the pharmacy?**

In general, per [§291.33\(b\)\(2\)](#), the prescription department shall be secured from entry when a pharmacist is not onsite. Outside of regular operational hours of the pharmacy's business day (e.g., before opening or after close of business), [§291.33\(b\)\(2\)\(C\)](#) and (D) address authorization of individuals allowed to enter the prescription department when a pharmacist is not onsite and what duties are permitted during such times.

During regular operational hours of the pharmacy's business day, [§291.33\(b\)\(3\)](#) addresses the temporary absence of a pharmacist. Specifically, [§291.33\(b\)\(3\)\(A\)](#) discusses general security and what personnel duties are permitted during brief periods of time that a pharmacy staffed with a single pharmacist who is onsite, but not within the prescription department, e.g., breaks and meal periods. Then, [§291.33\(b\)\(3\)\(B\)](#) discusses the same for scenarios when a pharmacist is off-site of the licensed location of the pharmacy.

### **What are acceptable reference library formats for a pharmacy?**

Pharmacies must maintain a reference library per [§291.33\(e\)](#) in hard copy or electronic format.

### **Can the prescriber's signature be stamped on the prescription drug order?**

Rubber stamped signatures may not be used. [§291.34\(b\)\(2\)\(A\)\(iii\)\(II\)](#)

### **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\(b\)\(2\)\(B\)](#)

### **If a prescription drug order has been issued by an advanced practice nurse or physician assistant (collectively, MLP), what additional information is the drug order required to contain?**

The address and telephone number of the clinic where the prescription drug order was carried out or signed. Additionally, if the prescription is for a controlled substance, the DEA number of the MLP and the supervising practitioner. [§291.34\(b\)\(7\)\(A\)\(iii\)](#) and (xi)

### **Is a pharmacy allowed to distribute drugs to another pharmacy or a practitioner?**

[§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 can be distributed to another pharmacy or a practitioner, and the record keeping requirements are set forth in [§291.34\(i\)](#).

### **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.

### **What is required for a Class D (Clinic Pharmacy) to expand its formulary?**

Clinics with a patient population consisting of at least 80% indigent patients may petition TSBP to operate with an expanded formulary as set forth in [§291.93\(e\)\(1\)\(D\)](#).

### **For license renewal, how many hours of continuing education are required for a pharmacist engaged in sterile compounding?**

Per [§291.133\(c\)\(2\)\(B\)\(iii\)](#), during the previous licensure period and of the 30 hours required for renewal, a pharmacist engaged in low and medium risk sterile compounding shall complete a minimum of two hours of ACPE-accredited CE related to compounding, and a pharmacist engaged in high risk sterile compounding shall complete four hours of the 30 hours required for general renewal of ACPE-accredited CE related to compounding. Acceptable CE related to compounding shall be in one or more of the following areas: aseptic technique; critical area contamination factors; environmental monitoring; structure and engineering controls related to facilities; equipment and supplies; sterile preparation calculations and terminology; sterile preparation compounding documentation; quality assurance procedures; aseptic preparation procedures including proper gowning and gloving technique; handling of hazardous drugs; cleaning procedures; and general conduct in the clean room.

### **Can a pharmacy dispense and deliver drugs for office use by a practitioner?**

Compounded drug preparations (both nonsterile, [§291.131\(f\)](#) and sterile [§291.133\(f\)](#)) in a reasonable quantity are allowed to be dispensed, as a prescription labeled for office use, to a practitioner for office use by the practitioner.

Other than compounded preparations, a pharmacy should adhere to drug distribution procedures to provide a prescriber's office with prescription drugs, per [§291.34\(h\)](#).

### **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.

### **What is drug therapy management (DTM) by a pharmacist?**

DTM is the performance of specific acts by a pharmacist as authorized by a physician through a written protocol. [§295.13](#)

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

Individuals who are not registered with TSBP may not be employed as or perform the duties of a pharmacy technician or pharmacy technician trainee. Persons who have applied for registration and paid fees must ensure that the registration has been issued. Best practice is to utilize the Registration Verification on TSBP's website at [https://www.pharmacy.texas.gov/dbsearch/tech\\_search.asp](https://www.pharmacy.texas.gov/dbsearch/tech_search.asp) to search by first and last name to determine issuance of the registration. Pharmacies and pharmacists-in-charge, who allow non-registered employees to perform or technicians who perform pharmacy technician duties without the issuance of a registration are subject to potential disciplinary action by TSBP. [§297.3\(a\)\(1\)](#)

## Is there a day-supply limitation on a prescription?

Regarding the treatment of acute pain with an opioid, practitioners are limited from issuing a prescription that exceeds 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 90-day 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 day-supply 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.

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

## Is there an age requirement for a person to pick up a prescription from the pharmacy?

TSBP rules do not address a specific age requirement to pick up a dispensed prescription for a dangerous drug or for a controlled substance. With any delivery of a controlled substance prescription, [§481.074\(a\)\(5\)](#) of the Texas Controlled Substances Act 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

### **Is a physician assistant allowed to write a prescription for a CII?**

Texas Medical Board Rule [§193.6\(c\)](#) allows for a physician assistant 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.

### **Is a PO Box allowed for the patient address?**

Requirements of the address of the patient is not defined in TSBP rules, the Texas Controlled Substances Act, or Texas Dangerous Drug Act. TSBP encourages pharmacists to know his/her patient and/or ask for identification upon delivery of dispensed prescriptions. Further, [§481.074\(a\)\(5\)](#) of the Texas Controlled Substances Act requires that a pharmacist know the person accepting delivery or require identification of the person taking possession of the controlled substance.

### **Is a pharmacist allowed to dispense a prescription written on an official prescription form for a drug other than a CII?**

Yes, a prescription calling for a CIII, IV or V controlled substance or a dangerous drug if written on an official prescription form does not affect the validity of the prescription. A pharmacist is authorized to dispense the prescription issued for a non-CII on the official prescription form.

### **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).

### **Can a physician assistant write for refills?**

Information on controlled substance prescriptions from physician assistants and advanced nurse practitioners is located on TSBP's website at [http://www.pharmacy.texas.gov/files\\_pdf/9Information\\_on\\_Controlled\\_Substance\\_Prescriptions\\_from\\_Advanced\\_Practice\\_Registered\\_Nurses\\_and\\_Physician\\_Assistants.pdf](http://www.pharmacy.texas.gov/files_pdf/9Information_on_Controlled_Substance_Prescriptions_from_Advanced_Practice_Registered_Nurses_and_Physician_Assistants.pdf).

## **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](http://www.pharmacy.texas.gov/files_pdf/Telemedicine_FAQ.pdf)

## **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>

## **As a controlled substance registrant, how do I destroy dangerous drugs and controlled substances?**

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>

Upon clicking the "Drug Disposal Information" link, the inquirer is linked to DEA's website at [https://www.deadiversion.usdoj.gov/drug\\_disposal/index.html](https://www.deadiversion.usdoj.gov/drug_disposal/index.html)

## **Where do I locate a DEA 106 form?**

The reporting form for drug/theft loss information is available online only. For a paper form, inquirers should contact the assigned DEA Divisional Office. 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/>

Upon clicking the "Drug Enforcement Agency (DEA)" link, the inquirer is linked to DEA's website at <https://www.deadiversion.usdoj.gov/index.html>

While TSBP requires notification of a theft/loss of a controlled substance or a dangerous drug as specified [§291.3\(f\)](#), TSBP does not specify a reporting form for the required report of information.

## **May 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 [§481.074\(l\)\(5\)](#).

## **What can be modified on a prescription drug order? Is the existing prescription still valid?**

A pharmacist, in his/her 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.

## Can I accept a fax for a CII controlled substance?

DEA Pharmacist's Manual (2010 Edition) in Section IX-Valid Prescription Requirements, Facsimile Prescriptions for Schedule II Controlled Substances, provides the following: "In order to expedite the filling of a prescription, a prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept."

Further the DEA Pharmacist Manual (2010 Edition) provides three enumerated "Exceptions for Schedule II Facsimile Prescriptions" in Section IX-Valid Prescription Requirements.

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/>

Upon clicking the "DEA Pharmacist's Manual" link, the inquirer is linked to [https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf)

## 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 a 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 not able 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.

## **Does a partial fill count as a refill on a prescription?**

DEA Pharmacist's Manual (2010 Edition) in Section X-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/>

Upon clicking the "DEA Pharmacist's Manual" link, the inquirer is linked to [https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm\\_manual.pdf](https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf)

## **How do I report a theft or loss of drugs to TSBP?**

The theft or significant loss of any controlled substance by a pharmacy must be reported in writing to TSBP 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 information listed above is also discussed at No. 9 in the following document posted on TSBP's website at [https://www.pharmacy.texas.gov/files\\_pdf/top\\_10\\_pharmacy\\_operation.pdf](https://www.pharmacy.texas.gov/files_pdf/top_10_pharmacy_operation.pdf)