

TSBP Rules FAQ

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TSBP Rules Frequently Asked Questions

What is the amount of time a pharmacy can operate without a PIC?

Pharmacies that fail to employ a PIC are not in compliance with TSBP Rules and are subject to potential disciplinary action by TSBP. [§§291.1\(a\)\(8\)](#) and [291.3\(e\)\(2\)](#).

What are acceptable ways of delivering drugs to a patient?

A pharmacist or pharmacy by means of its employee or by use of a common carrier or the U.S. Mail, at the request of the patient, may deliver prescription drugs to the office or home of the prescriber unless the prescription is for a controlled substance for administration to the patient and the patient is not present, at the residence or place of employment of the person for whom the prescription was issued, or at the hospital or medical care facility in which the patient is receiving treatment. [§291.9](#)

*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 pharmacist-in-charge (PIC)? Is a change of PIC required?

The PIC has responsibility for the practice of pharmacy 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. [§291.17\(g\)](#) only addresses the procedure to change the PIC with TSBP. 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.

What drugs are required to be inventoried upon a change of pharmacist-in-charge (PIC)?

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an inventory taken at a change of PIC must include all stocks of all controlled substances (including any out-of-date drugs).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 inventories must be notarized?

Inventories conducted as initial, 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 ration 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.

Pharmacist-interns functioning as a pharmacy technician is not counted as a pharmacy technician in the ration 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 in 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 are allowed to 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 which consists of at least 80% indigent patients may petition TSBP to operate with a formulary which includes types of drugs and devices, other than those listed in [§291.93\(e\)\(1\)\(B\)](#) based upon documented objectives of the clinic, and under a petition to TSBP covering the requirements set forth in [§291.91\(e\)\(1\)\(D\)](#).

How many hours of continuing education are required for a pharmacist engaged in sterile compounding in order to renew his or her license?

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. The same section provides that 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.

What procedures allow distribution of compounded preparations to a practitioner for office use?

Regarding nonsterile preparations, [§291.131\(f\)](#) provides that a pharmacy may dispense and deliver a reasonable quantity of a compounded preparation to a practitioner for office use by the practitioner.

Regarding sterile preparations, [§291.133\(f\)](#) applies, and provides the same.

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 by a pharmacist?

Drug Therapy Management (DTM) is defined in [§295.13](#) and includes the performance of specific acts by a pharmacist as authorized by a physician through a written protocol. DTM does NOT include selection of products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from the standing protocol. DTM may include the following:

- (A) collecting and reviewing patient drug use histories;
- (B) ordering or performing routine drug therapy related patient assessment procedures including temperature, pulse, and respiration;
- (C) ordering drug therapy related laboratory tests;
- (D) implementing or modifying drug therapy following diagnosis, initial patient assessment, and ordering of drug therapy by a physician as detailed in the protocol; or
- (E) any other drug therapy related act delegated by a physician.

See [§295.13](#) for additional details and requirements

What is medication therapy management by a pharmacist?

Medication Therapy Management (MTM) was defined and approved by members who represented 11 national pharmacy organizations and were invited to serve on the MTM Services Working Group, in Spring 2004, by July 27, 2004 the definition was approved by each organization's chief executive (Bluml, 2005).

MTM is a distinct service or group of services that optimize therapeutic outcomes for individual patients. The services are independent of, but can occur in conjunction with, the provision of a medication product. MTM encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice (Bluml, 2005).

The MTM service model in pharmacy practice includes the following five core elements:

- Medication therapy review (MTR)
 - Personal medication record (PMR)
 - Medication-related action plan (MAP)
 - Intervention and/or referral
 - Documentation and follow-up
- (2008, APhA & NACDS Foundation)

Sources:

American Pharmacy Association & National Association Chain Drug Stores Foundation. (2008, March). Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model, Version 2.0. APhA & NACDS Foundation. Retrieved from http://www.pharmacist.com/sites/default/files/files/core_elements_of_an_mtm_practice.pdf

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 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 for a controlled substance?

Regarding 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.

Regarding CIII, IV or V controlled substances, although there is no day-supply limitation for a prescription issued by a physician, a pharmacist may not dispense a prescription for a controlled substance unless issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Excessive quantities of a controlled substance could be a prescription red flag factor indicating an invalid or fraudulent prescription drug order. Texas Medical Board Rule [§193.6\(b\)](#) limits physician assistants from prescribing greater than 90 days' supply of CIII, IV, or V controlled substances.

Is there an age limit for a person picking up a prescription from the pharmacy?

TSBP rules do not address a specific age requirements 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\(n\)](#). This section requires the pharmacy to maintain all relevant information on the person to whom the controlled substance is delivered, including the name, address, and date of birth or age of the person. TSBP cautions that the pharmacist exercise common-sense and consider any potential for misuse and possible diversion-risks when delivering a dangerous

drug or controlled substance prescription to any person other than the patient for whom the drug was prescribed, regardless of age.

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.

Can I call a prescriber to get an issuance date for a prescription if the date is left blank on the drug order?

Yes, the issuance date is a required element of a prescription per [§291.34\(b\)\(7\)](#). The authorization of issuance date requires contacting the prescriber and documenting the issuance date. For a dangerous drug prescription or CIII, IV or V controlled substance, best pharmacy practice considers that the prescription lacking the issuance date as void, and necessitates creating for prescriber approval a new telephonic prescription initiated by the pharmacist to obtain the issuance date.

*Note: Clearly erroneous issuance dates allow for pharmacist professional discretion and judgment in deciding the necessity for clarifying with the prescriber, e.g., a prescription purporting the prior year shortly after the start of a new calendar year. 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.

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

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

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>

Is a prescription for office use valid?

A prescription not for a compounded preparation is not allowed for office use. A pharmacy should adhere to distribution procedures to provide another pharmacy or prescriber's office with controlled substances and dangerous drugs. "Distribution of Controlled Substances and Dangerous Drugs Between Registrants" is a procedure contained on page 525 of the Texas Pharmacy Laws and Regulations Book, 2018 edition.

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

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 added/changed on a CII controlled substance prescription at the time of dispensing?

A pharmacist cannot change the name of the patient, name of the practitioner, name of the controlled substance prescribed, or the date the prescription is issued.

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

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

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