## **Operational Standards**

Governor Greg Abbott has declared a state of disaster in Texas due to COVID-19 (coronavirus).

The laws and rules governing the practice of pharmacy in Texas require pharmacies and pharmacists to comply with certain operational standards, including the provision of patient counseling. Specifically, board rule 291.33(c)(1)(B)(iii) states that such communication shall be communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication.

The Texas State Board of Pharmacy has determined that strict compliance with these laws could prevent, hinder, or delay the delivery of pharmaceutical services in relation to efforts to cope with the declared disaster.

Accordingly, the Office of the Governor has temporarily suspended the requirement of in-person contact in board rule 291.33(c)(1)(B)(iii) to allow for telephonic consultation. This suspension is in effect until terminated by the Office of the Governor or until the March 13, 2020, disaster declaration is lifted or expires.

## §291.33 Operational Standards

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) 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;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. This information may 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.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to assure that the drugs are delivered to the appropriate patient.

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).