

Remote Pharmacy Services

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 impose requirements for providing remote pharmacy services. Specifically, board rule [291.121\(d\)\(3\)](#), [\(4\)\(C\)\(i\)](#) imposes general requirements and operational standards for remote pharmacy services using automated storage and delivery systems.

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 requirements of board rule 291.121(d)(3), (4)(C)(i) to the extent necessary to expand the pilot program for automated systems in order to allow for remote automated dispensing. 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.

§291.121 Remote Pharmacy Services

(d) Remote pharmacy services using automated storage and delivery systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated storage and delivery system.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated storage and delivery system--A mechanical system that delivers dispensed prescription drugs to patients at a remote delivery site and maintains related transaction information.

(B) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(C) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote delivery site--A location at which remote pharmacy services are provided using an automated storage and delivery system.

(F) Remote pharmacy service--The provision of pharmacy services, including the storage and delivery of prescription drugs, in remote delivery sites.

(3) General requirements for a provider pharmacy to provide remote pharmacy services using an automated storage and delivery system to **dispense and** deliver a ~~previously verified~~ prescription that is **verified**~~dispensed~~ by the provider pharmacy to a patient or patient's agent.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated storage and delivery system located at the remote delivery site including supervision of the automated storage and delivery system and compliance with this section.

(B) The patient or patient's agent shall receive counseling via a direct link to audio or video communication by a Texas licensed pharmacist who has access to the complete patient medication record (patient profile) maintained by the provider pharmacy prior to the release of any new prescription released from the system.

(C) A pharmacist shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs delivered through the use of the automated storage and delivery system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(D) The patient or patient's agent shall be given the option whether to use the system.

(E) An electronic notice shall be provided to the patient or patient's agent at the remote delivery site with the following information:

(i) the name and address of the pharmacy that verified the previously dispensed prescription; and

(ii) a statement that a pharmacist is available 24 hours a day, 7 days a week through the use of telephonic communication.

(F) Drugs stored in the automated storage and distribution system shall be stored at proper temperatures, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(G) A provider pharmacy may only provide remote pharmacy services using an automated storage and delivery system to patients at a board-approved remote delivery site.

(H) A provider pharmacy may provide remote pharmacy services at more than one remote delivery site.

(I) Before providing remote pharmacy services, the automated storage and delivery system at the remote delivery site must be tested by the provider pharmacy and found to deliver accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(J) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records for Class A (Community) Pharmacies) and this section.

(4) Operational standards.

(A) Application to provide remote pharmacy services using an automated storage and delivery system.

(i) A community (Class A) or institutional (Class C) pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated storage and delivery system.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the provider pharmacy.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service.

(ii) A provider pharmacy shall comply with appropriate controlled substance registrations for each remote delivery site if dispensed controlled substances are maintained within an automated storage and delivery system at the facility.

(iii) A provider pharmacy shall file an application for change of location and/or name of a remote delivery site as specified in §291.3 of this title (relating to Notifications).

(C) Environment/Security.

(i) A provider pharmacy shall only store ~~prescription dispensed~~ **prescription dispensed** drugs at a remote delivery site within an automated storage and delivery system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) Access to the automated storage and delivery system shall be limited to pharmacists, and pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated storage and delivery system.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 (relating to Storage of Drugs) and §291.33(c)(8) (relating to Returning Undelivered Medication to Stock) of this title, including the requirements for temperature and the return of undelivered medication to stock.

(iv) the automated storage and delivery system must have an adequate security system, including security camera(s), to prevent unauthorized access and to maintain patient confidentiality.

(D) Stocking an automated storage and delivery system. Stocking of dispensed prescriptions in an automated storage and delivery system shall be completed under the supervision of a pharmacist.

(E) Quality assurance program. A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall operate according to a written program for quality assurance of the automated storage and delivery system which:

(i) requires continuous supervision of the automated storage and delivery system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated storage and delivery system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(ii) A pharmacy that provides pharmacy services through an automated storage and delivery system at a remote delivery site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated storage and delivery system shall maintain a written plan for recovery from an event which interrupts the ability of the automated storage and delivery system to deliver dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated storage and delivery system is experiencing downtime;

(II) procedures for response when an automated storage and delivery system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.