

Proposed Rules Title 22

§291.33.Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class A pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications). [§291.4 of this title (relating to Change of Ownership).]

(3) A Class A pharmacy which changes location and/or name shall notify the board within ten days of the change and file for an amended license as specified in §291.3 of this title (relating to Required Notifications). [§291.2 of this title (relating to Change of Location and/or Name).]

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures in §291.3 of this title (relating to Required Notifications [Change of Managing Officers]).

(5) - (8) (No change.)

(9) A Class A (community) pharmacy engaged in the compounding of non-sterile pharmaceuticals shall comply with the provisions of §291.131 [§291.25] of this title (relating to Pharmacies Compounding Non-sterile Preparations [Pharmaceuticals]).

(10) A Class A (community) pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 [§291.26] of this title (relating to Pharmacies Compounding Sterile Preparations [Pharmaceuticals]).

(11) A Class A (Community) pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 [§291.20] of this title (relating to Remote Pharmacy Services).

(12) Class A (Community) pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing). [§291.37 of this title (relating to Centralized Prescription Dispensing) and/or §291.38 of this title (relating to Centralized Prescription Drug or Medication Order Processing).]

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall:

(I) be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

(II) be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs; the temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, guide dogs accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) Any area of a pharmacy that contains prescription drugs shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) Any area of a pharmacy that contains prescription drugs constructed after September 1, 2008, shall be enclosed by walls, partitions or other means of floor-to-ceiling enclosure. Pharmacies licensed prior to September 1, 2008, shall be exempt from this provision unless the pharmacy changes its address.

(ii) Effective, September 1, 2008, the pharmacy's key, combination or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) Effective, September 1, 2008, at a minimum, the pharmacy must have a basic alarm system and an electronic monitoring system to track individuals entering the area of a pharmacy that contains prescription drugs.

(C) Prior to authorizing individuals to enter the pharmacy, the pharmacist-in-charge may designate persons who may enter the pharmacy to perform functions documented by the pharmacist-in-charge including access to the pharmacy by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than pharmacy personnel who accessed the pharmacy when a pharmacist is not on-site.

(D) Only persons designated in writing by the pharmacist-in-charge may unlock the area of a pharmacy that contains prescription drugs except in emergency situations. An additional key to the area of a pharmacy that contains prescription drugs may be maintained in a secure location outside the area of a pharmacy that contains prescription drugs for use during an emergency or as designated by the pharmacist-in-charge for entry by another pharmacist.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies and procedures may include quarterly audits of controlled substances commonly abused or diverted, perpetual inventories, and monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy.

[(B) The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on-site. However, the pharmacist-in-charge may designate persons who may enter the pharmacy to perform functions designated by the pharmacist-in-charge (e.g., janitorial services).]

(3) Temporary absence of pharmacist.

(A) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period;

(IV) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, or other pharmacy personnel from the prescription department during his or her absence; and

(V) a notice is posted which includes the following information:

(-a-) the fact that the pharmacist is on a break and the time the pharmacist will return; and

(-b-) the fact that pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container provided the pharmacy technician:

(-a-) has completed the training requirements outlined in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training); and

(-b-) is registered as a pharmacy technician within the provisions of §297.3 of this title (relating to Registration Requirements); and

(VI) prepackaging and labeling prepackaged drugs.

(iii) Upon return to the prescription department, the pharmacist shall:

(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and

(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(B) Pharmacist is off-site.

(i) In a prescription department staffed by only one pharmacist during a shift, an agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:

(I) no more than a total of three pharmacy technicians or pharmacy technician trainees may remain in the pharmacy; however, at least one of the individuals must be a pharmacy technician;

(II) short periods of time may not exceed two consecutive hours in a 24 hour period and on no more than two occasions in a calendar month;

(III) the pharmacist reasonably believes the security of the pharmacy will be maintained in his or her absence. If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy during his or her absence;

(IV) a notice is posted which includes the following information:

(-a-) the fact that the pharmacist is off-site and not present in the pharmacy;

(-b-) the fact that no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return; and

(V) the pharmacy must maintain written documentation of the absences of the pharmacist(s).

(ii) During the time, a pharmacist is absent from the pharmacy and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription;

(V) signature of the person picking up the prescription; and

(VI) dates and times that prescription drug orders were delivered to patients or patients' agents in the absence of the pharmacist;

(iii) Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(iv) In pharmacies with two or more pharmacists working during a shift, the pharmacists shall stagger their schedules so that the pharmacy is not left without a pharmacist on duty.

[(A) If a pharmacy is staffed by a single pharmacist, the pharmacist may leave the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy technicians and other pharmacy personnel from the prescription department provided the following conditions are met:]

[(i) at least one registered pharmacy technician remains in the prescription department;]

[(ii) the pharmacist remains on-site at the licensed location of the pharmacy and available for an emergency;]

[(iii) the absence does not exceed 30 minutes at a time and a total of one hour in a 12 hour period;]

[(iv) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians or other pharmacy personnel from the prescription department during his or her absence; and]

[(v) a notice is posted which includes the following information:]

[(I) the fact that pharmacist is on a break and the time the pharmacist will return; and]

[(II) the fact that pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist absence but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist returns and verifies the accuracy of the prescription.]

[(B) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:]

[(i) initiating and receiving refill authorization requests;]

[(ii) entering prescription data into a data processing system;]

[(iii) taking a stock bottle from the shelf for a prescription;]

[(iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring liquids and placing them in the prescription container);]

[(v) affixing prescription labels and auxiliary labels to the prescription container provided the pharmacy technician:]

[(I) has completed the training requirements outlined in §297.6 of this title (relating to Pharmacy Technician Training); and]

[(II) is registered as a pharmacy technician within the provisions of §297.3 of this title (relating to Registration Requirements); and]

[(vi) prepackaging and labeling prepackaged drugs.]

[(C) Upon return to the prescription department, the pharmacist shall:]

[(i) conduct a drug regimen review as specified in subsection (c)(2) of this section; and]

[(ii) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.]

[(D) An agent of the pharmacist may deliver a prescription drug order to the patient or his or her agent provided a record of the delivery is maintained containing the following information:]

[(i) date of the delivery;]

[(ii) unique identification number of the prescription drug order;]

[(iii) patient's name;]

[(iv) patient's phone number or the phone number of the person picking up the prescription; and]

[(v) signature of the person picking up the prescription.]

[(E) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.]

[(F) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.]

[(G) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.]

(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) the 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:

(i) shall be provided with each new prescription drug order;

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

(iii) 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; and

(iv) shall be reinforced with written information. The following is applicable concerning this written information.

(I) Written information designed for the consumer such as the USP DI patient information leaflets shall be provided.

(II) When a compounded product 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.

(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 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. [or clause (ii) of this subparagraph.]

[(ii) An agent of the pharmacist may deliver a prescription drug order to the patient or his or her agent during short periods of time when a pharmacist is absent from the pharmacy, provided the short periods of time do not exceed two hours in a 24 hour period, and provided a record of the delivery is maintained containing the following information:]

[(I) date of the delivery;]

[(II) unique identification number of the prescription drug order;]

[(III) patient's name;]

[(IV) patient's phone number or the phone number of the person picking up the prescription; and]

[(V) signature of the person picking up the prescription.]

(ii) [(iii)] 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.

(iii) [(iv)] A Class A pharmacy shall make available for use by the public a current or updated edition of the United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient), or another source of such information designed for the consumer.

(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 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) Except as specified in subparagraph (B) of this paragraph, in the best interest of the public health and to optimize drug therapy, upon delivery of a refill prescription, a pharmacist shall ensure that the patient or patient's agent is offered information about the refilled prescription. Either a pharmacist or other pharmacy personnel shall inform the patient or patient's agent that a pharmacist is available to discuss the patient's prescription and provide information.

(H) A pharmacy shall post a sign no smaller than 8.5 inches by 11 inches in clear public view at all locations in the pharmacy where a patient may pick up prescriptions. The sign shall contain the following statement in a font that is easily readable: "Do you have questions about your prescription? Ask the pharmacist." Such notification shall be in both English and Spanish.

(I) 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).

(2) - (5) (No change.)

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) - (8) (No change.)

(d) - (g) (No change.)

(h) Customized patient medication packages.

(1) - (2) (No change.)

(3) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

(viii) the date of preparation of the patient med-pak and the beyond-use date assigned to the patient med-pak (which such beyond-use date shall not be later than 60 days from the date of preparation);

(ix) the name, address, and telephone number of the pharmacy;

(x) the initials or an identification code of the dispensing pharmacist; and

(xi) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 34-day supply or 100 dosage units, whichever is less, is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that [the system employed by the pharmacy in dispensing the prescription drug order] adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of each drug product dispensed;

(-d-) name of the patient;

(-e-) name of the prescribing practitioner of each drug product and if applicable, the name of the advanced practice nurse or physician assistant who signed the prescription drug order ; and

(II) for each drug product sets forth the directions for use and cautionary statements, if any , contained on the prescription drug order or required by law.

(4) - (7) (No change.)