



PA 24-73—sSB 133
General Law Committee

**AN ACT CONCERNING REGULATION OF PRESCRIPTION DRUGS
AND RELATED PROFESSIONS**

SUMMARY: This act makes various changes to laws on pharmacies and pharmacists. It establishes the advanced pharmacy technician and clerk occupational categories and sets certain parameters for their allowable duties.

The act authorizes pharmacists and advanced pharmacy technicians to dispense to patients their prescription drugs in compliance packaging (generally, packaging that separates drugs into individual compartments by dose). Under the act, pharmacies that provide compliance packaging must meet certain requirements, including keeping records on dispensed drugs and patients.

The act also allows for the redispensing of pharmaceutical drug compliance packaging if the prescriber modifies the prescription, subject to certain requirements. This includes the requirement to return any drugs removed from compliance packaging to the patient with directions on how to properly dispose of the drugs.

The act makes it a punishable offense for pharmacists, pharmacy operators, pharmacy interns, and pharmacy technicians to return any drug that has been sold or delivered to a patient to the pharmacy's general inventory or regular drug stock (unless otherwise allowed or required by law). Existing law prohibits returns of drugs exposed to possible contamination or substitution.

The act allows individuals enrolled in pharmacy technician education programs to engage in pharmacy technician duties if they are directly supervised by a pharmacist who is an instructor in the program.

The act allows pharmacists to order and prescribe, not just administer, vaccines for certain patients, and applies this authority to all federally approved vaccines on the Centers for Disease Control and Prevention's (CDC) age-appropriate immunization schedule. It allows pharmacists to delegate to advanced pharmacy technicians (1) authority to administer these vaccines, as well as COVID-19, influenza, and HIV tests, and (2) the responsibility to conduct final verification checks of prescriptions and administer vaccines as well as COVID-19, influenza, and HIV related tests.

The act establishes a task force to study the impact of unannounced retail pharmacy closures.

The act also makes minor, technical, and conforming changes, such as certain minor changes to definitions under the state's pharmacy laws.

EFFECTIVE DATE: October 1, 2024, except that (1) a conforming change is effective July 1, 2025 (§ 8), and (2) the task force provisions are effective upon passage (§ 11).

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§§ 1, 2, 7 & 8 — ADVANCED PHARMACY TECHNICIANS

The act establishes the advanced pharmacy technician occupational category. It prohibits pharmacy technicians from performing this occupational category's duties without getting an advanced pharmacy technician designation from the Department of Consumer Protection (DCP) commissioner. To get the designation, a person must:

1. submit a completed application and pay a \$25 fee;
2. be an actively registered and qualified pharmacy technician;
3. have been registered as a pharmacy technician for the three-year period immediately before applying;
4. have continuously held a certification from the Pharmacy Technician Certification Board, or equivalent certification program approved by DCP, for the three-year period immediately before applying, and keep that certification in good standing;
5. have successfully completed an educational course accredited by a nationally recognized accreditation body within one year before initially applying (or a course the commissioner deems equivalent);
6. have successfully completed a competency assessment proctored by a pharmacist in keeping with requirements to be set by the commissioner;
7. be employed by a pharmacy (including institutional pharmacies) that satisfies certain supervisory and staffing requirements (see below); and
8. work under the direct supervision of a licensed pharmacist or be supervised by a pharmacist using electronic technology or telepharmacy capabilities, or in any manner approved by the commissioner or pharmacy commission.

An advanced pharmacy technician designation is valid for one year and may be renewed for successive one-year periods for a \$25 fee (in addition to the \$50 technician fee).

An advanced pharmacy technician's duties may include, among other things, dispensing or redispensing to patients compatible drugs in compliance packaging (see § 4 below).

Delegation of Responsibilities to Advanced Pharmacy Technicians

Under the act, pharmacists that directly supervise advanced pharmacy technicians may delegate their authority to:

1. perform final verifications of prescriptions (the last review to verify the dispensed product conforms to the prescription issued by the prescribing practitioner, including comparing the prescription, label, and contents of the container) if certain requirements are met (see below) and
2. administer vaccines and COVID-19, influenza, and HIV-related tests (see §§ 9 & 10 below).

The act prohibits pharmacists from similarly delegating (1) their authority to present COVID-19, influenza, and HIV-related test results to patients or (2) any discretionary decision-making authority concerning the propriety of any drug in relation to a patient's medical condition or treatment plan.

Supervisory and Staffing Requirements

Under the act, a pharmacy that employs an advanced pharmacy technician must:

1. use bar codes or a DCP-approved technology to help dispense drugs and confirm accurate dispensing and
2. keep the on-site ratio of advanced pharmacy technicians to pharmacists providing direct supervision at no more than 1:1, unless authorized by the DCP commissioner or the pharmacy commission.

Advanced pharmacy technicians do not count towards the existing 3:1 ratio of pharmacy technicians to supervising pharmacists.

Under the act, at most pharmacies, advanced pharmacy technicians may not perform final verifications unless the advanced pharmacy technician uses a technology that includes images of each type of drugs. Institutional pharmacies (e.g., hospitals) employing advanced pharmacy technicians instead must use bar code scanning (or another DCP-approved method) at the point of administration to the patient to confirm the correct drugs have been dispensed.

Regulations

The act requires the DCP commissioner to adopt implementing regulations that at least set (1) performance requirements for the competency assessment required for designation as an advanced pharmacy technician, (2) ratios of pharmacists to advanced pharmacy technicians, and (3) additional requirements for advanced pharmacy technician duties.

§§ 3, 7 & 8 — PHARMACY CLERKS

The act establishes the clerk occupational category. It prohibits anyone from working in an area of a pharmacy where controlled substances or other prescription drugs are dispensed by pharmacists (or dispensed under their supervision) unless the person is a registered clerk or already registered with or licensed by DCP as another category of pharmacy professional. For institutional pharmacies, places outside the area commonly known as the pharmacy, including patient care areas or automated prescription dispensing machines, are excluded. Clerks do not include people who are employed or contracted by a pharmacy only to deliver drugs to patients off the pharmacy premises.

To become registered as a clerk, an applicant must apply to DCP and satisfy any registration requirements set by DCP regulations (see below). A clerk's registration is valid for two years and may be renewed for successive two-year periods. The initial registration and renewal fee is \$25.

The act prohibits DCP from refusing to issue a clerk registration or renewal because the applicant has been convicted of a felony, except as allowed under existing standards in law (based on factors such as the nature of the crime and the time since the conviction or release).

Under a pharmacist's direct supervision, clerks may:

1. handle dispensed drugs and deliver them to patients;

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2. collect patient demographic information;
3. collect a prescription number for a refill;
4. deliver a drug to an automated prescription dispensing machine or other care-giving area within a caregiving, correctional, or juvenile training institution;
5. perform cashier duties;
6. manage inventory;
7. return to stock any product used to fill a prescription but not sold to a patient; and
8. perform any other duties set in DCP regulations.

The act prohibits clerks from:

1. reviewing any drug to determine if it is an appropriate treatment;
2. verifying the accuracy of the prescription, the prescription label or container contents, or the prescription data entered into an electronic data processing system used by a pharmacy;
3. performing any task that requires professional pharmaceutical judgment; or
4. participating in order entry (generally, entering prescription data into the pharmacy's electronic data processing system).

Clerks must also not be involved in the dispensing process or preparing a prescription for final verification.

The act authorizes the DCP commissioner to establish regulations that include among other things, creating additional requirements for clerk registration.

§ 4 — COMPLIANCE PACKAGING

The act authorizes pharmacists and advanced pharmacy technicians to dispense compatible drugs in compliance packaging, at the patient's (or their representative's) or prescribing practitioner's request. Compliance packaging is packaging prepared at a pharmacy that separates drugs into individual compartments or containers according to their directions for use and when they are to be taken.

Reusable Components, Multiple Drugs, and Repackaging

Under the act, if a patient's prescribing practitioner changes a prescription, the pharmacy that first dispensed the drugs to the patient in compliance packaging may (1) accept the compliance packaging from the patient or representative, (2) receive and remove any drugs contained in it and redispense the drugs to the patient (including in compliance packaging), and (3) dispense any compatible drugs newly prescribed to the patient in redispensed compliance packaging. The pharmacy may do so upon request from the patient, their representative, or the prescribing practitioner, and the pharmacy must document the change in writing.

The act requires any pharmacy that accepts compliance packaging returned under these provisions to do so only to (1) dispense to the patient any newly prescribed compatible drugs and (2) redispense to the patient any drugs in the returned packaging in the same quantities that were contained in the returned

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packaging.

The act requires each pharmacy that redispenses drugs in returned compliance packaging to redispense the prescribed drugs to the patient in (1) compliance packaging that only includes drugs prescribed to the patient or (2) a separate container that is properly labeled.

If a pharmacy accepts returned compliance packaging with drugs that have been decribed, discontinued, or deemed inappropriate for inclusion in compliance packaging, the pharmacy must redispense them to the patient in a separate container or containers that (1) include no more than one drug type or dosage and (2) have a label that includes the patient's name, the original prescription's serial number, the drug's name, the dosage form, the quantity of redispensed drugs, and instructions for the use or disposal of the drugs. These instructions must include the procedures to lawfully destroy the drugs at home and the nearest location permitted to accept prescription drugs for destruction.

Under the act, any drugs that were previously in compliance packaging and returned to the pharmacy cannot be returned to the pharmacy's general inventory or regular stock, unless otherwise permitted or required by law.

The act requires compliance packaging to:

1. only contain individual compartments that are tamper-evident;
2. only contain drugs currently prescribed to a single patient by their prescribing practitioner and dispensed or redispensed to that patient by a pharmacist or an advanced pharmacy technician;
3. be labeled or relabeled by a pharmacist under existing requirements (except the packaging only needs to include one warning sticker or label for opioid drugs, not one for each individual compartment);
4. be child-resistant unless the patient acknowledges that it is not and signs a waiver;
5. identify on each individual compartment the name and strength of any drug it contains;
6. not contain more than a 90-day supply of any drug (unless otherwise allowed by state or federal law); and
7. comply with the United States Pharmacopeia.

The act allows individual compartments of compliance packaging to contain multiple prescribed drugs if:

1. a pharmacist has determined that all drugs in the compartment are compatible,
2. all drugs in the compartment have the same instructions for time of administration, and
3. the drugs' administration directions are not on an "as needed" basis.

The act prohibits controlled substances from being dispensed in compliance packaging with other drugs, except for other controlled substances of the same type prescribed at different doses.

Standard Operating Procedures

The act requires pharmacies that choose to provide compliance packaging

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services to maintain an area dedicated to that purpose that contains the equipment necessary to (1) ensure all compliance packaging is accurately prepared, (2) prevent contamination of drugs going into compliance packaging, and (3) maintain standard operating procedures.

The act requires these pharmacies to maintain a set of standard operating procedures for using compliance packaging and associated equipment that covers at least the following:

1. compliance packaging integrity inspections,
2. cleaning,
3. labeling,
4. dispensing and redispensing,
5. proper hand hygiene,
6. quarantine, and
7. handling of dispensed drugs that are removed from compliance packaging and redispensed to patients.

The standard operating procedures also must specify which drugs (1) are not compatible, (2) are suitable to be dispensed or redispensed in compliance packaging, or (3) require special consideration to be dispensed in this way.

Recordkeeping

The act requires pharmacies that provide compliance packaging services to maintain a log (record) of drugs that the pharmacy dispenses to a patient in this packaging. The log must have:

1. the patient's name and address;
2. the compliance package's identification number, if any;
3. the date the package was prepared;
4. the initials of the individuals who prepared the packaging and performed a final verification;
5. the drug's name, strength, lot number, and national drug code number;
6. the prescription's serial number; and
7. a visual description of the dispensed drug.

The act also requires these pharmacies to maintain a record of compliance packages accepted by the pharmacy for return and redispensing to the patient. Each record must contain the:

1. patient's name and address;
2. compliance packaging identification number, if any;
3. date when the pharmacy accepted the compliance package for return and redispensing to the patient;
4. name of the pharmacist or pharmacy technician that documented the return; and
5. name, formulation, and quantity of each drug in the compliance package when it was accepted for return and redispensing, including a designation of any deprescribed drugs in the compliance package.

The act requires these pharmacies to maintain a record of compliance packaging containing drugs that have been redispensed and returned to the patient. Each record

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must contain the:

1. patient's name and address;
2. compliance packaging identification number, if any;
3. date the compliance packaging was prepared for redispensing;
4. serial number of the prescription for each drug redispensed in the compliance packaging;
5. name, formulation, and quantity of each drug redispensed in the compliance packaging;
6. redispensing pharmacist's name or initials;
7. initials of the person who prepared the compliance packaging for redispensing; and
8. initials of the person who performed a final verification of the compliance packaging for redispensing.

The act also requires pharmacies to maintain a record of all drugs the pharmacy redispenses to a patient in a container other than compliance packaging. Each record must contain the:

1. patient's name and address;
2. date the drug was prepared for redispensing;
3. prescription's serial number;
4. redispensed drug's name, formulation, and quantity; and
5. redispensing pharmacist's name or initials.

The act requires each pharmacy to keep all records required by this section for at least three years. Within 48 hours after a request, pharmacies must give DCP any of these records in electronic form or paper if electronic means is not available.

Regulations

The act allows the DCP commissioner to adopt regulations implementing its provisions on compliance packaging.

§ 5 — CAUSES OF DISCIPLINE FOR PHARMACY PROFESSIONALS

The act allows the Pharmacy Commission to take disciplinary action against pharmacies or certain pharmacy personnel for returning to the general inventory or regular stock any drug sold or delivered to a patient (unless otherwise permitted or required by law). Existing law already allows the commission to take these actions if the person has accepted for return to regular stock any drug already (1) dispensed in good faith or delivered and (2) exposed to possible contamination or substitution.

Under existing law, the possible disciplinary actions include, among other things, (1) refusing to issue or renew, revoking, suspending, or placing conditions on a license to practice pharmacy, a license to operate a pharmacy, a pharmacy intern registration, or a pharmacy technician registration or (2) imposing a civil penalty of up to \$1,000.

§ 6 — PHARMACY TECHNICIANS

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The act authorizes individuals enrolled in accredited pharmacy technician education programs to engage in pharmacy technician duties as part of the education program if they are under the direct supervision of a pharmacist who is an instructor in that program.

The act requires anyone seeking a pharmacy technician registration to present evidence to DCP that they are qualified to work under a pharmacist's general supervision, instead of direct (in-person) supervision as under prior law.

The act also specifies that DCP, when issuing credentials for pharmacy technicians, does not need the Pharmacy Commission's specific authorization.

§ 9 — ORDERING AND ADMINISTERING VACCINES

Existing law allows pharmacists to administer certain vaccines to (1) adult patients or (2) patients ages 12 to 17 with a legal guardian's consent (or who are emancipated minors). The act additionally authorizes pharmacists to order and prescribe these vaccines for these patients.

It allows them to administer any vaccine approved or authorized by the U.S. Food and Drug Administration and listed on the CDC's age-appropriate immunization schedule, instead of on the adult immunization schedule as under prior law, and additionally allows them to order and prescribe these vaccines. It also specifically allows them to order and prescribe to adult patients other vaccines that they may administer under existing law, including (1) vaccines not on the adult immunization schedule, but with administration instructions available on the CDC website, and (2) vaccines prescribed (verbally or written) by a practitioner for a specific patient.

Under existing law, pharmacists must complete specified training before administering vaccinations.

Additionally, the act allows pharmacists to delegate their authority to administer these vaccines to advanced pharmacy technicians, so long as the technicians administer them under the pharmacist's direct supervision and following related state law and regulations.

It correspondingly authorizes the DCP commissioner to amend existing regulations on pharmacists' vaccine administration to establish additional requirements for delegating this authority to advanced pharmacy technicians and the technicians' administration of the vaccines.

§ 10 — DELEGATION OF AUTHORITY TO ADMINISTER COVID-19, INFLUENZA, AND HIV TESTS

The act allows pharmacists to delegate responsibility for administering COVID-19, influenza, and HIV tests to advanced pharmacy technicians if the technicians (1) complete any training DCP requires for properly administering the tests and (2) administer the tests under a pharmacist's direct supervision, according to related state law and regulations.

However, the act prohibits pharmacists from delegating to advanced pharmacy technicians the responsibility for giving patients their written COVID-19,

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influenza, or HIV test results that the pharmacists, or their technicians, administer. Existing law requires pharmacists to (1) maintain a record of the written test results for at least three years; (2) notify the patient's primary care provider, if the patient identifies one, local health director for the area where the patient lives, and the Department of Public Health, in the same way as required for reportable diseases; and (3) disclose the results to the DCP commissioner or his designee, upon request.

Currently, if a pharmacist orders and administers an HIV-related test and the result is negative, the pharmacist generally may prescribe and dispense to the patient pre- or post-exposure HIV-related prophylaxis. The act correspondingly allows the pharmacist to do this when a negative test is administered by an advanced pharmacy technician under the pharmacist's direct supervision.

Lastly, the act authorizes the DCP commissioner to amend the department's existing regulations on administering COVID-19, influenza, and HIV tests by pharmacists to establish additional requirements for delegating this authority to advanced pharmacy technicians and the technicians' administration of the tests.

§ 11 — TASK FORCE ON UNANNOUNCED RETAIL PHARMACY CLOSURES

The act establishes an 11-member task force to study the impact of unannounced retail pharmacy closures. The study must examine available means to ensure patients can maintain access to their prescriptions.

The task force consists of eight members appointed by the legislative leaders (two each by the House speaker and Senate president pro tempore, and one each by the House and Senate majority and minority leaders), the DCP commissioner or his designee, and two people appointed by the Governor. Legislative appointees may be legislators. Appointing authorities must make their initial appointments to the task force by June 27, 2024, and fill any vacancy.

The House speaker and Senate president pro tempore select the task force chairpersons from among its members. The chairpersons must schedule and hold the first task force meeting by July 27, 2024.

The General Law Committee's administrative staff must serve as the task force's administrative staff.

The task force must issue a report on its findings and recommendations to the General Law Committee by January 1, 2025. The task force terminates when it submits the report or on January 1, 2025, whichever is later.