OLR Bill Analysis

sSB 133

AN ACT CONCERNING REGULATION OF PRESCRIPTION DRUGS AND RELATED PROFESSIONS.

SUMMARY

This bill makes various changes to laws on pharmacies and pharmacists.

It establishes the advanced pharmacy technician and clerk occupational categories. Among other related provisions, it sets certain parameters of their allowable duties.

The bill authorizes pharmacists and advanced pharmacy technicians to dispense to patients their prescription drugs in compliance packaging (packaging that separates drugs into individual compartments by dose) if they follow certain criteria. Pharmacies that provide compliance packaging are required to keep logs with specific details of the drugs they dispense and who they dispense them to.

The bill also allows for the repackaging of pharmaceutical drug compliance packaging, 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 bill makes it a punishable offense for pharmacists, pharmacy operators, pharmacy interns, and pharmacy technicians to return to the general inventory or regular drug stock of the pharmacy any drug that has been sold or delivered to a patient, in addition to existing law's prohibition on such returns of drugs exposed to possible contamination or substitution.

The bill allows individuals enrolled in pharmacy technician

education programs to engage in duties of a pharmacy technician if they are under the direct supervision of a pharmacist who is an instructor in the program.

It allows pharmacists to order and administer, 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.

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

For purposes of the state's pharmacy laws, the bill generally defines a "patient" as a human or other animal receiving health care services from a provider to treat a current or future medical condition (§ 1).

The bill also makes minor, technical, and conforming changes.

EFFECTIVE DATE: October 1, 2024, except (1) upon passage for provisions on pharmacists ordering vaccinations and the task force and (2) July 1, 2025, for a technical change.

§§ 1 & 2 — ADVANCED PHARMACY TECHNICIANS

The bill establishes the advanced pharmacy technician occupational category. It prohibits anyone from performing the duties of this occupation without getting an advanced pharmacy technician endorsement from the Department of Consumer Protection (DCP). To get the endorsement, a person must:

1. be an actively registered and qualified pharmacy technician;

2. have been registered as a pharmacy technician for the three-year period immediately before applying for an advanced pharmacy technician endorsement;

3. 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 for an advanced pharmacy

technician endorsement, and keep that certification in good standing;

4. have successfully completed an educational course accredited by a nationally recognized accreditation body within one year of the date of applying to be an advanced pharmacy technician;

5. have successfully completed a competency assessment proctored by a pharmacist in keeping with requirements to be set by the commissioner;

6. work under the direct supervision of a licensed pharmacist; and

7. be employed by a pharmacy (including institutional pharmacies).

An advanced pharmacy technician endorsement is valid for one year and may be renewed for successive one-year periods.

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

Supervisory and Staffing Requirements

Under the bill, a pharmacist that directly supervises an advanced pharmacy technician generally must perform all drug utilization reviews (generally, reviewing a pharmacist's prescribing, dispensing, and utilization activities to ensure appropriate decision-making), and verify that (1) prescription drug data entered in the pharmacy software systems is correct and (2) the original prescription and contents of the label and container are correct. However, a pharmacist may allow the advanced pharmacy technician himself or herself to verify the accuracy of the original prescription and the contents of the label and container.

A pharmacy that employs an advanced pharmacy technician must:

1. use bar codes or a similar technology approved by DCP to assist in the dispensing of drugs and

2. keep the on-site ratio of advanced pharmacy technicians to pharmacists providing direct supervision at no more than 1:1.

Advanced pharmacy technicians do not count towards the existing 3:1 ratio of pharmacy technicians to supervising pharmacists if the advanced pharmacy technician exclusively performs duties of an advanced technician.

Pharmacies that employ advanced pharmacy technicians are required to use technology that includes images of each type of medication as part of a final verification check of dispensed drugs. Institutional pharmacies employing advanced pharmacy technicians must use bar code scanning at the point of administration to the patient to confirm the correct drugs have been dispensed.

Regulations

The bill requires the DCP commissioner to adopt implementing regulations that, at minimum, set (1) performance requirements for the competency assessment required for endorsement as an advanced pharmacy technician, and (2) additional requirements for the duties of advanced pharmacy technicians.

§ 3 — PHARMACY CLERKS

The bill establishes the clerk occupational category and prohibits anyone from performing a clerk's duties unless registered as such with DCP.

To become registered, an applicant must satisfy the registration requirements set by any DCP regulations on the matter (see below). A clerk's registration is valid for one year and may be renewed for successive one-year periods.

Clerks are authorized to handle dispensed drugs and deliver those drugs to patients under the direct supervision of a pharmacist or otherwise as authorized in regulations.

Clerks may not:

1. perform drug utilization reviews;

2. verify the accuracy of prescription data entered into the pharmacy's software system, the prescription itself, and the contents of a prescription label or container;

3. perform any task that requires professional pharmaceutical judgment; or

4. participate in order entry (generally, the process of entering prescription data into the pharmacy's software system).

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

The commissioner is authorized to establish regulations that include, among other things, creating additional requirements for clerk registration, the scope of clerks' professional authority, and the professional duties of clerks.

§ 4 — COMPLIANCE PACKAGING

The bill authorizes pharmacists and advanced pharmacy technicians to dispense to patients compatible drugs in compliance packaging, at the patient's or prescribing practitioner's request. Generally, compliance packaging is packaging prepared at a pharmacy that separates drugs into individual compartments by dose as prescribed to an individual patient.

Compliance packaging must:

1. only contain individual compartments that are tamper-proof and tamper-evident,

2. only contain drugs prescribed to a single patient by their prescribing practitioner and dispensed to that patient by a pharmacist or an advanced pharmacy technician,

3. be labeled or relabeled by a pharmacist under existing requirements,

4. be child-resistant unless the patient signs a waiver,

5. identify on each individual compartment the name and strength of the drug it contains,

6. not contain more than a 65-day supply of any drug, and

7. be compliant with the United States Pharmacopeia.

Reusable Components, Multiple Drugs, and Repackaging

The bill allows compliance packaging to contain reusable components and multiple drugs (for one patient) within individual compartments in the same package. It also allows an individual compartment to contain multiple drugs if (1) a pharmacist determines that the drugs are compatible (i.e., not contraindicated or adversely impacted by each other); (2) the drugs have the same instructions for the time between doses and none are to be taken on an as-needed basis; and (3) none of the drugs are controlled substances.

The bill allows a pharmacy that dispensed drugs in compliance packaging to remove dispensed drugs from the packaging and repack them in keeping with a modified prescription from the patient's prescribing practitioner. To repackage compliance packaging, a pharmacist must:

1. remove any drugs that the patient's prescribing practitioner has deprescribed or issued a new prescription for,

2. dispense the new prescribed compatible drugs in compliance packaging,

3. dispense the previously dispensed compatible drugs in compliance packaging,

4. label the new compliance packaging, and

5. never return any drug removed from compliance packaging into the pharmacy's general inventory.

The bill requires a pharmacist to return any drugs removed from compliance packaging to the patient in a separate container with instructions for proper use or disposal, as applicable (e.g., the location of the nearest pharmacy that accepts drugs for disposal).

Standard Operating Procedures

The bill requires pharmacies that provide compliance packaging services to maintain an area dedicated to that purpose and that contains the equipment necessary to ensure all compliance packaging is accurate and drug contaminant free.

The bill also requires these pharmacies to maintain a set of standard operating procedures for the use of compliance packaging and associated equipment that includes at least the following:

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

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

Requirement to Maintain Records

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

1. the patient's name and address;

2. the compliance package's identification number;

3. the date the package was prepared;

4. the initials of the individuals who prepared the packaging and performed the final check of it;

5. the drug's name, strength, lot number, and national drug code number;

6. the serial number of the prescription; and

7. a visual description of the dispensed drug.

The bill also requires these pharmacies to maintain a log of controlled substances that are removed from compliance packaging and returned to patients, and a separate log for removed and returned drugs that are not controlled substances. Each log must contain the:

1. patient's name,

2. compliance package's identification number,

3. serial number of the prescription,

4. date the drug was dispensed,

5. name and strength of the drug, and

6. quantity of the drug that was removed and returned to the patient.

The bill requires pharmacies to give DCP a copy of any drug removal logs within 48 hours of a request. The logs must be given in electronic form, or paper if electronic means is not available.

Regulations

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

§ 5 — CAUSES OF DISCIPLINE FOR PHARMACY PROFESSIONALS

The bill adds, to the reasons for which the state Pharmacy Commission may take disciplinary action against pharmacies or certain pharmacy personnel, that the person has accepted for return to the general inventory or regular stock any drug sold or delivered to a patient. 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

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

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

§ 9 — ORDERING AND ADMINISTRATION OF VACCINES

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

It allows them to order and 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 current law. It also specifically allows them to order and administer other vaccines that they may administer under current 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.

(Under temporary federal rules, pharmacists can also currently administer certain vaccines to children ages three and older.)

§ 10 — TASK FORCE ON UNANNOUNCED RETAIL PHARMACY CLOSURES

The bill establishes an 11-member task force to study the impact of unannounced retail pharmacy closures. The study must include an examination of available means to ensure patients are able to 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 by 30 days after the bill's passage 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 the first meeting, which must be held by 60 days after the bill's passage.

The General Law Committee's administrative staff serves in that capacity for the task force.

The task force must issue a report on its findings and recommendations to the General Law Committee no later than January 1, 2025. The task force terminates when it submits the report or on January 1, 2025, whichever is later.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 22 Nay 0 (03/07/2024)