OLR Bill Analysis

sSB 133 (File 89, as amended by Senate "A")*

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 (generally, packaging that separates drugs into individual compartments by dose) if they follow certain criteria. Pharmacies that provide compliance packaging are required to keep records with specific details of the drugs they dispense and who they dispense them to.

The bill 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 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 (unless otherwise allowed or required by law) 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.

The bill 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 authority to administer these vaccines, as well as COVID-19, influenza, and HIV tests.

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 pharmacist or other health care provider related to a past, current, or future medical condition or research-related purposes (§ 1).

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

*Senate Amendment "A" replaces the underlying bill. It makes several changes to the underlying provisions, such as (1) allowing pharmacists to delegate to advanced pharmacy technicians the final verification of prescriptions if certain requirements are met, (2) establishing initial application and renewal fees for advanced pharmacy technician designations and clerk registrations, (3) changing certain required procedures related to the redispensing of compliance packaging, (4) amending certain definitions, and (5) making numerous minor or clarifying changes. It also adds provisions on pharmacists delegating to advanced pharmacy technicians the authority to administer vaccines and COVID-19, influenza, and HIV tests.

EFFECTIVE DATE: October 1, 2024, except for (1) July 1, 2025, for a conforming change (§ 8), and (2) upon passage for the task force

provisions (§ 11).

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

The bill establishes the advanced pharmacy technician occupational category. It prohibits pharmacy technicians from performing the duties of this occupation 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 (in addition to the $100 technician registration 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 for an advanced pharmacy technician designation;

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 for an advanced pharmacy technician designation, 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 to be an advanced pharmacy technician (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 requirements; and

8. work under the direct supervision of a licensed pharmacist who satisfies certain requirements, or is supervised by a pharmacist

using electronic technology or telepharmacy capabilities, or in any manner approved by the commissioner or commission of pharmacy.

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 bill, a pharmacist that directly supervises an advanced pharmacy technician may delegate their authority to:

1. perform final verifications (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).

Under the bill, advanced pharmacy technicians may not present the results of COVID-19, influenza, and HIV-related tests to patients. Pharmacists may also not delegate to advanced pharmacy technicians 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

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 confirming accurate dispensing; and

2. keep the on-site ratio of advanced pharmacy technicians to pharmacists providing direct supervision at no more than 1:1, except if authorized by the DCP commissioner or the Commission of Pharmacy.

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

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 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 bill requires the DCP commissioner to adopt implementing regulations that, at minimum, 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 the duties of advanced pharmacy technicians.

§§ 3 & 7-8 — PHARMACY CLERKS

The bill establishes the clerk occupational category. It prohibits anyone from working in an area of a pharmacy where controlled substances or other legend 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. 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 on the matter (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 bill prohibits DCP from refusing to issue a clerk registration or reviewal 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 the direct supervision of a pharmacist, clerks are authorized to:

1. handle dispensed drugs and deliver those drugs to patients,
2. collect patient demographic information,
3. collect a prescription number for the purposes of a refill,
4. deliver a drug to an automated prescription dispensing machine or other care-giving area within a care-giving institution or within a correctional or juvenile training institution,
5. perform the duties of a cashier,
6. conduct inventory management,
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 regulations adopted by the DCP commissioner.

Clerks may not:

1. review any drug to determine if it is an appropriate treatment;
2. verify the accuracy of prescription data entered into an electronic data processing system used by a pharmacy, 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 electronic data processing 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.

For purposes of the bill's clerk registration and related requirements, an institutional pharmacy does not include patient care areas or automated prescription dispensing machines located outside of the pharmacy area.

§ 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 their representative) or prescribing practitioner's request. Generally, 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 bill, if a patient's prescribing practitioner modifies 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 their representative, (2) receive and remove any drugs contained in the compliance packaging 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 at the request of the patient or their representative or prescribing practitioner, and the pharmacy must document the change in writing.

The bill 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 packaging.

The bill requires each pharmacy that redispenses drugs contained 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 deprescribed, 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.

The bill prohibits the return to a pharmacy's general inventory or regular stock any returned drugs that were previously contained in compliance packaging returned to the pharmacy, unless otherwise permitted or required by law.

The bill 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 compliance packaging that contains an opioid drug must only have one sticker or label affixed to the compliance packaging),

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 the drug or drugs it contains,

6. not contain more than a 90-day supply of any drug (unless otherwise allowed by state or federal law), and

7. be compliant with the United States Pharmacopeia.

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

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 (1) ensure all compliance packaging is accurately prepared, (2) prevent contamination of drugs going into compliance packaging, and (3) maintain standard operating procedures.

The bill 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 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.

Requirement to Maintain Records

The bill requires pharmacies that provide compliance packaging services to maintain a log (record) of drugs that the pharmacy dispenses to a patient in this packaging. That 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 serial number of the prescription; and

7. a visual description of the dispensed drug.

The bill 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. identification number of the compliance packaging, 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 of the compliance package; and

5. name, formulation, and quantity of each drug contained in the compliance package when it was accepted for return and redispensing, including a designation of any drugs in the compliance package that have been deprescribed.

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

1. patient's name and address;

2. identification number of the compliance packaging, 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. name or initials of the redispensing pharmacist;

7. initials of the individual who prepared the compliance packaging

for redispensing; and

8. initials of the individual who performed a final verification of the compliance packaging for redispensing.

The bill 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. serial number of the prescription;

4. name, formulation, and quantity of the drug that was redispensed; and

5. name or initials of the redispensing pharmacist.

The bill requires each pharmacy to keep all records required by this section for at least three years. Pharmacies must give DCP any of these records within 48 hours of a request. The records 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 (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

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 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 current law. Existing law, unchanged by the bill, requires pharmacy technicians to be under the direct supervision of a pharmacist when helping with the dispensing of drugs or devices (CGS § 20-613(c)).

The bill 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 the legal guardian's consent (or who are emancipated minors). The bill authorizes pharmacists to order, prescribe, 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 to adult patients 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.)

Additionally, the bill allows pharmacists to delegate their authority to administer these vaccines to advanced pharmacy technicians, so long as the technicians administer them (1) under the pharmacist's direct supervision and (2) in accordance with related state law and regulations.

It correspondingly authorizes the DCP commissioner to amend existing regulations on pharmacists' vaccine administration to establish additional requirements related to their delegation of 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 bill allows pharmacists to delegate responsibility for administering COVID-19, influenza, and HIV tests (see BACKGROUND) to advanced pharmacy technicians if the technicians (1) completed 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 bill prohibits pharmacists from delegating to advanced pharmacy technicians responsibility for giving patients their written test results from COVID-19, influenza, or HIV tests that the pharmacists, or their technicians, administer. As under current law, pharmacists must also maintain a record of the written test results for at least three years and notify the (1) patient's primary care provider, if the patient identifies one, and (2) local health director for the area in which the patient lives and DPH, in the same way as required for reportable diseases. Pharmacists must also disclose the results to the DCP

commissioner or his designee, upon request.

Under current law, 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 bill correspondingly allows the pharmacist to do this when a negative test is administered by an advanced pharmacy technician under his or her direct supervision.

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

§ 11 — 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 within 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 within 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.

BACKGROUND

Pharmacists Administering COVID-19, Influenza, and HIV Tests

Existing law allows pharmacists to order and administer COVID-19 and influenza tests if they are employed by a (1) hospital or (2) pharmacy that has specified DPH-approved certification for these tests. They may do so for any patient age 18 or older. For patients who are ages 12 to 17, they may only do so with (1) the consent of the patient's parent, legal, guardian, or other person having legal custody or (2) proof that the patient is an emancipated minor.

Additionally, after DCP adopts regulations on HIV testing and prophylaxis required under existing law, pharmacists may also order and administer HIV-related tests, under substantially similar conditions that apply to COVID-19 and influenza testing (e.g., they must work for a qualifying pharmacy and cannot test children under age 12) (CGS § 20-633f).

COMMITTEE ACTION

General Law Committee

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