
OLR Bill Analysis

sSB 1102

AN ACT CONCERNING PHARMACIES AND PHARMACISTS.

SUMMARY

This bill makes changes in the laws concerning pharmacists and consumer access to medications. Specifically, it:

1. establishes a licensing process for institutional pharmacies located in health care facilities (e.g., hospitals) to compound sterile pharmaceuticals and sell them at retail;
2. allows pharmacists to order and administer tests for COVID-19, HIV, and influenza;
3. allows pharmacists to prescribe and dispense HIV-related prophylaxis if a patient tests negative after a pharmacist-administered HIV test;
4. expands the vaccine types that pharmacists can administer;
5. allows pharmacists to administer an epinephrine cartridge injector to someone experiencing anaphylaxis;
6. allows pharmacies to operate mobile pharmacies in temporary locations with the Department of Consumer Protection's (DCP) approval;
7. requires pharmacies to maintain a plan to manage unscheduled closings and specifies actions that can and must be taken during these closures; and
8. requires DCP to adopt regulations on prescription pickup lockers at pharmacies, but allows for their use before the regulations are adopted under specified circumstances.

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

EFFECTIVE DATE: July 1, 2023

**§§ 1 & 6-16 — HEALTH CARE INSTITUTIONAL PHARMACIES’
STERILE COMPOUNDING**

The bill establishes a process to allow institutional pharmacies located in licensed healthcare facilities (“health care institutional pharmacies”) to compound sterile pharmaceuticals for retail sale and subjects them to the same requirements that apply to other retail pharmacies compounding sterile pharmaceuticals. Under current law, health care institutional pharmacies (1) are generally not licensed as pharmacies and (2) do not compound sterile pharmaceuticals for retail sale. The bill authorizes DCP to adopt regulations creating a class or classes of pharmacy licenses specifically for health care institutional pharmacies. It also explicitly authorizes health care institutions to apply for a pharmacy license, subject to the same existing licensure requirements as pharmacists and others applying for a license.

Sterile Compounding for Retail Sales

Under existing law, if a pharmacy licensee intends to compound sterile pharmaceuticals, it must seek DCP’s approval by applying for an addendum to its pharmacy license application and submitting to a DCP inspection. The bill requires a health care institutional pharmacy that wants to sell compounded sterile pharmaceuticals at retail to obtain a pharmacy license and similarly apply for an addendum and undergo an inspection.

By deeming health care institutional pharmacies that compound sterile pharmaceuticals for retail sale “sterile compounding pharmacies,” the bill also subjects them to the same requirements that apply to other retail pharmacies (e.g., required notices to DCP), including requirements adopted by regulation.

Compounding for Non-Retail Uses

Under current law, if an institutional pharmacy within a licensed health care facility compounds sterile pharmaceuticals, it does not need

to apply for DCP approval, but like other sterile compounding pharmacies, it must comply with applicable state, federal, and U.S. Pharmacopeia standards, unless it receives a temporary extension to do so. The bill generally eliminates provisions in law regulating these institutional pharmacies' compounding of sterile pharmaceuticals and specifies that the law on retail sterile compounding pharmacies does not prohibit a licensed hospital from compounding sterile pharmaceuticals for its patients consistent with federal law. In doing so, it also eliminates provisions specifically requiring institutional pharmacies to (1) prepare and maintain a policy and procedure manual and (2) inform DCP which pharmacist is responsible for overseeing the compounding of sterile pharmaceuticals.

§§ 2 & 5 — EXPANDING PHARMACISTS' SCOPE OF PRACTICE

The bill expands pharmacists' scope of practice by authorizing them to (1) administer additional vaccinations and epinephrine cartridge injectors (§ 5); (2) order and administer COVID-19, HIV, and influenza related tests (§ 2); and (3) prescribe HIV-related prophylaxis if an HIV test they ordered and administered comes back negative (§ 2).

Vaccinations

By law, pharmacists who comply with DCP regulations on vaccine administration training may administer to adults any approved vaccine on the Centers for Disease Control and Prevention's (CDC) adult immunization schedule. Currently, for children ages 12-17, they may administer an influenza vaccine ordered by a health care provider if they have the parent or guardian's consent. (Additionally, under temporary federal rules (see BACKGROUND), pharmacists can currently administer various vaccines to children ages 3 and older.)

The bill permanently expands the types of vaccines pharmacists can administer to people ages 12 or older. Under the bill, they must be administered in compliance with DCP regulations and according to the manufacturer's package insert or a prescribing practitioner's (e.g., doctor or APRN) orders. Specifically, the bill allows pharmacists to additionally administer any vaccine:

1. on the adult immunization schedule and authorized by the FDA,
2. not on the adult immunization schedule but for which the vaccine administration instructions are available on the CDC's website, or
3. prescribed by a prescribing practitioner for a specific patient.

Under the bill, pharmacists can administer vaccines to any patient ages 18 or older. For patients who are ages 12-17, 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. For current law's limits on influenza vaccines for minors, the bill correspondingly (1) eliminates the requirement that an influenza vaccine only be administered if ordered by a health care provider and (2) aligns the parameters on consent with those described above for other vaccines under the bill.

Before administering a vaccine, the pharmacist must make a reasonable effort to review the patient's vaccination history to prevent a requested vaccine's inappropriate use.

Under existing law, DCP must adopt regulations requiring that pharmacists administering vaccines complete an immunization training course. The bill correspondingly extends this training requirement to pharmacists administering the additional vaccines the bill allows pharmacists to administer.

Administering Epinephrine

If a pharmacist has taken the training required to administer a vaccine (see above), the bill allows him or her to administer an epinephrine cartridge injector to a patient reasonably believed, based on the pharmacist's knowledge and training, to be experiencing anaphylaxis. This authorization applies regardless of whether the patient has a prescription for an epinephrine cartridge injector.

The pharmacist or his or her designee must call 9-1-1 either before or immediately after administering the epinephrine cartridge injector. The

pharmacist must also document the date, time, and circumstances in which he or she administered it, and maintain the documentation for at least three years.

COVID-19, HIV, and Influenza Testing

Under temporary federal rules, pharmacists can currently order and administer COVID-related tests. The bill permanently allows pharmacists to order and administer COVID-19, HIV, and influenza related tests if they are employed by a:

1. hospital or
2. pharmacy that has given the Department of Public Health (DPH) a complete clinical laboratory improvement amendment application for certification for a COVID-19, HIV, or influenza related test.

They may do so for any patient ages 18 or older. For patients who are at least age 12, but younger than 18, 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.

When pharmacists order and administer a test, they must give the patient the test results in writing and maintain a record of them for at least three years.

Prescribing HIV Prophylaxis

If a pharmacist orders and administers an HIV-related test and the result is negative, the pharmacist may prescribe and dispense to the patient pre-exposure or post-exposure HIV-related prophylaxis. The pharmacist may do so only if the (1) patient meets the criteria on the package insert and (2) prophylaxis is prescribed and dispensed in conformity with the state's pharmacy laws.

Sharing Test Results and HIV Prophylaxis Information With DCP

Upon the DCP commissioner or his or her designee's request, a pharmacist must share the results of a COVID-19, HIV, or influenza related test with DCP. Similarly, if a pharmacist prescribes HIV-related

prophylaxis, DCP may request a copy of the test results, prescription records, and any other documents the commissioner requires by regulations. (Presumably, the regulations DCP must adopt, as described below, will address applicable privacy laws.)

Regulations Related to Testing and HIV Prophylaxis Prescribing

The bill requires the DCP commissioner, in consultation with the DPH commissioner and Commission of Pharmacy, to adopt regulations to implement the bill's testing and prescribing authorizations. The regulations must (1) identify qualifying training programs accredited by the CDC, the Accreditation Council for Pharmacy Education, or another appropriate national accrediting body and (2) establish a control and reporting system.

§ 3 — OPERATING MOBILE PHARMACIES

The bill allows retail pharmacies to apply to DCP for permission to operate a mobile pharmacy that offers (1) temporary clinics, vaccination events, or opioid antagonist training and prescribing events or (2) pharmacy services to an underserved community. DCP sets the application form and must approve it, in writing, before a mobile pharmacy can operate. DCP may inspect the mobile pharmacy as it finds necessary, including before it begins operations.

With the advice and consent of the Commission of Pharmacy, the DCP commissioner may adopt regulations to implement the bill's mobile pharmacy provisions.

Operational Requirements

Unless DCP approves an exception, mobile pharmacies cannot (1) operate in one place for more than seven consecutive days, (2) operate for more than 14 days within a five-mile radius of the prior mobile pharmacy location, or (3) serve as an overnight storage space for drugs.

Mobile pharmacies must be supervised by a pharmacist. The pharmacy that operates them must:

1. keep records indicating which drugs it removes from the pharmacy premises for use in the mobile pharmacy and which

- ones it dispenses;
2. update the pharmacy's records within 24 hours after dispensing a drug through a mobile pharmacy;
 3. inventory and return unused drugs to the pharmacy premises by the close of business each day unless DCP waives the bill's prohibition on storing drugs in the mobile pharmacy overnight;
 4. store drugs in a way that prevents diversion, and meets the storage conditions specified by drugs' manufacturers;
 5. establish and maintain a patient communication plan to ensure patient access to prescription refills if the mobile pharmacy is unavailable; and
 6. store and handle controlled substances in conformity with DCP regulations, if the FDA allows mobile pharmacies to store controlled substances.

DCP may order a mobile pharmacy to close if it determines that (1) it failed to comply with the bill's requirements, (2) it is unsafe to store drugs in it or dispense them from it, or (3) there is insufficient security.

§ 4 — UNSCHEDULED PHARMACY CLOSURES AND PRESCRIPTION PICKUP LOCKERS

The bill creates rules for pharmacies when they face an unscheduled closure (which the bill does not define), including customer and prescriber notification and planning requirements. It requires DCP to adopt regulations to (1) implement the bill's provisions on unscheduled pharmacy closures and (2) allow and regulate prescription pickup lockers (see below).

Plan's Contents

The bill requires retail pharmacies to have a plan to manage unscheduled closings and annually review and update it. The plan must also be given to and reviewed with all pharmacy personnel annually.

The plan must include the name of:

1. the person responsible for notifying the Commission of Pharmacy about an unscheduled closing;
2. the person responsible for updating the operation hours in the pharmacy's electronic record system so that it will not accept electronically transmitted prescriptions during the unscheduled closing;
3. the person responsible for updating the pharmacy's telephone system during an unscheduled closing to (a) ensure orally transmitted prescriptions are not accepted during the unscheduled closing and (b) provide a message that alerts patients to the closure and their ability to obtain their prescriptions from a nearby pharmacy;
4. all pharmacies located within a two-mile radius, or the next closest pharmacy if there is no pharmacy within that radius; and
5. the person responsible for posting a sign stating the closure's duration at the pharmacy's entrance and at each entrance of the structure containing it, if any.

Requirements During Unscheduled Closing

When a pharmacy experiences an unscheduled closing, the pharmacist manager of the pharmacy or, if the pharmacy operates more than five pharmacy locations in Connecticut, the pharmacy district manager must:

1. modify the pharmacy's operating hours in its pharmacy's electronic record system to prevent accepting electronically transmitted prescriptions during the unscheduled closing;
2. adjust the pharmacy's telephone system to prevent accepting orally transmitted prescriptions during the unscheduled closing;
3. provide a telephone system message alert to patients notifying them that the pharmacy is closed and they may obtain medications from a nearby pharmacy;

4. post signs at the pharmacy's entrance, and at each entrance of the structure if the pharmacy is located within another structure, stating that the pharmacy is closed, the duration of the unscheduled closing, and providing (a) a list of all pharmacies within a two-mile radius or (b) the next closest pharmacy if there is no pharmacy within a two-mile radius; and
5. on the request of another pharmacy, transfer a prescription and reverse any third-party payor claims associated with the already dispensed prescription.

Under the bill, the "pharmacy district manager" is the person who supervises at least three Connecticut pharmacies and is responsible for their activities, including staffing, payroll, and hiring.

Dispensing Prescriptions That Are Awaiting Pickup at a Closed Pharmacy

If a pharmacy verifies that another pharmacy is experiencing an unscheduled closing, on a patient's request, it may dispense a prescription that is dispensed and waiting for pickup at the closed pharmacy. It may do so using information from the closed pharmacy, the electronic prescription drug monitoring program, or another source that the pharmacist believes is reasonably accurate. If a prescription is dispensed under these circumstances, the dispensing pharmacy must contact the closed pharmacy within 24 hours after it reopens to transfer the prescription.

Under the bill, these transfers are subject to existing requirements for prescription transfers, which generally require the:

1. transferring pharmacist to cancel the original prescription in his or her records and indicate in the records the pharmacy to which the prescription is transferred and transfer date and
2. receiving pharmacist to indicate in his or her records the (a) transfer and the transferring pharmacy and pharmacist's names, (b) original prescription's issue date and number, (c) date the original prescription was first dispensed, (d) number of refills

authorized by the original prescription and complete refill record as of the transfer date, and (e) number of valid refills remaining as of the transfer date.

The bill requires the pharmacy that experienced the unscheduled closure to give the dispensing pharmacy all information necessary for the transfer. It must also reverse any third-party payor claims associated with the transferred prescription within 24 hours after it reopens.

Secure Prescription Pickup Lockers

The bill requires DCP to adopt regulations on unscheduled pharmacy closures and include provisions on placing a “secured container” at a pharmacy that allows patients to collect dispensed prescriptions (prescription pickup lockers).

Before adopting the regulations, DCP may temporarily allow the use of prescription pickup lockers. Pharmacies must first submit protocols on using these lockers to DCP for its written approval. They may only be approved if the lockers:

1. (a) weigh more than 750 pounds or are affixed to the pharmacy building’s structure and (b) are located immediately adjacent to the pharmacy’s location;
2. limit access to authorized pharmacy personnel and individuals retrieving prescriptions with a unique identification system;
3. are under constant video surveillance;
4. are able to maintain a record of all products placed inside and the date and time each individual prescription is accessed; and
5. comply with any other DCP protocols ensuring patient confidentiality, protecting public health and safety, and preventing prescription diversion.

BACKGROUND

Federal PREP Act and Pharmacists’ Administration of Vaccines

The federal Public Readiness and Emergency Preparedness Act

authorizes the federal Health and Human Services (HHS) secretary to issue declarations protecting certain covered persons from liability related to the administration or use of medical countermeasures (42 U.S.C. § 247d-6d). Under this authority, the HHS secretary issued a declaration authorizing state-licensed pharmacists, under certain criteria, to (1) order and administer vaccinations to minors ages 3 and older and (2) order and administer COVID-19 tests.

Related Bill

sHB 6788, favorably reported by the General Law Committee, (1) establishes a new DCP registration for dispensing group practices and dispensing assistants that dispense prescriptions directly to patients, (2) authorizes pharmacists to refill prescriptions for certain legend devices; (3) authorizes pharmacists to prescribe emergency or hormonal contraception, (4) expands reasons for enforcement action against a pharmacy to include delaying patients' access to prescribed drugs or other pharmacy services, and (5) makes minor changes to laws related to compounding pharmaceuticals.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute

Yea 16 Nay 7 (03/09/2023)