



PA 23-19—sSB 1102
General Law Committee

AN ACT CONCERNING PHARMACIES AND PHARMACISTS

SUMMARY: This act makes changes in the laws on pharmacists and consumer access to medications. Specifically, it:

1. creates 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 and allows pharmacy technicians to administer vaccines;
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;
8. requires DCP to adopt regulations on prescription pickup lockers at pharmacies, and allows for their use before the regulations are adopted under specified circumstances; and
9. requires the Department of Public Health (DPH) to establish and contract for a statewide program providing HIV pre- and post-exposure prophylaxis drug assistance, if there is specified funding for it (in doing so, the act replaces an existing, narrower program).

The act also makes minor, technical, and conforming changes (§§ 9-16).

EFFECTIVE DATE: July 1, 2023, except the HIV prophylaxis drug program provision is effective upon passage.

§§ 1 & 6-8 — HEALTH CARE INSTITUTIONAL PHARMACIES’ STERILE COMPOUNDING

The act establishes a process to allow institutional pharmacies located in licensed health care 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 prior law, health care institutional pharmacies (1) were generally not licensed as pharmacies and (2) could not compound sterile pharmaceuticals for retail sale. The act authorizes DCP to adopt regulations creating a class or classes of pharmacy

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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 wants to compound sterile pharmaceuticals, it must seek DCP's approval by applying for an addendum to its pharmacy license application and submit to a DCP inspection. The act 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 act 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 prior law, an institutional pharmacy within a licensed health care facility did not need to apply for DCP approval to compound sterile pharmaceuticals. But like other sterile compounding pharmacies, it had to comply with applicable state, federal, and U.S. Pharmacopeia standards, unless it received a temporary extension to do so. The act 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 — EXPANDED SCOPE OF PRACTICE

The act expands pharmacists' scope of practice by authorizing them to (1) administer additional vaccines 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). It also allows pharmacy technicians meeting certain criteria to administer the same vaccines as pharmacists (§ 5).

Pharmacists' Administration of Vaccines

By law, pharmacists who comply with DCP regulations on vaccine administration training may administer to adults any approved vaccine on the

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Centers for Disease Control and Prevention's (CDC) adult immunization schedule, if ordered by a health care provider. Under prior law, for children ages 12 to 17, they could administer an influenza vaccine ordered by a health care provider if they had the parent's or guardian's consent. (Under temporary federal rules, pharmacists can also currently administer various vaccines to children ages three and older (see BACKGROUND).)

The act permanently expands the types of vaccines pharmacists can administer to people ages 12 or older. It also eliminates the requirement that a pharmacist-administered vaccine only be administered if ordered by a health care provider. Under the act, vaccines 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 an advanced practice registered nurse) orders. Specifically, the act allows pharmacists to additionally administer any vaccine:

1. on the adult immunization schedule and authorized by the U.S. Food and Drug Administration (FDA) (prior law only permitted administration of approved vaccines; the FDA sometimes issues emergency authorizations for vaccines before full approval);
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 act, pharmacists can administer vaccines to any patient ages 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. The act correspondingly aligns the law on consenting to influenza vaccines for minors with these requirements.

The act requires the pharmacist, before administering a vaccine, to 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 act correspondingly extends this training requirement to pharmacists administering the additional vaccines the act allows them to administer.

Pharmacy Technicians' Administration of Vaccines

The act extends to registered and certified pharmacy technicians the authority to administer the same vaccines that pharmacists can administer (see above). (Under temporary federal rules, pharmacy technicians may already administer certain vaccines (see BACKGROUND).)

Under the act, a pharmacy technician can administer vaccines if the technician:

1. successfully completes (a) a course, certified by the American Council for Pharmacy Education, of hands-on training on vaccine administration and (b) at least one hour of annual continuing education on immunization;
2. received training at their employing pharmacy on the process for administering vaccines to patients and was evaluated by the managing pharmacist (who must be authorized to administer vaccines); and

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3. only administers vaccines at the direction of the pharmacist on duty.

The act also specifies that each year, from September 1 through the following March 31, a certified and registered pharmacy technician does not count toward the minimum pharmacist-to-technician ratio set in regulations if the technician is authorized to administer vaccines under the act and exclusively performs duties related to administering vaccines during that period.

Pharmacists' Administration of Epinephrine

If a pharmacist has taken the training required to administer a vaccine (see above), the act 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 by Pharmacists

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

1. hospital or
2. pharmacy that has a DPH-approved complete clinical laboratory improvement amendment application for certification for a COVID-19 or influenza test.

They may do so for any patient aged 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. The act specifies that pharmacists working outside a hospital must comply with any training requirements DCP sets.

HIV Testing. After DCP adopts regulations on HIV testing and prophylaxis (see below), pharmacists may 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). The act specifies that pharmacists working outside a hospital must comply with any training requirements set in regulation.

Pharmacists 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- or post-exposure HIV-related prophylaxis. The pharmacist may do so only if (1) he or she

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completed the training required by regulations (see below), (2) the patient meets the criteria on the package insert, and (3) prophylaxis is prescribed and dispensed in conformity with the state's pharmacy laws and related regulations.

Disclosure of Test Results and Prophylaxis Prescriptions

Under the act, when pharmacists administer a COVID-19, influenza, or HIV test, they must give the patient written test results and maintain a record of them for at least three years. They must also 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. 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.

Confidentiality. The act requires any information disclosed by a pharmacist to DCP under the act or related regulations to be kept confidential, regardless of any conflicting provisions in the Freedom of Information Act. The act limits DCP's use of the information to performing its pharmacy law-related enforcement duties.

If DCP brings an enforcement action and in it uses any information the act makes confidential, the act allows DCP to disclose it to the parties to the action only if required by applicable law. Further disclosure is prohibited, except to a tribunal, the Commission of Pharmacy, an administrative agency, or the court with jurisdiction. These entities must ensure that the information is subject to a qualified protective order, as defined by the federal Health Insurance Portability and Accountability Act (HIPAA) (i.e., ensure information cannot be used for other purposes and must be returned or destroyed at the end of the proceeding).

Regulations Related to Testing and HIV Prophylaxis Prescribing

The act requires the DCP commissioner to adopt regulations to implement the act's testing and prescribing authorizations. In doing so, he must consult with the DPH commissioner, the Commission of Pharmacy, a statewide professional society representing the interests of physicians practicing medicine in Connecticut, and a statewide organization representing the interests of health care professionals and scientists specializing in the control and prevention of infectious diseases. The regulations must:

1. ensure compliance with all applicable CDC guidance;
2. ensure that HIV-related prophylaxis is prescribed and dispensed in accordance with its FDA approval;
3. establish permissible administration routes;
4. establish prescription duration limits of up to 60 days for any pre-exposure prophylaxis and 30 days for any post-exposure prophylaxis;
5. specify how frequently a pharmacist must treat a patient and when the patient must be referred to his or her primary care provider or other identified health care provider;

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6. specify circumstances in which a pharmacist must recommend that a patient undergo screenings for sexually transmitted infections other than HIV;
7. establish requirements on private areas for consultations between pharmacists and patients;
8. establish training requirements on (a) how to obtain a patient's complete sexual history, (b) delivering a positive HIV-related test result to a patient, (c) referring a patient who has tested positive for HIV to available services, and (d) using HIV-related prophylaxes for patients who have tested negative;
9. identify qualifying training programs accredited by the CDC, the Accreditation Council for Pharmacy Education, or another appropriate national accrediting body; and
10. establish a control and reporting system.

§ 3 — OPERATING MOBILE PHARMACIES

The act allows retail pharmacies to apply to DCP for permission to operate a mobile pharmacy that (1) conducts temporary pharmacy operations, vaccination events, or opioid antagonist training and prescribing events or (2) offers 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 needed, including before it begins operations.

With the Commission of Pharmacy's advice and consent, the DCP commissioner may adopt regulations to implement the act'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. A pharmacy that operates one must:

1. keep records on 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 the mobile pharmacy;
3. inventory and return unused drugs to the pharmacy premises by the close of business each day unless DCP waives the act'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 the 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,

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if the federal Drug Enforcement Administration allows mobile pharmacies to store controlled substances.

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

§ 4 — UNSCHEDULED PHARMACY CLOSURES AND PRESCRIPTION PICKUP LOCKERS

The act creates rules for pharmacies when they face an unscheduled closure, including customer and prescriber notification and planning requirements. It requires DCP to adopt regulations to (1) implement the act's provisions on unscheduled pharmacy closures and (2) allow and regulate prescription pickup lockers (see below).

Plan's Contents

The act requires retail pharmacies to have a plan to manage unscheduled closings and annually review and, if necessary, 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 electronic record system to prevent accepting electronically transmitted prescriptions during the unscheduled closing;

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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 act, 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 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 act, 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 act requires the pharmacy that experienced the unscheduled closure to give the dispensing pharmacy all information needed 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 act 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).

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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. can 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.

§ 17 — HIV PROPHYLAXIS DRUG ASSISTANCE PROGRAM

The act requires DPH to establish and contract for a statewide program providing HIV pre- and post-exposure prophylaxis (PrEP and PEP) drug assistance, as long as there is at least \$25,000 of annual AIDS service funding for it. The act's program replaces an existing, narrower program providing \$25,000 in annual PEP funding for certain under- or uninsured sexual assault victims.

The new program must give financial assistance to people at risk of acquiring HIV to help pay for these medications. This may include, among other things, (1) payments for copayments, coinsurance, or other out-of-pocket costs and (2) up to full cost payments toward deductibles for people who are underinsured and for whom the program is the payer of last resort.

DPH must give priority to people at increased risk of acquiring HIV or who have had a recent exposure, but cannot purchase PrEP or PEP medication and for whom the program is a payer of last resort.

Similar to the existing, program, medications funded under the act must be prescribed by a physician and consistent with the CDC's recommendations.

The act allows the DPH commissioner to adopt implementing regulations. She may also implement necessary policies and procedures to administer the program, as long as she posts her intent to adopt regulations in the eRegulations System within 20 days after their implementation. The policies and procedures remain in effect until the regulations are adopted.

BACKGROUND

Federal PREP Act and 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 declarations authorizing (1) state-licensed pharmacists, under

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certain criteria, to order and administer (a) vaccinations to minors ages three and older and (b) COVID-19 tests and (2) pharmacy technicians to administer certain vaccinations under a pharmacist's supervision. (HHS recently issued guidance stating that it plans to extend specified authority under these provisions through 2024.)

PrEP and PEP

According to the CDC, PrEP is a way for people with substantial risk of contracting HIV to lower that risk by taking specified medication as either a daily pill or an injection every two months. When someone is exposed to HIV these medications can prevent the virus from causing a permanent infection.

PEP is the use of antiretroviral medications to lower the risk of contracting HIV after a single high-risk potential exposure. For maximum effectiveness, it should be taken as soon as possible after the exposure and must be taken within 72 hours.