OLR Bill Analysis

sHB 6768 (as amended by House "A")*

AN ACT CONCERNING THE DEPARTMENT OF CONSUMER PROTECTION'S RECOMMENDATIONS REGARDING PRESCRIPTION DRUG REGULATION.

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§ 13 — MEDICAL MARIJUANA CERTIFICATION VIA TELEHEALTH

Indefinitely permits providers to certify medical marijuana patients and provide follow-up care via telehealth

BACKGROUND

SUMMARY

This bill makes various changes related to the practice of pharmacy and access to medications. Among other things, it:

1. establishes a new Department of Consumer Protection (DCP) registration for dispensing group practices and dispensing assistants that dispense prescriptions directly to patients instead of through pharmacies,

2. authorizes pharmacists to dispense emergency or hormonal contraception to patients under certain conditions,

3. allows businesses to operate vending machines selling over-the-counter (OTC) medications if they obtain a DCP permit, and

4. allows prescribing practitioners and pharmacists to work with various entities to increase the public's access to opioid antagonists.

*House Amendment "A" eliminates provisions in the underlying bill that (1) required a pharmacist who morally or ethically opposed prescribing emergency or hormonal contraception to provide patients with nearby pharmacies that may prescribe them, (2) specifically required prescribing practitioners who compound the prescriptions they dispense to their patients to comply with applicable provisions in the United States Pharmacopeia on compounding, and (3) expanded the statutory reasons the Commission of Pharmacy can take enforcement action against a pharmacy business to include issues related to unsafe conditions and practices and delayed patient access to prescribed drugs.

EFFECTIVE DATE: Upon passage, except the provision creating a new DCP registration for dispensing group practices and dispensing

assistants (§ 1) is effective January 1, 2024.

§ 1 — REGISTRATION FOR DISPENSING GROUP PRACTICES AND ASSISTANTS

Establishes a new DCP registration for dispensing group practices and dispensing assistants that dispense prescriptions directly to patients instead of through pharmacies; establishes related registration and advertising requirements and disciplinary actions

The bill establishes a new DCP registration for "dispensing group practices" that dispense legend drugs or devices directly to patients instead of through pharmacies.

Under the bill, a "dispensing group practice" is a group practice with two or more physicians that dispenses legend drugs or devices prescribed by prescribing practitioners the practice employs or affiliates with. It dispenses the drugs or devices through either a (1) centralized dispensing practitioner or (2) pharmacist it employs.

A "centralized dispensing practitioner" is a prescribing practitioner the dispensing group practice employs or affiliates with that it designates as the prescribing practitioner authorized to dispense legend drugs and devices on behalf of the practice's other prescribing practitioners.

"Legend drugs" and "legend devices" are those that federal or state law requires to be dispensed by prescription or that federal law requires to bear one of two specialized labels stating that federal law prohibits dispensing without a prescription or a veterinarian's order.

DCP Registration

The bill prohibits a group practice from dispensing legend drugs or devices as a dispensing group practice unless it gets a DCP registration.

A group practice must apply to DCP as the department prescribes and designate a centralized dispensing practitioner or pharmacist it employs to be DCP's primary contact.

The bill establishes an initial and renewal registration fee of $200 and requires renewal every two years.

Prescription Drug Monitoring Program Registration

The bill requires dispensing group practices that dispense, or propose to dispense, more than a 72-hour supply of a legend drug or device to (1) register for access to the state's electronic prescription drug monitoring program and (2) comply with the program's reporting and usage requirements.

Under the bill, dispensing group practices are exempt from this registration requirement if they (1) dispense, or propose to dispense, less than a 72-hour supply of a legend drug or device and (2) only dispense them as professional samples.

Pharmacy License

Under the bill, a dispensing group practice that employs a pharmacist to dispense legend drugs or devices is not required to get a pharmacy license for the practice's premises.

The bill requires the pharmacist to directly report to a prescribing practitioner the group practice employs or is affiliated with. The pharmacist may also (1) supervise dispensing assistants the group practice employs, (2) perform in-process and final checks without getting any additional verification from the prescribing practitioner, and (3) perform any component of pharmacy practice.

Dispensing Assistant Registration

The bill establishes a new registration for dispensing assistants and prohibits anyone from acting as a dispensing assistant unless they obtain a DCP registration. It establishes an initial and renewal registration fee of $100 and requires renewal every two years.

Under the bill, a registered dispensing assistant employed by a dispensing group practice may perform the duties of a pharmacy technician, if he or she is under the supervision of a (1) prescribing practitioner the practice employs or affiliates with or (2) pharmacist the practice employs.

Dispensing assistants are subject to the same responsibilities and liabilities in state law and regulation that apply to pharmacy

technicians.

Prescribing Practitioners

The bill permits a prescribing practitioner employed by, or affiliated with, a dispensing group practice to dispense legend drugs or devices to his or her patients without using a centralized dispensing practitioner or pharmacist employed by the practice.

It also prohibits a centralized dispensing practitioner or pharmacist employed by a dispensing group practice from dispensing, or ordering the dispensing of, a legend drug or device or a controlled substance for a person who is not being treated by one of the practice's prescribing practitioners.

It similarly prohibits a dispensing group practice from accepting or dispensing a prescription from a prescribing practitioner it does not employ or affiliate with.

Advertising

The bill prohibits a dispensing group practice from exhibiting inside or outside of its premises or including in any of its advertising (1) the words "drug store," "pharmacy," "apothecary," or "medicine shop," or any combination of these, or (2) any other display, symbol, or word indicating that the dispensing group practice or its premises is a pharmacy.

Disciplinary Action

The bill authorizes DCP to take the following disciplinary actions against a dispensing group practice or dispensing assistant:

1. deny an initial or renewal registration;

2. revoke, suspend, or place conditions on a registration; and

3. assess a civil penalty of up to $1,000 per violation.

The department may take these actions if the dispensing group practice or a centralized dispensing practitioner, dispensing agent, or pharmacist employed by, or acting on behalf of, the group practice

violates the bill's provisions or state pharmacy laws or regulations on dispensing legend drugs or devices.

§ 2 — PHARMACISTS' AUTHORITY TO DISPENSE LEGEND DEVICES

Authorizes pharmacists to refill prescriptions for legend devices approved to be used in combination with prescription medications; establishes related notification requirements

The bill authorizes pharmacists to refill a prescription for a legend device if the device is approved by the federal Food and Drug Administration for combined use with a drug a prescribing practitioner prescribes to a patient.

A pharmacist who does so must identify the prescribing practitioner who prescribed the drug associated with the legend device and notify the practitioner in writing, within 72 hours of the dispensing, disclosing that the pharmacist dispensed the legend device to the patient.

Under existing law, unchanged by the bill, a "legend device" is one that federal or state law requires to be dispensed by prescription or that federal law requires to bear one of two specialized labels stating that federal law prohibits dispensing without a prescription or a veterinarian's order.

§ 3 — PHARMACISTS' AUTHORITY TO PRESCRIBE EMERGENCY AND HORMONAL CONTRACEPTION

Authorizes pharmacists to dispense emergency or hormonal contraception to patients under certain conditions

The bill authorizes pharmacists to prescribe, in good faith, emergency or hormonal contraception to a patient if the pharmacist completes the actions listed below before doing so.

It also allows DCP to adopt implementing regulations.

Educational Training Program

Under the bill, the pharmacist must complete an educational training program that does the following:

1. covers prescribing emergency and hormonal contraceptives by pharmacists;

2. addresses appropriate patient medical screenings, contraindications, drug interactions, treatment strategies, and modifications, and when to refer patients to medical providers; and

3. is accredited by the Accreditation Council for Pharmacy Education.

Document Review

The bill requires the pharmacist to review the most current version of the federal Centers for Disease Control and Prevention's (CDC) U.S. Medical Eligibility Criteria for Contraceptive Use, or any successor document, before prescribing emergency or hormonal contraception. If the pharmacist deviates from this document's guidance, the bill requires that the pharmacist document his or her rationale for doing so.

Screening Document

Under the bill, the pharmacist must complete a screening document (presumably, for a patient) prior to dispensing emergency or hormonal contraception, and at least annually after that for a returning patient.

DCP must make the screening document available on its website. The pharmacist, or the pharmacy he or she works for, must keep the document for at least three years. The pharmacy must also make the document available to DCP for inspection, upon request.

The bill explicitly states that it does not prevent the pharmacist, in his or her professional discretion, from (1) requiring more frequent screenings or (2) issuing a prescription for hormonal contraception for up to 12 months.

Counseling and Notification Requirements

If a pharmacist determines that prescribing a patient emergency or hormonal contraception is clinically appropriate, the pharmacist must do the following:

1. counsel the patient on what they should monitor and when to seek more medical attention;

2. notify any health care provider the patient identifies as their primary care provider or, if the patient does not disclose this, give them any relevant documentation; and

3. give the patient a document outlining age-appropriate health screenings that are consistent with CDC recommendations.

Pharmacy Technicians

The bill authorizes pharmacy technicians, at a pharmacist's request, to help the pharmacist prescribe emergency or hormonal contraception to a patient by (1) giving the patient screening documentation; (2) taking and recording the patient's blood pressure; and (3) documenting the patient's medical history, so long as the pharmacy technician completed an educational training program that meets the same requirements as those for pharmacists described above.

§ 4 — PHARMACIES AND MEDICATION ABORTION

Requires pharmacists to give patients a list of nearby pharmacies that dispense medication to terminate a pregnancy if the pharmacy does not have a supply of the medication

The bill requires a pharmacist employed by a pharmacy approved to dispense medication to terminate a pregnancy, to provide a patient seeking the medication a list of the nearest pharmacies that dispense the medication if the pharmacy does not have a supply of the medication.

Under the bill, a pharmacist currently or previously licensed in another state or jurisdiction cannot be subject to automatic reciprocal discipline in Connecticut for any disciplinary action taken in another state or jurisdiction if it was based solely on terminating a pregnancy under conditions that do not violate Connecticut law.

§§ 5 & 7 — FLAVORING ADDITIVES IN COMPOUNDED DRUGS

Allows flavoring agents already approved for use to be added to prescriptions by pharmacies that do not otherwise compound sterile pharmaceuticals

The bill exempts the addition of flavoring agents from laws on sterile compounding. Existing law already allows pharmacies to add flavoring agents meeting certain requirements to a prescription (e.g., oral children's medication) at a prescriber or patient's, among others', request. The bill also expands an existing authorization to adopt

regulations on sterile compounding to include this exemption.

§ 6 — MEDICATION SALES VIA VENDING MACHINES

Additionally allows businesses to operate vending machines selling OTC medications like acetaminophen and ibuprofen and related testing devices, if they get a DCP nonlegend drug permit

Under current law, in order to sell OTC drugs at retail outside a pharmacy, a store must annually get a nonlegend drug permit from DCP. The bill also allows DCP to issue these permits to businesses seeking to operate vending machines.

The bill also makes a violation of the nonlegend drug permit law punishable by a fine of up to $1,000, rather than $100-$500 as under current law.

Under the bill, vending machines containing OTC medications must be owned and operated by a business holding a nonlegend drug permit. Businesses need only one permit per location where vending machines are operated. Each machine must also be registered with DCP. When registering the machine, the applicant must designate an individual who is responsible for properly maintaining it.

Machine Operation

Under the bill, vending machines can sell OTC drugs as well as:

1. OTC devices or test strips that allow someone to test for a particular substance prior to injection, inhalation, or ingestion to prevent accidental overdose and

2. sundries and other nonperishable items.

The bill requires the business registering a vending machine, as well as the person designated as responsible for its maintenance, to ensure each machine:

1. maintains the proper temperature and humidity for each drug offered in the machine, as required by the drug's manufacturer;

2. does not contain drug packages that have more than a five-day

supply, according to the manufacturer's directions;

3. contains only drugs and devices in their original containers, labeled and packaged as state and federal law require;

4. offers drugs and devices that are unexpired and unadulterated and not recalled (if a drug is recalled, it must be promptly removed); and

5. does not offer drugs or devices that (a) require age verification or (b) are subject to quantity limits or sales restriction under state or federal law.

The bill also requires vending machines to have:

1. a clear and conspicuous written statement attached to them (a) disclosing the name, address, and toll-free telephone number of its owner and operator and (b) advising a consumer to check the expiration date of drug and device products before using them; and

2. attached a written notice, in a size and prominent location visible to consumers, stating: "Drug tampering or expired product? Notify the Department of Consumer Protection, Drug Control Division, by calling (toll-free DCP telephone number)."

§§ 8-11 — UNIFORM FOOD, DRUG AND COSMETIC ACT

Makes a minor clarifying change to the Uniform Food, Drug and Cosmetic Act

The bill specifies that failure to comply with applicable provisions in the United States Pharmacopeia on sterile and nonsterile compounding is prohibited under the state's Uniform Food, Drug and Cosmetic Act (§ 11).

The bill also makes technical and conforming changes.

§ 12 — EXPANDING OPIOID ANTAGONIST ACCESS

Allows prescribing practitioners and pharmacists to work with various entities (e.g., law enforcement and school boards) to increase the public's access to opioid antagonists, for example, by making them available in vending machines and needle exchange machines

Existing law allows prescribing practitioners and pharmacists to enter into agreements to distribute opioid antagonists (used to treat opioid overdose, e.g., Narcan), for further distribution or administration, to community health organizations, emergency medical service providers, government agencies, law enforcement agencies, and local and regional boards of education ("host agencies"). The bill specifies that they may enter into agreements with these host agencies to provide any intranasally or orally administered opioid antagonist. The bill also allows prescribing practitioners and pharmacists to enter into agreements with host agencies and syringe services programs to distribute opioid antagonists through secured boxes or machines or vending machines meeting the bill's specifications, as described below.

The bill extends existing law's criminal, civil, and administrative liability protection provisions to prescribing practitioners and pharmacists who enter into agreements with host agencies and syringe services programs under the bill's provisions on secured machines and boxes and vending machines. It also expands the DCP commissioner's authority to adopt regulations to include implementing the bill's provisions.

The bill specifies that its provisions do not prevent the inclusion of an opioid antagonist in a container that also includes an automated external defibrillator or any other product used to treat a medical emergency (i.e., a container that would not qualify under the bill as a secure box or machine or vending machine).

Secure Boxes on Host Agencies' Premises

The bill allows prescribing practitioners and pharmacists to enter into agreements with host agencies to permit the agencies to install on the agency's premises a secure box containing an intranasally or orally administered opioid antagonist. Under the bill, a "secure box" is a container that:

1. is securely affixed in a public location and tamper-resistant;

2. can be accessed by people for public use, but does not contain

more opioid antagonist than necessary to serve the local community;

3. is temperature controlled or stored in an environment with temperature controls; and

4. is equipped with an alarm capable of (1) detecting and transmitting a signal when accessed by someone and (2) alerting first responders to the access unless it is commercially impracticable.

These agreements must:

1. address environmental controls necessary to store the opioid antagonist;

2. set procedures for (a) replenishing opioid antagonists and (b) monitoring their expiration dates and disposing of them when expired; and

3. require signage on (a) the presence of opioid antagonists and (b) usage directions, in the language or languages spoken in the local community.

The bill specifies that if the host agency is unable to stock and maintain the secure box, it must remove it and related signage within five days or sooner.

Vending Machines Operated in Cooperation With Host Agencies

The bill allows prescribing practitioners and pharmacists to enter into agreements with host agencies to operate a vending machine for distributing an opioid antagonist for nasal administration. The bill requires these vending machines to be in an area that maintains a temperature that is consistent with the manufacturer's instructions, or have the ability to maintain the appropriate environment itself. Presumably, unlike secure boxes (see above), vending machines do not have to be located on the host agency's premises.

The bill requires the following to be clearly and conspicuously

displayed on the outside of each vending machine, adjacent to it, or upon its distribution of an opioid antagonist:

1. information on the signs and symptoms of an overdose and how to use the opioid antagonist;

2. information on services to treat opioid use disorder; and

3. a website or a quick response code (QRC) directing people to online information on the signs and symptoms of an overdose, overdose response, and how to use an opioid antagonist.

Syringe Services Programs' Secured Machines

Existing law allows registered syringe services programs, after receiving DCP approval, to use secure, immobile machines to provide patients with up to 10 hypodermic needles and syringes at a time. The machines must prevent unauthorized access and dispense only to patients using a patient-specific access number, personalized magnetic strip card, or another technology that identifies individual patients (CGS § 21a-65). (Syringe services programs, overseen by the Department of Public Health, provide needle and syringe exchange services to intravenous drug users in communities impacted by HIV or hepatitis C.)

The bill allows prescribing practitioners and pharmacists to enter into agreements with syringe services programs to include an opioid antagonist in the programs' DCP-registered, secure needle exchange machines. As is the case for agreements on host agencies' secure boxes (see above), the agreements with syringe services programs must:

1. address environmental controls necessary to store opioid antagonists;

2. set procedures for (a) replenishing opioid antagonists and (b) monitoring their expiration dates and disposing of them when expired; and

3. require signage on (a) the presence of opioid antagonists and (b)

usage directions, in the language or languages spoken in the local community.

The bill specifies that these secured needle exchange machines can also distribute test strips that allow someone to test for a particular substance prior to injection, inhalation, or ingestion to prevent accidental overdose.

§ 13 — MEDICAL MARIJUANA CERTIFICATION VIA TELEHEALTH

Indefinitely permits providers to certify medical marijuana patients and provide follow-up care via telehealth

The bill indefinitely permits physicians, APRNs, and physician assistants to certify a qualifying patient's use of medical marijuana and provide follow-up care using telehealth if they comply with other statutory certification and recordkeeping requirements. They may do so notwithstanding existing laws and regulations on medical marijuana certifications.

Existing law allows physicians and APRNs to do this through June 30, 2023.

BACKGROUND

Commission of Pharmacy

The commission has jurisdiction over pharmacy practice in the state and approves the licensure and registration of pharmacies, pharmacists, and pharmacy interns. It operates within DCP and has seven members appointed by the Governor.

Related Bill

sSB 1102 (File 221), as amended by Senate Amendment "A" and passed by the Senate, allows (1) pharmacists to order and administer tests for COVID-19, HIV, and influenza and prescribe and dispense HIV-related prophylaxis and (2) pharmacies to operate mobile pharmacies in temporary locations, including for purposes of offering an opioid antagonist training and prescribing event.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute
Yea 15 Nay 8 (03/09/2023)