**PA 23-52**—sHB 6768
*General Law Committee*

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

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**SUMMARY:** This act makes various changes related to the practice of pharmacy and access to medications. Among other things, it does the following:

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 prescribe emergency or hormonal contraception 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.

EFFECTIVE DATE: Upon passage, except the provision creating a new DCP registration for dispensing group practices and dispensing assistants 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 requirements, advertising restrictions, and grounds for disciplinary actions*

The act establishes a new DCP registration for "dispensing group practices" that dispense legend (i.e., prescription) drugs or devices directly to patients instead of through pharmacies.

Under the act, 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 centralized dispensing practitioner or pharmacist it employs.

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

### *Dispensing Group Practice Registration*

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

*Prescription Drug Monitoring Program Registration*

The act 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 act, dispensing group practices are exempt from this 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.

*Pharmacist Duties*

Under the act, 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 act requires the pharmacist to directly report to a prescribing practitioner who 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 act establishes a new DCP registration for dispensing assistants and prohibits anyone from acting as a dispensing assistant unless they obtain this registration. It establishes an initial and renewal registration fee of $100 and requires renewal every two years.

Under the act, 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 act 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 act 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 act 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 assistant, or pharmacist employed by, or acting on behalf of, the group practice violates the act's provisions or state pharmacy laws or regulations on dispensing legend drugs or devices.

## § 2 — PHARMACISTS' AUTHORITY TO DISPENSE LEGEND DEVICES

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

The act allows pharmacists to authorize or 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 that a prescribing practitioner prescribes to a patient.

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

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

*Authorizes pharmacists to prescribe emergency or hormonal contraception to patients under certain conditions*

The act 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 act, the pharmacist must complete an educational training program, accredited by the Accreditation Council for Pharmacy Education, that (1) covers prescribing emergency and hormonal contraceptives by pharmacists and (2) addresses appropriate (a) patient medical screenings, contraindications, drug interactions, treatment strategies, and modifications and (b) patient referrals to medical providers.

*Document Review*

The act 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 act requires that the pharmacist document his or her rationale for doing so.

*Screening Document*

Under the act, the pharmacist must complete a screening document before the initial dispensing of emergency or hormonal contraception to a patient. The document must be completed for returning patients at least once per calendar year after that.

DCP must make the screening document available on its website. The pharmacist, or the pharmacy that 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 act 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, then the pharmacist must do the following:

1. counsel the patient on what he or she should monitor and when to seek more medical attention,
2. notify any health care provider the patient identifies as his or her primary care provider or give the patient any relevant documentation if he or she does not disclose this, and
3. give the patient a document outlining age-appropriate health screenings that are consistent with CDC recommendations.

*Pharmacy Technicians*

The act 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; prohibits pharmacists from being subject to automatic reciprocal discipline in Connecticut for another jurisdiction's disciplinary action based solely on terminating a pregnancy*

If a pharmacy is approved to dispense medication to terminate a pregnancy but does not have a supply of it, then the act requires its pharmacist to provide a patient seeking the medication a list of the nearest pharmacies that dispense it.

Under the act, 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.

*Background — Related Acts*

PA 23-31, § 18, rescinds automatic reciprocal discipline against a pharmacist or health care professional licensed in another state or jurisdiction if the discipline in that location was based solely on terminating a pregnancy under conditions that would not violate Connecticut law or regulation.

PA 23-128, §§ 1 & 2, generally prohibits the Department of Public Health (DPH) and DCP (and related boards and commissions) from denying a credential or disciplining a credentialed provider due to disciplinary actions in other U.S. jurisdictions solely based on the person's alleged participation in reproductive health care services.

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

## § 6 — MEDICATION SALES VIA VENDING MACHINES

*Allows businesses to operate vending machines selling OTC medications like acetaminophen and ibuprofen and drug testing devices if they get a DCP nonlegend drug permit*

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

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

Under the act, 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 act, 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 act requires the business registering a vending machine, as well as the person designated as responsible for its maintenance, to ensure that each machine meets the following criteria:

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 only 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 act also requires them to ensure that vending machines have the following features:

1. a clear and conspicuous attached written statement (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. an attached 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 act 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 act also makes technical and conforming changes.

## § 12 — EXPANDING OPIOID ANTAGONIST ACCESS

*Allows prescribing practitioners and pharmacists to work with various entities 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 or 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 act specifies that they may enter into agreements with these host agencies to provide any intranasally or orally administered opioid antagonist. The act also allows prescribing practitioners or pharmacists to enter into agreements with host agencies to distribute opioid antagonists through secured boxes or vending machines, or with syringe services programs to distribute them through secured machines, meeting the act's specifications as described below.

The act 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 act'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 act's provisions.

The act specifies that its provisions as to host agencies 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 act as a secure box or machine or vending machine).

For pharmacists, as under existing law, the act's provisions only apply to those who are certified to prescribe opioid antagonists.

### *Secure Boxes on Host Agencies' Premises*

The act allows prescribing practitioners or 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 act, a "secure box" is a container that meets the following criteria:

1. is securely affixed in a public location and is 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 (a) detecting and transmitting a signal when accessed by someone and (b) alerting first responders to the access unless it is commercially impracticable.

These agreements must contain provisions that do the following:

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 act specifies that if the host agency is unable to stock and maintain the secure box, then it must remove it and related signage within five days or sooner after discovering this.

*Vending Machines Operated in Cooperation With Host Agencies*

The act allows prescribing practitioners or pharmacists to enter into agreements with host agencies to operate a vending machine for distributing an opioid antagonist for nasal administration. The act requires these vending machines to (1) be in an area that maintains a temperature consistent with the manufacturer's instructions or (2) 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 act 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 directions for using the opioid antagonist;
2. information on in-state 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 directions for using 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 DPH, provide needle and syringe exchange services to intravenous drug users in communities impacted by HIV or hepatitis C.)

The act allows prescribing practitioners or 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 contain provisions that do the following:

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 act 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 act indefinitely permits physicians, advanced practice registered nurses, 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 through telehealth.

Prior law allowed these providers to do this only through June 30, 2023.