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## OLR Bill Analysis

### sSB 1355

#### ***AN ACT CONCERNING PRESCRIPTION DRUGS, DEVICES AND NONLEGEND DRUGS.***

#### **SUMMARY**

This bill makes a number of unrelated changes. Among other things, it:

1. requires the Department of Consumer Protection (DCP), in consultation with the Commission of Pharmacy, to adopt certain regulations (a) regarding nonsterile compounding pharmacies, including to ensure access to certain products that contain levonorgestrel, mifepristone, misoprostol, or similar ingredients, and (b) to import levonorgestrel, mifepristone, misoprostol, and similar drugs and components to offer ready access to drug products that include them (§ 1);
2. eliminates a requirement that DCP prominently post lists of pharmaceutical representatives employed by registered pharmaceutical manufacturers on its website (but keeps the requirement that these manufacturers annually give these lists to DCP and update them within two weeks of any changes) (§ 2);
3. allows a licensed veterinarian to authorize another person to dispense a prescription veterinary drug under certain circumstances (§ 3);
4. authorizes DCP or the Commission of Pharmacy, depending on the credential, to take various actions when a credential holder takes certain actions involving a drug that the holder knows will be used by someone to execute a death sentence (§§ 4-12); and
5. (a) excludes, from the requirement to get a DCP permit to sell nonlegend drugs in a vending machine, distributing free

nonlegend naloxone through a legally compliant secure box; (b) makes various other changes regarding these permits; and (c) changes the requirements for secure boxes (§§ 13-15).

EFFECTIVE DATE: Upon passage, except the provisions related to drugs used to execute a death sentence are effective October 1, 2025.

## **§ 1 — NONSTERILE COMPOUNDING PHARMACY REGULATIONS**

The bill requires the DCP commissioner, in consultation with the Commission of Pharmacy, to adopt certain regulations on nonsterile compounding pharmacies, which are licensed pharmacies that dispense nonsterile compounded pharmaceutical products. These are drug products made by compounding at least one active or nonactive ingredient.

The bill requires the regulations to ensure that these pharmacies can engage in nonsterile compounding:

1. under state laws and regulations and the provisions of the United States Pharmacopeia standards on nonsterile preparations and
2. to maintain patients' ready access to nonsterile compounded pharmaceutical products that contain levonorgestrel, mifepristone, misoprostol, or a similar ingredient as an active ingredient.

The regulation must also provide for DCP (or public-private partnerships it is involved with) to import (a) levonorgestrel, mifepristone, and misoprostol as drug products and components and (b) similar drugs and components, in order to offer ready access to drug products with these, or similar, active ingredients.

The bill allows DCP to issue policies and procedures to implement these provisions before adopting the regulations. DCP must post the policies and procedures on its website and submit them for posting on the eRegulations System at least 15 days before they take effect. The policies and procedures expire when the regulations are adopted or 48 months after the bill takes effect if a regulation has not been submitted

to the Regulation Review Committee for consideration, whichever occurs first.

Levonorgestrel is an emergency contraceptive used to prevent pregnancy. Mifepristone and misoprostol are used together to end a pregnancy through 10 weeks gestation.

### **§ 3 — VETERINARIANS**

The bill allows a licensed veterinarian to authorize another person to dispense a prescription veterinary drug if done:

1. under a veterinarian's lawful written or oral order in the course of the veterinarian's professional practice and following federal and state laws and regulations on dispensing prescription veterinary drugs;
2. for an animal the veterinarian, or another veterinarian at the same practice who has access to the animal's medical records, has a veterinarian-client-patient relationship; and
3. under the direct supervision of one of the veterinarians described above.

The veterinarian who authorizes another person to dispense the drug must ensure that all requirements for dispensing the drug are followed.

The bill allows the Department of Public Health commissioner, in consultation with DCP and the Connecticut Board of Veterinary Medicine, to adopt regulations to implement these provisions.

### **§§ 4-12 — DRUGS USED TO EXECUTE DEATH SENTENCES**

Generally, the bill prohibits manufacturing, selling, or dispensing a drug while knowing that the person receiving it intends to use it to execute a death sentence. And the bill authorizes DCP or the Commission of Pharmacy (depending on the credential) to take various actions, based on a credential holder taking certain actions, under these circumstances.

#### ***Drug Manufacturers and Wholesalers (§§ 4-6)***

By law, drug manufacturers and wholesalers must register with DCP. Currently, a prison with a pharmacy that provides an emergency stock of certain drugs for its medical director is not a wholesaler and is not required to register. The bill provides that a prison with such a pharmacy is considered a wholesaler and required to register when it has actual knowledge that a noncontrolled drug or controlled substance will be used to execute a death sentence. (The bill does not specify how to attribute this knowledge to the institution.)

By law, the DCP commissioner can deny a registration certificate if issuing one would be inconsistent with the public interest. The law sets out a number of factors the commissioner must consider in making this determination, including certain convictions or regulatory actions, the applicant's past experience and regulatory compliance, and provision of adequate controls and security. The bill also requires the commissioner to consider if the applicant manufactured, sold, or dispensed a drug or device actually knowing that the person purchasing or receiving it directly from the applicant intended to use it to execute a death sentence.

The law specifies a number of reasons that are sufficient for the commissioner to suspend, revoke, or refuse to renew a registration, reprimand a registrant, or place a registrant on probation, such as criminal convictions related to drugs, providing false information, not providing adequate controls, or violating state or federal law related to drugs. The bill adds to this list manufacturing, selling, or dispensing a drug or device when actually knowing that the person purchasing or receiving it directly from the registrant intends to use it to execute a death sentence.

The bill requires an applicant or registrant seeking renewal to attest to the commissioner in a signed written statement that the applicant or registrant will not manufacture, sell, or dispense a drug or device when actually knowing that the person purchasing or receiving it directly from the applicant or registrant intends to use it to execute a death sentence. The DCP commissioner sets the form and manner of this statement.

The law requires a manufacturer or wholesaler to obtain a DCP license to sell and dispense controlled substances. The bill prohibits a licensed manufacturer or wholesaler from selling or dispensing a controlled drug directly to another person while actually knowing that the person intends to use it to execute a death sentence.

### ***Certain Individuals (§ 6)***

Current law allows the person in charge of a hospital, college, scientific institution, or laboratory, an employee of this or another state or their political subdivisions, or a proper officer of a ship or aircraft who obtains a controlled substance to administer it within the scope of his or her employment or duty and only for scientific or medicinal purposes or research or analysis. The bill prohibits these individuals from obtaining, dispensing, or using a controlled drug to execute a death sentence.

### ***Pharmacists (§§ 7 & 8)***

By law, the Commission of Pharmacy can refuse to issue a temporary permit to practice pharmacy; refuse to issue or renew a license to practice pharmacy or operate a pharmacy or registration of a pharmacy intern or technician; revoke, suspend, or place conditions on any of these credentials; reprimand or place on probation a credential holder; or assess a civil penalty of up to \$1,000 per violation for numerous grounds. The bill adds to the permissible grounds for these actions that while holding the credential, the person dispensed or distributed a drug or device directly to someone while actually knowing that the person intended to use it to execute a death sentence.

The bill also prohibits the commission from renewing a pharmacist license if within the calendar year before the application the person dispensed or distributed a drug or device directly to someone while actually knowing that the person intended to use it to execute a death sentence.

### ***Prescriptions (§§ 9 & 10)***

The bill prohibits a prescribing practitioner (a person licensed by any state or U.S. jurisdiction who is authorized to issue a prescription within

the scope of the person's practice) from dispensing or transferring a drug or device directly to someone while actually knowing that the person intends to use it to execute a death sentence.

The bill makes any request for a controlled substance to execute a death sentence an invalid prescription and considers it outside the context of a valid practitioner-patient relationship.

***Nonresident Pharmacy Registration Certificate (§ 11)***

Current law allows the Commission of Pharmacy to deny, revoke, or suspend a registration certificate of a nonresident pharmacy for failing to comply with state or federal laws or regulations, delivering a legend drug or device that is adulterated or misbranded, or disciplinary actions taken against the pharmacy by any state or federal agency. The bill adds as an additional ground for these actions by the commission that the pharmacy delivered a legend drug or device directly to someone while actually knowing that the person intends to use it to execute a death sentence.

***Sterile Compounding Pharmacies (§ 12)***

The bill prohibits a sterile compounding pharmacy from providing, selling, or transferring a sterile pharmaceutical directly to someone while actually knowing that the person intends to use it to execute a death sentence.

**§§ 13-15 — VENDING MACHINES AND SECURE LOCKBOXES**

***Vending Machine Permits to Sell Nonlegend Drugs***

Current law requires a business that owns and operates a vending machine to obtain a permit from DCP or the Commission of Pharmacy in order to sell nonlegend drugs. The bill only allows DCP to issue these permits and allows the DCP commissioner to set the form and manner of an application.

The bill excludes from the permit requirement someone who only distributes nonlegend naloxone to the public through a secure, legally compliant lockbox (see below) for free.

The bill waives the \$140 application fee and \$100 renewal fee for a permit to sell nonlegend drugs for an applicant who attests on the application that the permit will be used only to distribute nonlegend drugs for free.

The bill specifies that the late fee on renewal of a permit is 10% of the renewal fee, but must be between \$10 and \$100.

Currently, a permit holder must notify the commission of a change in ownership, name, or location within five days after the change. The bill instead requires a permit holder to electronically submit the change to DCP in a form and manner set by the DCP commissioner, and requires notice of a change of permanent physical location rather than change of location of permit premises.

The bill eliminates a provision making these permits nontransferable.

### **Secure Boxes**

The bill changes certain requirements for secure lockboxes. As under current law, the box must be securely affixed in a public location and be accessible by people for public use. The bill deletes requirements that it be (1) temperature controlled or in a temperature-controlled environment; (2) tamper resistant; and (3) equipped with an alarm that transmits a signal and alerts first responders when accessed by someone. The bill adds that the box must display any sign DCP deems necessary or appropriate for the purposes of the relevant statute (DCP must post an image of the required sign on its website).

By law, a prescribing practitioner or pharmacist certified to prescribe an opioid antagonist can enter an agreement with a community health organization, emergency medical service provider, government or law enforcement agency, or board of education to install a secure box containing an opioid antagonist (such as naloxone). The agreement must address certain topics, such as environmental controls, replenishing contents, monitoring expiration dates, and signage about location and usage directions.

### **COMMITTEE ACTION**

General Law Committee

Joint Favorable Substitute

Yea 14 Nay 8 (03/24/2025)