

Securing a Safe & Fair Marketplace.

### 2023 Drug Control Legislative Updates

### **2023 Legislative Updates**

**PUBLIC ACT 23-19:** An Act Concerning Pharmacies and Pharmacists

**PUBLIC ACT 23-39:** Discharge Standards Regarding Follow-up Appointments and Prescription Medications for Patients Being Discharged from a Hospital or Nursing Home Facility

**PUBLIC ACT 23-52:** DCP Recommendations Regarding Prescription Drug Regulation

**PUBLIC ACT 23-97:** Health and Wellness For Connecticut Residents

**PUBLIC ACT 23-100:** Safe Storage and Disposal of Certain Prescription Drugs, Illegal Drugs and Cannabis and Cannabis Products

### 2023 Legislative Updates (cont.)

**PUBLIC ACT 23-128:** Preventing an Adverse Action Against a Health Care Provider Due to an Adverse Action Taken By Another State as a Result of Such Provider's Involvement in Providing Reproductive Health Care Services

**PUBLIC ACT 23-171:** Protecting Patients and Prohibiting Unnecessary Health Care Costs

PUBLIC ACT 23-204: Budget Bill

PUBLIC ACT 23-204: Implementer Bill



## ct.gov/dcp/dcd



Connecticut's Official State Website

Search Connecticut Government...

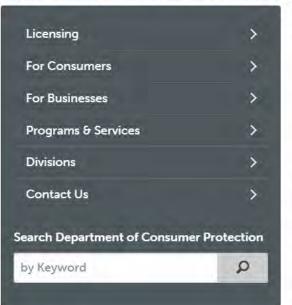
Q

Language + Settings



### Connecticut State Department of Consumer Protection

#### CT.gov Home / Department of Consumer Protection / Drug Control Division



#### **Drug Control Division**

**\*\*IMPORTANT\*\*** No later than January 1, 2023, each pharmacy shall post a sign notifying consumers that they may visit the Department of Consumer Protection website for information concerning the safe storage of prescription drugs and the disposal of unused and expired prescription drugs. To download materials, **click here**.

The Drug Control Division works to protect the health and safety of Connecticut residents by regulating all persons and firms involved in the distribution of all legal drugs, medical devices and cosmetics in Connecticut. The Division oversees Connecticut licensing for pharmacies, pharmacists, controlled substance providers and laboratories, pharmacy technicians, manufacturers and wholesalers of drugs, cosmetics and medical devices and medical marijuana. The Drug Control Division is also responsible for the Prescription Monitoring Program.

Adult-Use Cannabis Notification NOTICE: The Commissioner has authorized Dispensary Facilities that apply and are approved by the Department of Consumer Protection to conduct delivery services, to commence medical marijuana deliveries to qualifying patients and caregivers as of Monday,



# ct.gov/dcp/dcd

#### New Laws

2023

- Public Act 23-19 🗒 An Act Concerning Pharmacies and Pharmacists
  - Section 1: Definition Updates
  - Section 2: Pharmacist COVID, Influenza and HIV testing, HIV Prophylaxis Treatment Regulations
  - Section 3: Mobile Pharmacy
  - Section 4: Unscheduled Pharmacy Closing Plans, Pharmacy Pick-Up Lockers
  - Section 5: Pharmacist Immunization Update and Epinephrine Use
  - Section 6-8: Institutional Pharmacy License
- Public Act 23-31 An Act Concerning the Department of Public Health's Recommendations Regarding Various Revisions to the Public Health Statutes
  - Section 18: Removal of reciprocal discipline solely for termination of pregnancy
- Public Act 23-52 An Act Concerning the Department of Consumer Protection's Recommendations Regarding Prescription Drug Regulation
  - Section 1: Centralized Dispensing Practitioner
  - Section 2: Pharmacist Prescribing of Legend Devices
  - Section 3: Pharmacist Prescribing of Hormonal Contraception and Emergency Contraception
  - Section 4: Pharmacist Discipline for the Termination of Pregnancy
  - Section 5 & 7: Flavoring Exemption from USP 800
  - Section 6: Sale of Non-Legend (Over-the-Counter) Drugs in Vending Machines.
  - Section 9: Addition of Sterile and Non-Sterile Product to the Prohibited Acts in 21a-93
  - Section 12: Adding Naloxone to Secure Boxes, Syringe Service Vending Machines, or a Standalone Vending Machine as well as a test strip for the purpose of individual use

DOP



#### Public Act 23-19

- Section 1 Definition Update Effective July 1, 2023
- Section 2 Testing and HIV-related Prophylaxis Effective July 1, 2023
- Section 3 Mobile Pharmacy Effective July 1, 2023
- Section 4 Unscheduled Closing Effective July 1, 2023
- Section 5 Vaccination Update Effective July 1, 2023
- **Section 6** Conforming Changes (adding healthcare institutional pharmacies to 20-576) *Effective July 1, 2023*
- **Section 7** Conforming Changes (adding healthcare institutional pharmacies to 20-594) *Effective July 1, 2023*
- **Section 8** Sterile pharmaceuticals Healthcare Institutional Pharmacies *Effective July 1, 2023*
- Section 9-13 & 16 Conforming Changes Effective July 1, 2023
- Section 14, 15 & 17 Changes to the HIV program at DPH Sections 14 and 15 effective July 1, 2023. Section 17 effective upon passage



## Public Act 23-19

#### AN ACT CONCERNING PHARMACIES AND PHARMACISTS

- Section 1 & Sections 6 through 16. HEALTH CARE INSTITUTIONAL PHARMACIES' STERILE COMPOUNDING (Eff. July 1, 2023)
  - Establishes a process to allow institutional pharmacies located in licensed health care facilities to compound sterile pharmaceuticals for retail sale and subjects them to the same requirements that apply to other retail pharmacies compounding sterile pharmaceuticals.

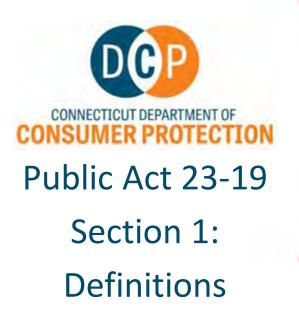
#### • Sections 2 & 5. EXPANDED SCOPE OF PRACTICE (Eff. July 1, 2023)

• 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).

#### • Section 3. OPERATING MOBILE PHARMACIES (Eff. July 1, 2023)

- 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.
- Section 4. UNSCHEDULED PHARMACY CLOSURES AND PRESCRIPTION PICKUP LOCKERS (Eff. July 1, 2023)
  - Creates rules for pharmacies when they face an unscheduled closure (which the bill does not define), including customer and prescriber notification and planning requirements





#### **Key Definitions**

(14) "Health care institution" means institution, as defined in section 19a-490;

(15) "Health care institutional pharmacy" means an institutional pharmacy located within a health care institution; and,

(23) "Nonresident pharmacy" has the same meaning as provided in section 20-627.





Public Act 23-19

Section 2: COVID and Influenza Testing; Testing and Prophylaxis for HIV

### **Testing and HIV Prophylaxis**

#### Definitions:

- 1. "COVID-19" means the respiratory disease designated by the World Health Organization on February 11, 2020, as coronavirus 2019, and any related mutation thereof recognized by said organization;
- 2. "COVID-19-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, COVID-19;
- 3. "HIV-related prophylaxis" means any drug approved by the federal Food and Drug Administration or any successor agency as a **preexposure** or **post-exposure** prophylaxis for the human immunodeficiency virus;
- 4. "HIV-related test" has the same meaning as provided in section 19a-7o of the general statutes; and,
- 5. "Influenza-related test" means any laboratory test, or series of laboratory tests, for any virus, antibody, antigen or etiologic agent thought to cause, or indicate the presence of, influenza disease.



### **COVID-19 or Influenza Testing**

Any Connecticut Licensed Pharmacist may order and administer a COVID-19related or influenza-related test if the pharmacist :

- 1. Works in a pharmacy with an approved CLIA waiver from CT DPH (except pharmacists employed by a hospital); and,
- 2. Has completed any training required by the Department of Consumer Protection.

The test may be administered to a patient who is:

- 1. 18 years of age or older; or,
- 2. At least 12 years of age but younger than 18 years of age with:
  - a. The consent of such patient's parent, legal guardian or other person having legal custody of such patient; or,
  - b. Proof that such patient is an emancipated minor.





### **HIV Testing and PEP/PrEP**

### Regulations must first be adopted.

Any Connecticut Licensed Pharmacist may order and administer an HIV-related test if the pharmacist:

- 1. Works in a pharmacy with an approved CLIA waiver from CT DPH (except pharmacists employed by a hospital); and,
- 2. Has completed any training required by the Department of Consumer Protection.

The test may be administered to a patient who is:

- 1. 18 years of age or older; or,
- 2. At least 12 years of age but younger than 18 years of age with:
  - a. The consent of such patient's parent, legal guardian or other person having legal custody of such patient; or,
    - Proof that such patient is an emancipated minor.



#### Required Documentation and Reporting

For any COVID-19, Influenza, or HIV-Related test ordered and administered by the pharmacist, the pharmacist shall provide the result of such test to:

- a. The patient, in writing;
- b. The patient's primary care provider;
- c. DCP upon request;
- d. The Director of Health of the town, city or borough in which the patient resides; and,
- e. The Department of Public Health in the manner set forth in Section 10a-215 and applicable regulations.

The pharmacy shall also maintain a record of such test results for 3 years.



#### HIV PEP/PrEP

If a pharmacist orders and administers an HIV-related test and the results are negative, the pharmacist may prescribe and dispense to the patient any HIV-related prophylaxis (PEP/PrEP) according to the manufacturer's package insert provided:

- 1. Such pharmacist has completed the training required under the regulations;
- 2. The patient satisfies the criteria established in such package insert;
- 3. Such HIV-related prophylaxis is prescribed and dispensed in accordance with all regulations adopted pursuant to this statute; and,
- 4. The pharmacist:
  - a. Provides a copy of the results of the test (as stated previously);
  - b. Maintains prescription information as required; and,
  - c. Maintains any other documentation required in the regulations.





#### Confidentiality

If the Department takes an administrative or other disciplinary action and obtains information related to testing, the disclosure of the testingrelated information shall remain confidential.



Regulations to be drafted in consultation with:

- 1. The Commissioner of Public Health;
- 2. The Commission of Pharmacy;
- 3. A state-wide professional society representing the interests of physicians practicing medicine in this state; and,
- 4. A state-wide organization representing the interests of health care professionals and scientists specializing in the control and prevention of infectious diseases.



#### **PEP/PrEP** Regulations

Minimum Requirements:

- 1. Ensure compliance with all applicable guidance issued by the CDC;
- 2. Ensure each HIV-related prophylaxis prescribed and dispensed is based on FDA approval for such purpose;
- Establish permissible routes of administration; 3.
- Establish prescription duration limits not to exceed: 4.
  - 60 days for any pre-exposure HIV-related prophylaxis; or, а.
  - 30 days for any post-exposure HIV related prophylaxis. b.
- 5. Specify:
  - How frequently a pharmacist may provide treatment to a patient а. under this section;
  - When a pharmacist providing treatment to a patient under this section shall refer the patient to their primary care provider or any other health care provider the patient identifies; and, b.



The circumstances in which a pharmacist shall recommend that a patient undergo screenings for sexually transmitted infections other than HIV.

#### **PEP/PrEP** Regulations

- 6. Establish requirements concerning private areas for consultations between pharmacists and patients; and,
- 7. Establish training requirements concerning:
  - a. Methods 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 services available to the patient;
  - d. Using HIV-related prophylaxes for patients who have tested negative for HIV;
  - e. Identify qualifying training programs, which are accredited by the National Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education or another appropriate national accrediting body; and,
    - Establish a system of control and reporting.



(continued on next slide)

What type of waiver issued by the Department of Public Health must a pharmacy have to administer COVID-19, influenza or HIV tests?

- Vaccination waiver
- **CLIA** waiver
- Infectious disease waiver
- Testing waiver



What type of waiver issued by the Department of Public Health must a pharmacy have to administer COVID-19, influenza or HIV tests?

- X Vaccination waiver
- CLIA waiver
- Infectious disease waiver
- X Testing waiver



If a patient tests negative for HIV, what should the pharmacist do?

- □ Tell the patient's partner or spouse.
- Shred information pertaining to the patient, including the test results and any prescriptions, to maintain confidentiality.
- Provide the patient a written copy of the results.
- Upload the test results into the Connecticut Prescription Monitoring and Reporting System.



If a patient tests negative for HIV, what should the pharmacist do?

- X Tell the patient's partner or spouse.
- Shred information pertaining to the patient, including the test results and any prescriptions, to maintain confidentiality.
- Provide the patient a written copy of the results.
- Upload the test results into the Connecticut Prescription Monitoring and Reporting System.



# You can administer a flu test to a 5-year-old child as long as the parent requests it.



# You can administer a flu test to a 5-year-old child as long as the parent requests it.

#### FALSE.





A pharmacy may operate a mobile pharmacy in a temporary location for the purpose of:

- 1. Conducting a:
  - 1. Temporary pharmacy operation;
  - 2. Vaccination event; or,
  - 3. Opioid antagonist training and prescribing event.
- 2. Serving a community that may not have adequate access to pharmacy services





Requirements:

- 1. Prior written approval from DCP;
- 2. Supervision by a pharmacist;
- 3. The vehicle may be subject to inspection before services are provided and at any time during usual business hours or while such mobile pharmacy is in operation;
- 4. Maintain record of all drugs removed from the pharmacy premises for the purpose of operating such mobile pharmacy;
- 5. Maintain a record of each drug that is dispensed at such mobile pharmacy and include such record in the pharmacy's records not later that 24 hours after the drug is dispensed. Return all unused drugs to the pharmacy premises by the close of business each day



(continued on next slide)

- 6. While operating such mobile pharmacy, store all drugs in such mobile pharmacy in a manner that:
  - a. Prevents any drug diversion; and,
  - b. Is consistent with the storage conditions specified by the manufacturers of such drugs.
- 7. Establish and maintain a patient communication plan to ensure that patients can obtain prescription refills if such mobile pharmacy is unavailable; and,
- 8. If permitted by the DEA, store controlled substances in accordance with regulations adopted by the commissioner.



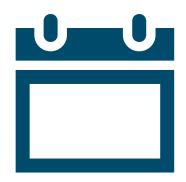
Order to Close may be issued if the mobile pharmacy has failed to:

- Comply with any provision of this section or Chapter 400j;
- 2. Comply with any regulation adopted pursuant to this section;
- 3. Comply with any applicable law or regulation of any jurisdiction concerning drugs, devices or the practice of pharmacy;
- 4. Provide safe conditions to store or dispense drugs; or,
- 5. Provide sufficient security at such mobile pharmacy.



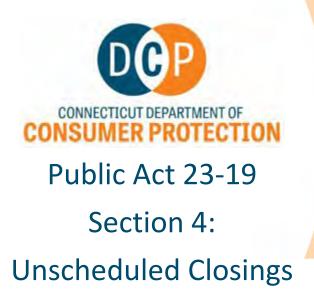
Mobile Pharmacies cannot:

- 1. Operate for more than:
  - a. Seven days in a single location; or,
  - b. 14 days within a five-mile radius of the prior mobile pharmacy location.
- 2. Store drugs overnight in a mobile pharmacy or outside of the pharmacy premises.









#### **Unscheduled Closing**

Each pharmacy shall maintain a plan to manage unscheduled closings which shall be reviewed on an annual basis and provided to and reviewed with <u>all pharmacy personnel on an annual basis</u>.

Unscheduled Closing Plans must contain:

- 1. The name of the individual responsible for notifying the Commission of Pharmacy of an unscheduled closing;
- 2. The name of the individual responsible for updating the hours of operation in the pharmacy's electronic record system to prevent acceptance of electronically transmitted prescriptions during an unscheduled closing;
- 3. The name of the individual who is responsible for updating the pharmacy's telephone system during an unscheduled closing to:
  - a. Prevent the acceptance of orally transmitted prescriptions during the unscheduled closing; and,
  - b. Provide a message that alerts patient that such pharmacy will be closed and their prescriptions may be obtained from a nearby pharmacy;



(continued on next slide)

#### **Unscheduled Closing**

- 4. A list of all pharmacies located within a two-mile radius of the pharmacy experiencing an unscheduled closing, or the next closest pharmacy if there is no pharmacy within such two-mile radius; and,
- 5. The name of the individual responsible for posting, at the entrance of the pharmacy and at each entrance of the structure if the pharmacy is located within another structure, signage stating the duration of the unscheduled closing.





#### **Unscheduled Closing**

In the event of an unscheduled closing the pharmacy manager of the pharmacy or if the pharmacy operates more than 5 pharmacy locations in this state, the pharmacy district manager, shall:

- 1. Modify such pharmacy's hours of operation in such pharmacy's electronic record system to prevent the acceptance of electronically transmitted prescriptions during the unscheduled closing;
- 2. Adjust such pharmacy's telephone system to prevent the acceptance of orally transmitted prescriptions during the unscheduled closing;
- 3. Provide a telephone system message that alerts patients that:
  - a. The pharmacy is not open; and,
  - b. Patients may obtain medications from a nearby pharmacy;
- 4. Post signage at the entrance to such pharmacy, and at each entrance of the structure if such pharmacy is located within another structure:
  - a. Stating that the pharmacy is closed;
  - b. Disclosing the duration of the unscheduled closing; and,
  - c. Providing:
    - i. A list of pharmacies located within a two-miles radius; and,
    - ii. The next closest pharmacy if there is no pharmacy within a two-miles radius; and,
- 5. Upon request by another pharmacy to transfer a prescription to such other pharmacy, transfer any prescription dispensed by the pharmacy experiencing the unscheduled closing and reverse any third-party payor claims associated with the prescription.



# **Unscheduled Closing**

#### Transferring a Prescription

Any pharmacy that verifies that another pharmacy is experiencing an unscheduled closing may, upon a patient's request, dispense a prescription that is dispensed and waiting at the pharmacy experiencing the unscheduled closing by:

- 1. Using information obtained from the electronic prescription drug monitoring program; or,
- 2. Another source that the pharmacist dispensing such prescription believes provides a reasonable assurance of accurate information necessary to dispense such prescription (Examples: Another pharmacy in the chain, the prescriber or another reliable data source).





If another pharmacy dispenses the prescription during an unscheduled closing of the pharmacy:

- 1. The dispensing pharmacy shall contact the pharmacy experiencing the unscheduled closing within 24 hours after reopening to transfer the prescription;
- 2. The pharmacy that experienced the unscheduled closing shall provide to the pharmacy that dispensed the prescription all necessary information to complete the transfer; and,
- 3. The pharmacy that experienced the unscheduled closing shall reverse any third—party payor claims associated with the transferred prescription not later that 24 hours after the pharmacy reopens.



# **Self-Service Secure Containers**

# Department shall adopt regulations for self-service secure containers.

Prior to regulations, the Department may temporarily approve the use and placement of a secured container provided that the pharmacy provides written protocols before placing the container and that the container is:

- 1. >750 pounds or affixed to the physical structure of the building where the pharmacy is located and is located immediately adjacent to the portion of the building where such pharmacy is located;
- 2. Only permits access to authorized pharmacy personnel or individuals retrieving the prescriptions with a unique identification system;
- 3. Under video surveillance at all times;
- 4. Capable of maintaining a record of all products that are placed inside of the secure container and the date and time each individual prescription is accessed; and,
- 5. Complies with any other protocol required by the department to ensure confidentiality, ensure public health and safety and prevent diversion.



Which is NOT an approved purpose for conducting a mobile pharmacy?

- The pharmacy's license has been revoked
- Temporary pharmacy operation
- Vaccination event
- □ Naloxone training and prescribing event



Which is NOT an approved purpose for conducting a mobile pharmacy?

The pharmacy's license has been revoked

- **X** Temporary pharmacy operation
- X Vaccination event
- Naloxone training and prescribing event



How long after the pharmacy reopens from an unscheduled closure does the pharmacy have to transfer prescriptions and reverse third-party claims for prescriptions dispensed to patients at another pharmacy due to the closure?

12 hours

- 24 hours
- 48 hours
- 72 hours



How long after the pharmacy reopens from an unscheduled closure does the pharmacy have to transfer prescriptions and reverse third-party claims for prescriptions dispensed to patients at another pharmacy due to the closure?

12 hours
24 hours
48 hours
72 hours



In the event of an unscheduled closing, the pharmacy must provide patients with a list of pharmacies within \_\_\_\_\_ of the closed pharmacy.

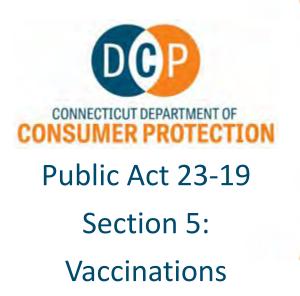
2 miles
5 miles
15 minutes
the same zip code



In the event of an unscheduled closing, the pharmacy must provide patients with a list of pharmacies within \_\_\_\_\_ of the closed pharmacy.

2 miles
5 miles
15 minutes
the same zip code





# Vaccinations\*

Any licensed pharmacist may administer an FDA-approved or authorized vaccination in accordance with the package insert of the vaccine after a reasonable attempt to review the patient's vaccination history for:

- 1. A vaccine on the CDC Adult Immunization Schedule;
- 2. Any vaccine not on the CDC schedule provided the instructions for such vaccination are available on the CDC website; or,
- 3. Any vaccine pursuant to a verbal or written prescription of a prescribing practitioner for a specific patient.

The vaccination may be administered under this section:

- 1. To any patient between 18 and over; or,
- 2. To a patient who is at least 12 years of age but younger than 18 years of age with:
  - a. Consent of the patient's parent, legal guardian or other person having legal custody of such patient; or,
  - b. Proof that such patient is an emancipated minor.



# Children Ages 3-18 Years Old

- The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity to qualified individuals, including pharmacists, authorized to administer COVID-19 and influenza vaccinations.
- Also authorizes pharmacists to order and administer approved COVID-19 and childhood vaccines to children ages 3-18 years through 2024.
- Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.



# Vaccinations

#### Regulations must first be adopted.

A pharmacist who has completed the required training may administer an epinephrine cartridge injector. The pharmacist:

- 1. Will have to reasonably believe that the patient is experiencing anaphylaxis;
- 2. Pharmacist or designee shall contact 911 either before or immediately after administration; and,
- 3. Shall document the date, time and circumstances in which such pharmacist administered such epinephrine cartridge injector and maintain it for at least 3 years.





# Vaccinations

#### Pharmacy Technicians

- 1. Certified and registered pharmacy technicians may administer a vaccine to a patient at a pharmacy if:
  - a. The managing pharmacist of such pharmacy is authorized to administer vaccines under this section; and,
  - b. Such pharmacy technician:
    - i. Has successfully completed a course of hands-on training certified by the American Council for Pharmacy Education concerning the administration of vaccines;
    - ii. Has been trained at such pharmacy regarding the process for administering vaccines to patients at such pharmacy;
    - iii. Successfully completes at least one hour of annual continuing education concerning immunization;
    - iv. Has been evaluated by the managing pharmacist of such pharmacy; and,
    - v. Administers such vaccine at the direction of the pharmacist on duty.
- 2. During the time period from September 1 and ending on March 31 of the succeeding year, a certified and registered pharmacy technician shall not count toward the pharmacist-to-technician ratio set forth in 20-576-33 if:
  - a. The pharmacy technician is authorized to administer vaccine under this section; and,







### Health Care Institutional Pharmacies

- "Health care institutional pharmacy" means an institutional pharmacy located within a health care institution.
- Can be licensed as a pharmacy by applying to the Department and subject to an inspection.
- Permits the acceptance of a prescription and the dispensation of sterile product from a health care institutional pharmacy.
- A new application process will be developed for interested health care institutional pharmacies.





DISCHARGE STANDARDS REGARDING FOLLOW-UP APPOINTMENTS AND PRESCRIPTION MEDICATIONS FOR PATIENTS BEING DISCHARGED FROM A HOSPITAL OR NURSING HOME FACILITY (Eff. October 1, 2023)

- Requires DPH to set minimum standards for hospital and nursing home discharge planning including the:
  - Date and location of each follow-up medical appointment scheduled before the patient's discharge; and
  - To the extent known to the facility, a list of all medications the patient is currently taking and will take after discharge.
- Requires facilities to send prescriptions they order for patients to the patient's pharmacy electronically.

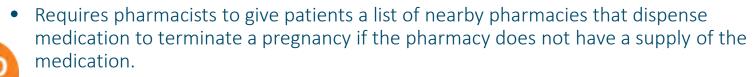




#### DCP RECOMMENDATIONS REGARDING PRESCRIPTION DRUG REGULATION

- Section 1. REGISTRATION FOR DISPENSING GROUP PRACTICES AND ASSISTANTS (Eff. Jan 1, 2024)
  - 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.
- Section 2. PHARMACISTS' AUTHORITY TO DISPENSE LEGEND DEVICES (Eff. upon passage)
  - Authorizes pharmacists to refill prescriptions for legend devices approved to be used in combination with prescription medications; establishes related notification requirements.
- Section 3. PHARMACISTS' AUTHORITY TO PRESCRIBE EMERGENCY AND HORMONAL CONTRACEPTION (Eff. upon passage)
  - Authorizes pharmacists to dispense emergency or hormonal contraception to patients under certain conditions.

#### • Section 4. PHARMACIES AND MEDICATION ABORTION (Eff. upon passage)



#### DCP RECOMMENDATIONS REGARDING PRESCRIPTION DRUG REGULATION (cont.)

- Sections 5 and 7. FLAVORING ADDITIVES IN COMPOUNDED DRUGS (Eff. upon passage)
  - Allows flavoring agents already approved for use to be added to prescriptions by pharmacies that do not otherwise compound sterile pharmaceuticals.
- Section 6. MEDICATION SALES VIA VENDING MACHINES (Eff. upon passage)
  - 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.
- Sections 8 through 11. TECHNICAL CHANGES (Eff. upon passage)

#### • Section 12. EXPANDING OPIOID ANTAGONIST ACCESS (Eff. upon passage)

• 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.

# • Section 13. MEDICAL MARIJUANA CERTIFICATION VIA TELEHEALTH (Eff. upon passage)

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

Section 1 – Centralized Dispensing Practitioner (Effective January 1, 2024)

Section 2 – Pharmacist Prescribing of Legend Devices

Section 3 – Pharmacist Prescribing of Hormonal Contraceptives and Emergency Contraceptive

Section 4 – Access to medications for the termination of pregnancy and discipline related to the termination of pregnancy

Section 5 – Flavoring exemption from USP 800

Section 6 – Non-legend Drugs in Vending Machine

Section 7 – Conforming Changes (Exemption of flavoring from USP)

Section 8 – Conforming Changes (Devices)

Section 9 – Failure to comply with USP Chapters makes it adulterated or misbranded product

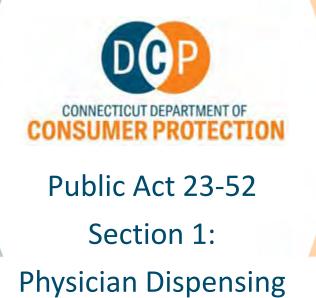
Section 11 – Conforming changes for adulterated drugs

Section 12 – Opioid antagonists in a secure box, a secured machine, syringe service program, vending machines

Section 13 – Telehealth for medical marijuana certifications

\* All listed sections are effective upon passage with the exception of Section 1 which is effective January 1, 2024.





# **Centralized Dispensing Practitioner**

#### Definitions

"Centralized dispensing practitioner" means a prescribing practitioner (A) who is employed by, or affiliated with, a dispensing group practice, and (B) whom the dispensing group practice designates as the prescribing practitioner who is authorized to dispense legend drugs and legend devices on behalf of other prescribing practitioners who are employed by, or affiliated with, such dispensing group practice;

"Dispensing assistant" means an individual who is (A) registered with the department under subdivision (1) of subsection (d) of this section, (B) employed by a dispensing group practice, and (C) supervised by (i) the centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice;

"Dispensing group practice" means a group practice that (A) centralizes the dispensing of legend drugs or legend devices prescribed by prescribing practitioners who are employed by, or affiliated with, the group practice through (i) a centralized dispensing practitioner, or (ii) a pharmacist employed by the dispensing group practice, and (B) is registered with the department pursuant to subsection (b) of this section; and,

"Seventy-two-hour supply" means a quantity of a legend drug or legend device that does not exceed the dosage amount necessary for seventy-two hours according to the directions for use of the legend drug or device.



# **Centralized Dispensing Practitioner**

#### New Credential for Dispensing Practitioners and Dispensing Assistants

- Dispensing Group Practice
  - \$200 biennial credential
  - \$200 renewal
- Dispensing Assistant
  - \$100 biennial registration
  - \$100 renewal
- Not required for dispensing of professional samples or less than a 72-hour supply of medication
- May employ a pharmacist without the requirement of a pharmacy license
- Permits the use of "dispensing assistants" who are registered with the Department
- Shall report to the Prescription Drug Monitoring Program any controlled substance dispensations
- Shall not use the word "drug store", "pharmacy" "apothecary" or "medicine shop" or any combination thereof or any display, symbol or word indication that such dispensing group practice or premises is a pharmacy





### Pharmacists Prescribing Legend Devices

- Pharmacists may authorize or refill a prescription for a legend device if such legend device is approved by the federal Food and Drug Administration for use in combination with a drug prescribed by a prescribing practitioner.
- Must notify the prescribing practitioner of the legend drug within 72 hours of dispensing the legend device.

1/3/202

- Devices that could apply (not all inclusive):
  - Pen Needles
  - Insulin Syringes
  - Spacer for Inhalers
  - Nebulizer
  - Equipment for Nebulizers





Pharmacist Prescribing Hormonal and Emergency Contraceptives

### Pharmacist Prescribing Hormonal and Emergency Contraceptives

"Emergency contraceptive" means a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure;

"Hormonal contraceptive" means a drug, including, but not limited to, a hormonal contraceptive patch, an intravaginal hormonal contraceptive or an oral hormonal contraceptive, composed of a hormone, or a combination of hormones, approved by the federal Food and Drug Administration to prevent pregnancy;

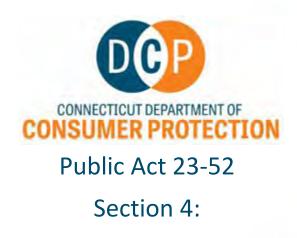


### Pharmacist Prescribing Hormonal and Emergency Contraceptives

- *NOTE: Regulations are required to commence this process and are currently in submission for approval.*
- Follow this page for updated information:
- https://portal.ct.gov/DCP/Drug-Control-Division/Drug-Control/Drug-Control---Pharmacist-Contraceptive-Prescribing
- Regulations will prescribe:
- Training requirements
- Screening requirements
- Requirements for prescribing
- Record keeping
- Transfers
- Communication between the pharmacist and primary care provider
- Confidentiality of records
- Prohibited acts







 Access to Drugs for the
 Termination of Pregnancy and Reciprocal Discipline

# Access to Drugs for the Termination of Pregnancy

- A pharmacy that has been approved to dispense drugs for the termination of pregnancy shall provide a list of the pharmacies nearest to the patient that dispenses such drug if the drug is not available at that pharmacy.
- An approved pharmacy should keep a list of other local pharmacies that have been approved.



### **Reciprocal Discipline**

The Commission and the Department cannot automatically discipline any pharmacist solely based on disciplinary action taken in another state or jurisdiction if the discipline was solely based on the termination of pregnancy under conditions which would not violate the laws of this state.



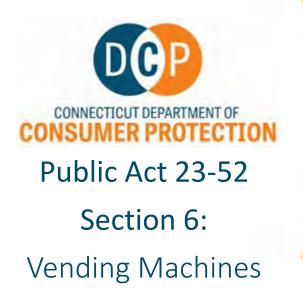




# **Flavoring Agent Exemption**

- The addition of a flavoring agent to a non-sterile compound is exempted from the requirements of the USP Chapter 795 and 800.
- Permits the addition of flavoring agents, to preparations like antibiotics, without the precautions required for hazardous compounding.





## Nonlegend Drug Permit

- Permits the use of vending machines for the sale of nonlegend drugs
- Vending machines must have a nonlegend drug permit associated with it
- Vending machines may contain testing strips to prevent accidental overdose (fentanyl test strips)
  - Initial Application Fee: \$140
  - Renewal: \$100
  - Expires annually on December 31st





Vending Machines:

- Shall maintain proper temperature and humidity for each nonlegend drug offered in the machine;
- May only contain products that remain in the original containers provided by the manufacturer;
- May only offer for sale products that are not expired or adulterated;
- May only offer for sale products that are not subject to a recall and products that become subject to a recall must be promptly removed; and,
- May ONLY offer for sale nonlegend drugs and nonlegend devices, sundries and other nonperishable items.



What is NOT required for pharmacy technicians to administer vaccinations?

- Hands-on training by the American Council for Pharmacy Education on the administration of vaccines
- Pharmacy training on the process for administering vaccines at the pharmacy
- One hour of annual continuing education concerning immunization
- Certification from the Centers for Disease Control and Prevention on the administration of vaccinations



What is NOT required for pharmacy technicians to administer vaccinations?

- Hands-on training by the American Council for Pharmacy Education on the administration of vaccines
- Pharmacy training on the process for administering vaccines at the pharmacy
- One hour of annual continuing education concerning immunization
- Certification from the Centers for Disease Control and Prevention on the administration of vaccinations



In the event a patient is experiencing anaphylaxis and a pharmacist administers an epinephrine cartridge injector, how long does the pharmacist need to maintain documentation of the date, time and circumstances in which they administered the epinephrine?

- One year
- Three years
- **Five years**
- Seven years



In the event a patient is experiencing anaphylaxis and a pharmacist administers an epinephrine cartridge injector, how long does the pharmacist need to maintain documentation of the date, time and circumstances in which they administered the epinephrine?

One year Three years

Five years

Seven years



What is defined as a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure?

- Prenatal vitamin
- □ Spermicide
- **Emergency contraceptive**
- Birth control



What is defined as a drug, or a combination of drugs, approved by the federal Food and Drug Administration to prevent pregnancy as soon as possible following (A) unprotected sexual intercourse, or (B) a known or suspected contraceptive failure?

🔀 Prenatal vitamin

**X** Spermicide

Emergency contraceptive

Birth control





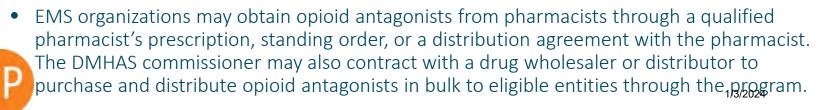
### HEALTH AND WELLNESS FOR CONNECTICUT RESIDENTS

### • Sections 3 and 4. Harm Reduction Centers

- Requires DMHAS, by July 1, 2027, and in consultation with DPH, to create a pilot program consisting of harm reduction centers to prevent drug overdoses.
- Centers must be established in three municipalities chosen by the commissioner of DMHAS and subject to the chief elected officials' approval.
- "Harm reduction centers" are defined as medical facilities where a person with a substance use disorder may receive various services, such as counseling, treatment referrals, and basic support services and use test strips to test a substance for fentanyl or certain other substances.
- Centers are not subject to DPH regulation until after the pilot program ends.

### • Section 5. Opioid Antagonist Bulk Purchase Fund

- DMHAS, in collaboration with DPH, must use the account's funds to provide opioid antagonists to municipalities, local and regional boards of education and non-public schools, district and municipal health departments, law enforcement agencies, and EMS organizations.
- Requires EMS personnel to give kits with opioid antagonists and related information to certain patients or their family members, caregivers, or friends.



#### HEALTH AND WELLNESS FOR CONNECTICUT RESIDENTS (cont.)

#### • Section 6. Co-prescribing of Opioid Antagonist

• Requires prescribing practitioners, when prescribing an opioid, to encourage the patient, and parents or guardian when applicable, to obtain an opioid antagonist. Effective October 1st.

#### • Section 35. Opioid Settlement Fund Advisory Committee

• Adds eight members to the Opioid Settlement Fund Advisory Committee.

#### • Section 42. EMS Personnel and Epinephrine Administration

- Requires EMS personnel to administer epinephrine using automatic prefilled cartridge injectors or prefilled vials and syringes when the EMS professional has been trained to do;
- Medication is administered according to written protocols and standing orders of a licensed physician serving as an emergency department director; and,
- EMS professional determines administering epinephrine is necessary to treat the person. Effective October 1st.





SAFE STORAGE AND DISPOSAL OF CERTAIN PRESCRIPTION DRUGS, ILLEGAL DRUGS AND CANNABIS AND CANNABIS PRODUCTS

- Section 1: STICKER ON ALL CONTROLLED SUBSTANCES (Eff. Jan. 1, 2024)
  - Pharmacies must affix an orange sticker on the packaging or labeling of all controlled substances dispensed the reads: DANGER TO CHILDREN. KEEP OUT OF REACH







# Public Act 128

PREVENTING AN ADVERSE ACTION AGAINST A HEALTH CARE PROVIDER DUE TO AN ADVERSE ACTION TAKE BY ANOTHER STATE AS A RESULT OF SUCH PROVIDER'S INVOLVEMENT IN PROVIDING REPRODUCTIVE HEALTH CARE SERVICES

- Section 2: Denial of Provider Credentials Prohibited
  - Prohibits DCP and the Commission of Pharmacy from denying a credential or disciplining a credentialed provider due to disciplinary actions (or pending actions or complaints) in other U.S. jurisdictions solely based on the person's alleged participation in reproductive health care services







### PROTECTING PATIENTS AND PROHIBITING UNNECESSARY HEALTH CARE COSTS

- Section 2. Expiration of Drug Patents (Eff. upon passage)
  - Requires DCP to report on a framework for a program to inform physicians about when drug patents expire and generic alternatives that exist for drugs with recently expired patents. Report due January 1, 2025.
- Sections 3 through 6. Pharmaceutical Sales Registrations (Eff. October 1, 2023)
  - Require pharmaceutical manufacturers that employ pharmaceutical sales representatives to register annually with DCP as "pharmaceutical marketing firms" and give DCP a list of their sales representatives.
  - DCP may adopt regulations to provide more specificity with enforcement provisions for the new registration.





## Public Acts 23-204 & 23-205

### Public Act 23-204: Budget Bill

#### • Section 227. Step Therapy Data Collection (Eff. upon passage)

- Task force membership includes the Commissioner of DCP or designee.
- Public Health Committee is responsible for administering the task force
- Report is due February 1, 2024

#### • Sections 251-259. Haven Health Program (Eff. October 1, 2023)

- Expand program established to provide education, prevention, intervention, referral assistance, rehabilitation and support services to health care professionals who have a chemical dependency, emotional or behavioral disorder or physical or mental illness to include pharmacists and pharmacy interns.
- Adds a \$5 fee to these licenses to help pay for the services provided by Haven Health.

### Public Act 23-205: Implementer Bill

- Section 160. Funding for Haven (Eff. upon passage)
  - Funds the assistance program for pharmacists and pharmacy interns administered by Haven (\$60,000)



What color is the sticker pharmacies are required to affix on labels for opioids and controlled substances as of January 1, 2024?

Orange

Yellow

Pink

Green



What color is the sticker pharmacies are required to affix on labels for opioids and controlled substances as of January 1, 2024?









HAVEN provides confidential assistance to healthcare professionals with which of the following potentially impairing conditions?

Substance use disorders
 Emotional and behavioral disorders
 Neurodegenerative conditions
 Physical or mental illness
 All of the above



HAVEN provides confidential assistance to healthcare professionals with which of the following potentially impairing conditions?

Substance use disorders
 Emotional and behavioral disorders
 Neurodegenerative conditions
 Physical or mental illness
 All of the above



How can a referral be made for a pharmacy professional to the HAVEN program?

- By submitting an online form on the HAVEN website
- □ Via an email with the professional's contact information and detailing the impairing condition
- Sending a handwritten referral through the mail or by fax
- By making a personal phone call



How can a referral be made for a pharmacy professional to the HAVEN program?

By submitting an online form on the HAVEN website

Via an email with the professional's contact information and detailing the impairing condition

Sending a handwritten referral through the mail or by fax

By making a personal phone call



What is the web address to the Department of Consumer Protection's Drug Control Division's webpage where you can get updated information on relevant laws, regulations and policies?

ct.gov/dcp/drugs

- ct.drugs.gov
- ct.gov/dcp/dcd
- □ ct.gov/drugs



What is the web address to the Department of Consumer Protection's Drug Control Division's webpage where you can get updated information on relevant laws, regulations and policies?

ct.gov/dcp/drugs
 ct.drugs.gov
 ct.gov/dcp/dcd
 ct.gov/drugs



## **Questions?**

### **Department of Consumer Protection Drug Control Division**





dcp.drugcontrol@ct.gov



