General Assembly

Raised Bill No. 5149

February Session, 2022

LCO No. **1207**

Referred to Committee on GENERAL LAW

Introduced by:
(GL)

AN ACT CONCERNING THE DEPARTMENT OF CONSUMER PROTECTION'S RECOMMENDATIONS REGARDING FOOD, DRUGS AND MEDICAL DEVICES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 20-578 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) Information received by the department, the commission or the Department of Public Health, through filed reports or inspection or as otherwise authorized under chapters 418, **[**and**]** 420b, 420c and 420f and sections 20-570 to 20-630, inclusive, shall not be disclosed publicly in such a manner as to identify individuals or institutions, except: (1) In a proceeding involving the question of licensure or the right to practice; **[**,**]** and (2) in a proceeding where the commission has voted in favor of formal disciplinary action against a pharmacist or pharmacy licensed pursuant to this chapter, when such disciplinary action is related to an error in the dispensing of medication. Nothing in this section shall be construed to prohibit the commissioner from disclosing information gained through the inspection of pharmacies and outlets holding

permits for the sale of nonlegend drugs if the commissioner considers such disclosure to be in the interest of public health.

(b) Notwithstanding the provisions of subsection (a) of this section, section 21a-265 and chapter 55, the Commissioners of Consumer Protection and Public Health and the authorized agents of said commissioners, in carrying out their duties under subsection (a) of this section, may: (1) Exchange information relating to a license or registration issued by their respective agencies; **[**,**]** or (2) exchange investigative information relating to violations of this chapter with each other, **[**with**]** the Chief State's Attorney and **[**with**]** any agencies charged with **[**the enforcement of**]** enforcing the pharmacy or drug laws of the United States, this state **[**and all**]** or other jurisdictions.

Sec. 2. Section 20-617a of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) For purposes of this section, "flavoring agent" means an additive used in food or drugs when such additive: (1) Is used in accordance with good manufacturing practice principles and in the minimum quantity required to produce its intended effect; **[**,**]** (2) consists of one or more ingredients generally recognized as safe in food and drugs, has been previously sanctioned for use in food and drugs by the state or the federal government **[**, meets United States Pharmacopeia standards**]** or is an additive permitted for direct addition to food for human consumption pursuant to 21 CFR 172; **[**,**]** (3) is inert and produces no effect other than the instillation or modification of flavor; **[**,**]** and (4) is not greater than five per cent of the total weight of the product.

(b) A flavoring agent may be added to a prescription product by: (1) A pharmacist upon the request of the prescribing practitioner, patient for whom the prescription is ordered or such patient's agent; **[**,**]** or (2) a pharmacist acting on behalf of a hospital, as defined in section 19a-490.

Sec. 3. Subsection (a) of section 20-621a of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) As used in this section: **[**,**]** (1) **[**"long-term care pharmacy"**]** "Long-term care pharmacy" (A) means a pharmacy licensed under section 20-594, or registered as a nonresident pharmacy under section 20-627, that stores and dispenses legend drugs and legend devices to patients or residents of licensed nursing homes, rest homes, residential care homes or other supervised residential facilities and from which related pharmaceutical care services are provided, and (B) includes pharmacies located both inside and outside of such facilities but does not include those that are part of a licensed hospital; **[**,**]** (2) "nursing home" has the same meaning as provided in section 19a-490; **[**,**]** and (3) "automated prescription dispensing machine" has the same meaning as provided in section 20-571. A long-term care pharmacy may operate an automated prescription dispensing machine in a nursing home in accordance with a protocol approved in writing by the Department of Consumer Protection, until such time as regulations are adopted pursuant to subsection (b) of this section. The annual fee to operate an automated prescription dispensing machine shall be one hundred dollars per machine.

Sec. 4. Section 21a-248 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) A licensed manufacturer or wholesaler may sell and dispense controlled drugs to any of the following-named persons, but in the case of schedule II drugs only on an official written order or electronically through the Drug Enforcement Agency's Controlled Substance Ordering System: (1) To a manufacturer, wholesaler or pharmacist; (2) to a physician, dentist or veterinarian; (3) to a person in charge of a hospital, incorporated college or scientific institution, but only for use by or in that hospital, incorporated college or scientific institution for medical or scientific purposes; (4) to a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes; and (5) to any registrant as defined in subdivision (47) of section 21a-240.

(b) A licensed manufacturer or wholesaler may sell controlled drugs

only to registrants when permitted under federal and state laws and regulations.

(c) An official **[**written**]** order for any schedule I or II drug shall be signed **[**in triplicate**]** by the person giving such order or by **[**his**]** such person's authorized agent and **[**the original**]** such order shall be presented to the person who sells or dispenses the drug or drugs named therein as provided by federal **[**laws**]** law. If such order is accepted by such person, each party to the transaction shall preserve **[**his**]** such party's copy of such order for a period of three years in such a way so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

(d) The manufacturer or wholesaler shall keep records of all sales and dispensing of controlled drugs and shall comply fully with applicable provisions of the federal controlled drug laws and the federal food and drug laws, and the state food, drug and cosmetic laws in such sale or dispensing of controlled drugs.

(e) Possession or control of controlled drugs obtained as authorized by this section shall be lawful only if obtained in the regular course of the business, occupation, profession, employment or duty of the possessor.

(f) A person in charge of a hospital, incorporated college or scientific institution, or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled drugs under the provisions of this section or otherwise, shall not administer, or dispense, or otherwise use such drugs within this state, except within the scope of **[**his**]** such person's, master's or officer's employment or official duty, and then only for scientific or medicinal purposes or for the purposes of research or analysis and subject to the provisions of this chapter.

Sec. 5. Section 28-32 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) For purposes of this section and section 28-32a:

(1) (A) "Drugs" means **[**(A)**]** (i) substances recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States **[**,**]** or official National Formulary, or any supplement to any of said publications, **[**; (B)**]** (ii) substances intended for use in **[**the diagnosis, cure, mitigation, treatment or prevention of**]** curing, diagnosing, mitigating, preventing or treating disease in **[**man**]** humans or other animals, **[**; (C)**]** (iii) substances, other than food, intended to affect the structure or any function of the body of **[**man**]** humans or other animals, **[**;**]** and **[**(D)**]** (iv) substances intended for use as a component of any article specified in **[**subparagraph (A), (B) or (C)**]** subparagraph (A)(i), (A)(ii) or (A)(iii) of this subdivision.

(B) "Drugs" does not include devices or their components, parts or accessories. **[**;**]**

(2) (A) "Controlled drugs" means those drugs which contain any quantity of a substance which has been designated as subject to the federal Controlled Substances Act, or which has been designated as a depressant or stimulant drug pursuant to federal food and drug laws, or which has been designated by the Commissioner of Consumer Protection pursuant to section 21a-243 as having a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and as having a tendency to promote abuse or psychological or physiological dependence, or both. Such controlled drugs are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant drugs.

(B) "Controlled drugs" does not include alcohol, nicotine or caffeine. **[**;**]**

(3) (A) "Controlled substance" means a drug, substance or immediate precursor in schedules I to V, inclusive, of the Connecticut controlled substance scheduling regulations adopted pursuant to section 21a-243.

(B) "Controlled substance" does not include alcohol, nicotine or caffeine.

(4) "Medical devices" means apparatuses, contrivances and instruments, including their accessories, components and parts, intended (A) for use in curing, diagnosing, mitigating, preventing or treating disease in humans or other animals, or (B) to affect the structure or any function of the body of humans or other animals.

(b) Upon declaration of an emergency by the Governor or the Governor's authorized representative having authority to declare emergencies, a hospital pharmacy, pharmacy or registrant authorized by state or federal law to be in possession of controlled substances may, in accordance with applicable federal regulations, policies and guidelines and with prior approval of the Commissioner of Consumer Protection, transfer or distribute **[**drugs or**]** controlled drugs, drugs or medical devices to a licensed pharmacy, a registrant authorized by state or federal law to be in possession of controlled substances, or a location authorized by the commissioner. Such registrant shall record the transfer accurately and in compliance with all state and federal statutes and regulations and shall report the transfer, in writing, to the commissioner.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2022*	20-578
Sec. 2	*July 1, 2022*	20-617a
Sec. 3	*July 1, 2022*	20-621a(a)
Sec. 4	*July 1, 2022*	21a-248
Sec. 5	*July 1, 2022*	28-32

Statement of Purpose:

To: (1) Provide that certain information received by the Department of Consumer Protection, Commission of Pharmacy or Department of Public Health shall not be publicly disclosed in a manner that would enable any person to identify certain individuals or institutions; (2) eliminate the requirement that certain flavoring agents used in food or

drugs meet United States Pharmacopeia standards; (3) allow drug wholesalers to electronically order schedule II controlled substances through the Drug Enforcement Agency's Controlled Substance Ordering System; (4) eliminate the requirement that an official order for a schedule I or II controlled substance be signed in triplicate; (5) redefine "long-term care pharmacy" to include a pharmacy that is registered as a nonresident pharmacy; (6) define "medical device"; and (7) authorize a hospital pharmacy, pharmacy or registrant to, upon declaration of an emergency, with prior approval of the Commissioner of Consumer Protection and subject to certain conditions, transfer or distribute medical devices.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]