



General Assembly

Substitute Bill No. 694

January Session, 2021



AN ACT CONCERNING REVISIONS TO PHARMACY AND DRUG CONTROL STATUTES.

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

1 Section 1. Section 21a-319 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2021*):

3 (a) No certificate of registration shall be issued, maintained or
4 renewed under this chapter unless or until the applicant has furnished
5 proof satisfactory to the Commissioner of Consumer Protection that he
6 or she is licensed or duly authorized to practice his or her profession by
7 the appropriate state licensing board, commission or registration
8 agency; or, in the case of a hospital or other institution, by the
9 appropriate state agency having jurisdiction over the licensure,
10 registration or approval of such establishment.

11 (b) The Commissioner of Consumer Protection may change the status
12 of a controlled substance registration to inactive for any practitioner
13 who fails to maintain a license, registration or approval of a license to
14 practice his or her medical profession for a period longer than ninety
15 days. Such change in license status shall not be considered disciplinary
16 and the registration shall be reinstated without additional fee, if the
17 practitioner restores his or her license, registration or approval to
18 practice his or her profession with the Department of Public Health or

19 associated board or commission, and the reinstatement occurs prior to
20 the expiration of the controlled substance registration.

21 Sec. 2. (NEW) (*Effective from passage*) (a) For purposes of this section,
22 "epinephrine auto injector" means a prefilled auto injector or similar
23 automatic injectable equipment used to deliver epinephrine in a
24 standard dose for emergency first aid response to allergic reactions.

25 (b) A pharmacist, in his or her professional discretion, may issue a
26 prescription for not more than two epinephrine auto injectors under the
27 following conditions:

28 (1) The pharmacist identifies that the patient requesting such
29 prescription has received an epinephrine auto injector by prescription
30 from another pharmacy within the previous two years;

31 (2) The pharmacist identifies the patient's practitioner specified by
32 the patient as his or her primary care provider at the time the request is
33 made;

34 (3) The pharmacist informs the patient's primary care provider of the
35 issuance of the prescription not later than seventy-two hours after such
36 issuance, by either phone, facsimile or electronic transmission; and

37 (4) The prescription issued by the pharmacist does not have any
38 refills and is not filled more than once per year.

39 (c) Nothing in this section shall prevent a pharmacist from verifying
40 a previous prescription at any pharmacy in any part of the United States,
41 including any state, district, commonwealth, territory or insular
42 possession thereof, or any area subject to the legal authority of the
43 United States of America.

44 Sec. 3. Subsection (f) of section 20-633b of the general statutes is
45 repealed and the following is substituted in lieu thereof (*Effective from*
46 *passage*):

47 (f) (1) If a sterile compounding pharmacy plans to remodel [a
48 pharmacy clean room within the sterile compounding facility] any area
49 utilized for the compounding of sterile pharmaceuticals or adjacent
50 space, relocate [a pharmacy clean room within the facility] any space
51 utilized for the compounding of sterile pharmaceuticals or upgrade or
52 conduct a nonemergency repair to the heating, ventilation, air
53 conditioning or primary or secondary engineering controls for [a
54 pharmacy clean room within the facility] any space utilized for the
55 compounding of sterile pharmaceuticals, the sterile compounding
56 pharmacy shall notify the Department of Consumer Protection, in
57 writing, not later than [ten] forty-five days prior to commencing such
58 remodel, relocation, upgrade or repair. Such written notification shall
59 include a plan for such remodel, relocation, upgrade or repair and such
60 plan shall be subject to department review and approval. If a sterile
61 compounding pharmacy makes an emergency repair, the sterile
62 compounding pharmacy shall notify the department of such emergency
63 repair, in writing, [as soon as possible] not later than twenty-four hours
64 after such repair is commenced.

65 (2) If the USP chapters require sterile recertification after such
66 remodel, relocation, upgrade or repair, the sterile compounding
67 pharmacy shall provide a copy of its sterile recertification to the
68 Department of Consumer Protection not later than five days after the
69 sterile recertification approval. The recertification shall only be
70 performed by an independent licensed environmental monitoring
71 entity.

72 Sec. 4. Subsection (d) of section 20-614 of the general statutes is
73 repealed and the following is substituted in lieu thereof (*Effective from*
74 *passage*):

75 (d) Prior to or simultaneous with the dispensing of a drug, [pursuant
76 to subsection (b) of this section] from a pharmacy licensed pursuant to
77 this chapter, a pharmacist or other employee of the pharmacy shall,
78 whenever practicable, offer for the pharmacist to discuss the drug to be
79 dispensed and to counsel the patient on the usage of the drug, except

80 when the person obtaining the prescription is other than the person
81 named on the prescription form or electronic record or the pharmacist
82 determines it is appropriate to make such offer in writing. Any such
83 written offer shall include an offer to communicate with the patient
84 either in person at the pharmacy or by telephone.

85 Sec. 5. Subsection (a) of section 21a-70 of the general statutes is
86 repealed and the following is substituted in lieu thereof (*Effective July 1,*
87 *2021*):

88 (a) As used in this section: (1) "Drugs", "devices" and "cosmetics" have
89 the same meanings as defined in section 21a-92, "wholesaler" or
90 "distributor" means a person, including, but not limited to, a medical
91 device and oxygen provider, a third-party logistics provider, a virtual
92 manufacturer or a virtual wholesale distributor, as such terms are
93 defined in section 20-571, whether within or without the boundaries of
94 the state of Connecticut, who supplies drugs, devices or cosmetics
95 prepared, produced or packaged by manufacturers, to other
96 wholesalers, manufacturers, distributors, hospitals, prescribing
97 practitioners, as defined in subdivision (24) of section 20-571,
98 pharmacies, federal, state or municipal agencies, clinics or any other
99 person as permitted under subsection (h) of this section, except that: (A)
100 A retail pharmacy or a pharmacy within a licensed hospital that
101 supplies to another such pharmacy a quantity of a noncontrolled drug
102 or a schedule II, III, IV or V controlled substance normally stocked by
103 such pharmacies to provide for the immediate needs of a patient
104 pursuant to a prescription or medication order of an authorized
105 practitioner, (B) a pharmacy within a licensed hospital that supplies
106 drugs to another hospital or an authorized practitioner for research
107 purposes, (C) a retail pharmacy that supplies a limited quantity of a
108 noncontrolled drug or of a schedule II, III, IV or V controlled substance
109 for emergency stock to a practitioner who is a medical director of a
110 chronic and convalescent nursing home, of a rest home with nursing
111 supervision, of a hospice inpatient facility licensed pursuant to section
112 19a-491 or of a state correctional institution, and (D) a pharmacy within

113 a licensed hospital that contains another hospital wholly within its
 114 physical structure that supplies to such contained hospital a quantity of
 115 a noncontrolled drug or a schedule II, III, IV, or V controlled substance
 116 normally stocked by such hospitals to provide for the needs of a patient,
 117 pursuant to a prescription or medication order of an authorized
 118 practitioner, receiving inpatient care on a unit that is operated by the
 119 contained hospital, or receiving outpatient care in a setting operated by
 120 the contained hospital and such drug or substance is administered on-
 121 site by the contained hospital, shall not be deemed a wholesaler under
 122 this section; (2) "manufacturer" means (A) a person, whether within or
 123 without the boundaries of the state of Connecticut, who produces,
 124 prepares, cultivates, grows, propagates, compounds, converts or
 125 processes, directly or indirectly, by extraction from substances of
 126 natural origin or by means of chemical synthesis or by a combination of
 127 extraction and chemical synthesis, or who packages, repackages, labels
 128 or relabels a container under such manufacturer's own or any other
 129 trademark or label any drug, device or cosmetic for the purpose of
 130 selling such items, or (B) a sterile compounding pharmacy, as defined
 131 in section 20-633b, as amended by this act, that dispenses sterile
 132 pharmaceuticals without a prescription or a patient-specific medical
 133 order; (3) "drug", "device" and "cosmetic" have the same meanings as
 134 provided in section 21a-92; and (4) "commissioner" means the
 135 Commissioner of Consumer Protection or his or her designee.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2021</i>	21a-319
Sec. 2	<i>from passage</i>	New section
Sec. 3	<i>from passage</i>	20-633b(f)
Sec. 4	<i>from passage</i>	20-614(d)
Sec. 5	<i>July 1, 2021</i>	21a-70(a)

Statement of Legislative Commissioners:

Section 2(b) was reorganized for clarity.

GL *Joint Favorable Subst.*