

Legislative Regulation Review Committee

2011-018

Department of Consumer Protection

STERILE COMPOUNDING

STATE OF CONNECTICUT
REGULATION
of the
DEPARTMENT OF CONSUMER PROTECTION
(NAME OF AGENCY)
concerning
STERILE COMPOUNDING
(SUBJECT MATTER OF REGULATION)

The Regulations of Connecticut State Agencies are amended by adding sections 20-576-64 to 20-576-68, inclusive, as follows:

(NEW) Section 1. Section 20-576-64. Definitions.

As used in sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Sterile compounding pharmacy" means a pharmacy licensed pursuant to section 20-594 of the general statutes that dispenses sterile pharmaceutical products but does not include a pharmacy that is part of a licensed hospital; and

(2) "Sterile pharmaceutical" means any dosage form of a drug, including but not limited to parenterals (e.g., injectables, surgical irrigants, and ophthalmics), devoid of viable microorganisms.

(NEW) Sec. 2. Section 20-576-65. Purpose.

The purpose of sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies is to ensure positive patient outcomes through the provision of standards for (1) pharmacist care; (2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies licensed pursuant to section 20-594 of the general statutes; and (3) product quality and characteristics.

(NEW) Sec. 3. Section 20-576-66. Standards.

(a) Sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies shall apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

(b) A sterile compounding pharmacy shall comply with sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies, and the current United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations. The United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations may be obtained via the Internet at the following location: <http://www.usp.org/products/797Guidebook/>.

(c) A sterile compounding pharmacy may provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision, except that the quantity shall be limited to a two-week supply.

(NEW) Sec. 4. Section 20-576-67. Policy and Procedure Manual.

A sterile compounding pharmacy shall prepare and maintain a policy and procedure manual for the compounding, dispensing, delivery, administration, storage and use of sterile pharmaceuticals. The policy and procedure manual shall be in compliance with the United States Pharmacopeia, Revised General Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

(NEW) Sec. 5. Section 20-576-68. Hours.

A sterile compounding pharmacy shall be open thirty-five (35) hours per week unless granted a waiver by the commission pursuant to section 20-576-59 of the Regulations of Connecticut State Agencies.

STATEMENT OF PURPOSE

(A) Purpose: Connecticut General Statutes, Section 20-576(a)(2) permits the Commissioner of Consumer Protection, with the advice and assistance of the Commission of Pharmacy, to adopt regulations specifying classes of pharmacies and setting requirements for specific classes of pharmacies. These regulations establish requirements for pharmacies classified as sterile compounding pharmacies.

(B) Summary: These new regulations set standards for pharmacies classified by the Commission of Pharmacy as sterile compounding pharmacies. Sterile compounding pharmacies mix and dispense sterile drugs and drug products. In addition to the laws applicable to all pharmacies, sterile compounding pharmacies must comply with the standards for sterile compounding set by the United States Pharmacopeia, a non-profit organization that establishes national standards for drug products. These regulations also require sterile compounding pharmacies to have a policy and procedure manual and to be open a minimum number of hours per week.

(C) Legal Effects: These regulations set additional standards for sterile compounding pharmacies to follow. If these regulations are violated, the pharmacy may face administrative action against its pharmacy license. The administrative remedies include revocation or suspension of the license, probation, civil penalties, or a letter of reprimand.

Be it known that the foregoing:

Regulations Emergency Regulations

Are:

Adopted Amended as hereinabove stated Repealed

By the aforesaid agency pursuant to:

Sections 4-168 and 20-576(a) of the General Statutes and

Section _____ of the General Statutes, as amended by Public Act No. _____ of the _____ Public Acts.

Public Act No. _____ of the _____ Public Acts.

After publication in the Connecticut Law Journal on _____ of the notice of the proposal to:

Adopt Amend Repeal such regulations

(If applicable): And the holding of an advertised public hearing on _____ day of _____ 20 _____

WHEREFORE, the foregoing regulations are hereby:

Adopted Amended as hereinabove stated Repealed

Effective:

When filed with the Secretary of the State.
(OR)

The _____ day of _____, 20 _____.

In Witness Whereof:	DATE 2/8/11	SIGNED (Head of Board, Agency or Commission) <i>Jerry Farwell</i>	OFFICIAL TITLE, DULY AUTHORIZED COMMISSIONER
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Approved by the Attorney General as to legal sufficiency in accordance with Sec. 4-169, as amended, C.G.S.:	SIGNED <i>Joseph Rubin</i>	DATE 4/5/11	OFFICIAL TITLE, DULY AUTHORIZED Assoc. A. G.
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- Approved
- Disapproved
- Disapproved in part, (Indicate Section Numbers disapproved only)
- Rejected without prejudice.

By the Legislative Regulation Review Committee in accordance with Sec. 4-170, as amended, of the General Statutes.	DATE	SIGNED (Clerk of the Legislative Regulation Review Committee)
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Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications in accordance with Section 4-172, as amended, of the General Statutes.

DATE	SIGNED (Secretary of the State)	BY
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INSTRUCTIONS

One copy of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the Attorney General for his determination of legal sufficiency. Section 4-169 of the General Statutes.

Seventeen copies of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the standing Legislative Regulation Review Committee for its approval. Section 4-170 of the General Statutes.

Each regulation must be in the form intended for publication and must include the appropriate regulation section number and section heading. Section 4-172 of the General Statutes.

Indicate by "(NEW)" in heading if new regulation. Amended regulations must contain new language in capital letters and deleted language in brackets. Section 4-170 of the General Statutes.