

STATE OF CONNECTICUT
REGULATION
of the
DEPARTMENT OF CONSUMER PROTECTION

(NAME OF AGENCY)

concerning
NON-STERILE COMPOUNDING

(SUBJECT MATTER OF REGULATION)

The Regulations of Connecticut State Agencies are amended by adding sections 20-576-69 to 20-576-73, inclusive, as follows:

(NEW) Section 20-576-69. Definitions.

As used in sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies:

- (1) "Commission" means the Commission of Pharmacy;
- (2) "Non-sterile compounding pharmacy" means a pharmacy that dispenses non-sterile compounded pharmaceutical products; and
- (3) "Non-sterile compounded pharmaceutical product" means a drug dosage form, a dietary supplement or a finished device made from the preparation of one or more substances.

(NEW) Section 20-576-70. Purpose.

The purpose of sections 20-576-69 to 20-576-73, 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 non-sterile compounded pharmaceutical products by pharmacies; and (3) product quality and characteristics.

(NEW) Section 20-576-71. Standards.

(a) Sections 20-576-64 to 20-576-68, inclusive, of the Regulations of Connecticut State Agencies shall apply to all non-sterile compounded pharmaceutical products, notwithstanding the location of the patient, including, for example: Home, hospital, nursing home, hospice, or doctor's office.

(b) A non-sterile compounding pharmacy shall comply with sections 20-576-69 to 20-576-73, inclusive, of the Regulations of Connecticut State Agencies, and the current United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations. The United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations may be obtained at http://www.pharmacopeia.cn/v29240/usp29nf24s0_c795.html.

(c) A non-sterile compounding pharmacy may provide non-sterile compounded pharmaceutical 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) Section 20-576-72. Policy and Procedure Manual.

A non-sterile compounding pharmacy shall prepare and maintain a policy and procedure manual for the compounding, dispensing, delivery, administration, storage, and use of non-sterile compounded pharmaceutical products. The policy and procedure manual shall be in compliance with the United States Pharmacopeia, Revised General Chapter 795, Pharmaceutical Compounding: Non-Sterile Preparations.

(NEW) Section 20-576-73. Hours.

A non-sterile compounding pharmacy shall be open thirty-five 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 non-sterile compounding pharmacies.

(B) Summary: These regulations set standards for pharmacies classified by the Commission of Pharmacy as non-sterile compounding pharmacies. In addition to the laws applicable to all pharmacies, non-sterile compounding pharmacies must comply with the standards for non-sterile compounding pharmacies set by the United States Pharmacopeia, a non-profit organization that establishes national standards for drug products. In addition, these regulations require non-sterile compounding pharmacies to have a policy and procedure manual.

(C) Legal Effects: These regulations set additional standards that non-sterile compounding pharmacies must 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 _____ 2011.

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	SIGNED (Head of Board, Agency or Commission)	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	OFFICIAL TITLE, DULY AUTHORIZED
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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.