R-39 Rev. 03/2012
(Title page)

IMPORTANT: Read instructions on back of last page (Certification Page) before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations

State of Connecticut
REGULATION
of

NAME OF AGENCY
The Department of Consumer Protection

Concerning

SUBJECT MATTER OF REGULATION
Non-Sterile Compounding

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 licensed pursuant to section 20-594 of the General Statues that dispenses non-sterile compounded pharmaceutical products, but does not include a pharmacy that is part of a licensed hospital; 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 licensed pursuant to section 20-594 of the General Statutes; and (3) product quality and characteristics.

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

(a) Sections 20-576-69 to 20-576-73, 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-patient specific 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 thirty day 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 at least 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

Pursuant to CGS Section 4-170(b)(3), "Each proposed regulation shall have a statement of its purpose following the final section of the regulation."

(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.

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(Certification page—see Instructions on back)

CERTIFICATION

This certification statement must be completed in full, including items 3 and 4, if they are applicable.

1) I hereby certify that the above *(check one)* ☒ Regulations ☐ Emergency Regulations

2) are *(check all that apply)* ☒ adopted ☐ amended ☐ repealed **by this agency pursuant to the following authority(ies):** *(complete all that apply)*

a. *Connecticut General Statutes* section(s) 4-168 and 20-576(a).

b. Public Act Number(s) _____.
(Provide public act number(s) if the act has not yet been codified in the Connecticut General Statutes.)

3) And I further certify that notice of intent to adopt, amend or repeal said regulations was published in the *Connecticut Law Journal* on April 24, 2012;
(Insert date of notice publication if publication was required by CGS Section 4-168.)

4) And that a public hearing regarding the proposed regulations was held on May 30, 2012;
(Insert date(s) of public hearing(s) held pursuant to CGS Section 4-168(a)(7), if any, or pursuant to other applicable statute.)

5) And that said regulations are EFFECTIVE *(check one, and complete as applicable)*

☒ When filed with the Secretary of the State

OR ☐ on *(insert date)* _____

SECRETARY OF THE STATE
LEGISLATION & ELECTIONS
ADMINISTRATION DIVISION
2012 NOV - 2 P 4:0

DATE	SIGNED *(Head of Board, Agency or Commission)*	OFFICIAL TITLE, DULY AUTHORIZED
7/12/12		Commissioner Department of Consumer Protection

***APPROVED** by the **Attorney General** as to legal sufficiency in accordance with CGS Section 4-169, as amended*

DATE	SIGNED *(Attorney General or AG's designated representative)*	OFFICIAL TITLE, DULY AUTHORIZED
8/13/12	Joseph Rubin	ASSOC. ATTY. GENERAL

*Proposed regulations are **DEEMED APPROVED** by the Attorney General in accordance with CGS Section 4-169, as amended, if the attorney General fails to give notice to the agency of any legal insufficiency within thirty (30) days of the receipt of the proposed regulation.*

(For Regulation Review Committee Use ONLY)

☐ Approved ☐ Rejected without prejudice

☒ Approved with technical corrections ☐ Disapproved in part, *(Indicate Section Numbers disapproved only)*

☐ Deemed approved pursuant to CGS Section 4-170(c)

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	DATE	SIGNED *(Administrator, Legislative Regulation Review Committee)*
	10/23/2012	Pamela B. Booth

Two certified copies received and filed and one such copy forwarded to the Commission on Official Legal Publications in accordance with CGS Section 4-172, as amended.

DATE	SIGNED *(Secretary of the State)*	BY

(For Secretary of the State Use ONLY)

GENERAL INSTRUCTIONS

1. All regulations proposed for adoption, amendment or repeal, *except* emergency regulations, must be presented to the Attorney General for his/her determination of legal sufficiency. (See CGS Section 4-169.)

2. After approval by the Attorney General, the original and one electronic copy (in Word format) of all regulations proposed for adoption, amendment or repeal must be presented to the Legislative Regulation Review Committee for its action. (See CGS Sections 4-168 and 4-170 as amended by Public Act 11-150, Sections 18 and 19.)

3. Each proposed regulation section must include the appropriate regulation section number and a section heading. (See CGS Section 4-172.)

4. New language added to an existing regulation must be in underlining or CAPITAL LETTERS, as determined by the Regulation Review Committee. (See CGS 4-170(b).)

5. Existing language to be deleted must be enclosed in brackets [ ]. (See CGS 4-170(b).)

6. A completely new regulation or a new section of an existing regulation must be preceded by the word "(NEW)" in capital letters. (See CGS Section 4-170(b).)

7. The proposed regulation must have a statement of its purpose following the final section of the regulation. (See CGS Section 4-170(b).)

8. The Certification Statement portion of the form must be completed, including all applicable information regarding *Connecticut Law Journal* notice publication date(s) and public hearing(s). (See more specific instructions below.)

9. Additional information regarding rules and procedures of the Legislative Regulation Review Committee can be found on the Committee's web site: http://www.cga.ct.gov/rr/ .

10. A copy of the Legislative Commissioners' Regulations Drafting Manual is located on the LCO website at http://www.cga.ct.gov/lco/pdfs/Regulations_Drafting_Manual.pdf.

CERTIFICATION STATEMENT INSTRUCTIONS

(Numbers below correspond to the numbered sections of the statement)

1. Indicate whether the regulation is a regular or an emergency regulation adopted under the provisions of CGS Section 4-168(f).

2. a) Indicate whether the regulations contains newly adopted sections, amendments to existing sections, and/or repeals existing sections. Check all cases that apply.

   b) Indicate the specific legal authority that authorizes or requires adoption, amendment or repeal of the regulation. If the relevant public act has been codified in the most current biennial edition of the *Connecticut General Statutes*, indicate the relevant statute number(s) instead of the public act number. If the public act has not yet been codified, indicate the relevant public act number.

3. Except for emergency regulations adopted under CGS 4-168(f), and technical amendments to an existing regulation adopted under CGS 4-168(g), an agency must publish notice of its intent to adopt a regulation in the *Connecticut Law Journal*. Enter the date of notice publication.

4. CGS Section 4-168(a)(7) prescribes requirements for the holding of an agency public hearing regarding proposed regulations. Enter the date(s) of the hearing(s) held under that section, if any; also enter the date(s) of any hearing(s) the agency was required to hold under the provisions of any other law.

5. As applicable, enter the effective date of the regulation here, or indicate that it is effective upon filing with the Secretary of the State. Please note the information below.

   Regulations are effective upon filing with the Secretary of the State or at a later specified date. See CGS Section 4-172(b) which provides that each regulation is effective upon filing, or, if a later date is required by statute or specified in the regulation, the later date is the effective date. An effective date may not precede the effective date of the public act requiring or permitting the regulation. Emergency regulations are effective immediately upon filing with the Secretary of the State, or at a stated date less than twenty days thereafter.