6100

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
Collaborative Drug Therapy Management

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 20-631-1 to 20-631-3, inclusive, as follows:

(NEW) Sec. 20-631-1. Competency Requirements.
To qualify for participation in a collaborative drug therapy management agreement, a pharmacist shall be licensed in this state and shall meet at least one of the following qualifications:

(1) Bachelor of Science degree in pharmacy with 10 years of clinical experience, or a Pharm.D. degree;
(2) Certification by the Board of Pharmaceutical Specialties;
(3) Certification by the Commission for Certification in Geriatric Pharmacy;
(4) A credential in disease state management from the National Institute for Standards in Pharmacist Credentialing;
(5) Pharmacy residency accredited by the American Society of Health-System Pharmacists; or
(6) Completion of a disease state management certification program approved by the Accreditation Council for Pharmacy Education.

(NEW) Sec. 20-631-2. Content of a Collaborative Drug Therapy Management Agreement.
A collaborative drug therapy management agreement shall include:

(1) The types of prescriptive authority decisions the pharmacist may make (e.g., initiation, continuation or modification);
(2) Patients who are eligible for treatment;
(3) The types of diseases, drugs, or drug categories involved (there are no limitations on disease states or conditions);
(4) The procedures, decision criteria, plans, or guidelines the pharmacist is to follow when making therapeutic decisions, particularly when initiating or modifying drug therapy;
(5) Required training;
(6) A plan for periodic review, feedback and quality assurance; and
(7) Procedures for documenting prescribing decisions.

(NEW) Sec. 20-631-3. Content of Patient Protocol.
A written protocol for a specific patient established pursuant to a collaborative drug therapy management agreement shall include, but need not be limited to, the following:

(1) The specific drug or drugs to be managed by the pharmacist;
(2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;

(3) The conditions and events that the pharmacist is required to report to the physician;
(4) The laboratory tests that may be ordered by the pharmacist; and
(5) The drugs that may be administered by the pharmacist.

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: These regulations establish requirements for collaborative drug therapy agreements between physicians and pharmacists. Section 91 of Public Act 10-117 requires the Commissioner of Consumer Protection to adopt these regulations.

(B) Summary: These regulations establish: 1. the competency requirements for pharmacists to qualify for participation in a drug therapy management agreement; 2. the minimum content of a collaborative drug therapy management agreement; and 3. the content of the written protocol for each patient. The Department of Public Health was consulted in drafting these regulations, pursuant to Section 20-631(b) of the General Statutes, as amended by Section 91 of Public Act 10-117.

(C) Legal Effects: These regulations establish requirements for collaborative drug therapy agreements between physicians and pharmacists. If a pharmacist enters into a collaborative drug therapy agreement but fails to comply with these regulations, he or she may face administrative action against the pharmacist's license. The administrative remedies include revocation or suspension of the license, probation, civil penalties or a letter of reprimand.

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R-39 Rev. 03/2012
(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 20-631(d).

b. Public Act Number(s) 117 of the 2010 Public Acts (Section 91).
(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 May 1, 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 June 4, 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)* _____

DATE	SIGNED *(Head of Board, Agency or Commission)*	OFFICIAL TITLE, DULY AUTHORIZED
11/29/12		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
9/25/12	Joseph Rubin	Assoc. A. G.

*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)*
	12/18/2012	Pamela B. Booth, Administrator

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
1-2-2013		

(For Secretary of the State Use ONLY)

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SECRETARY OF THE STATE
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Regulation
of the

Department of Consumer Protection

CONCERNING

Collaborative Drug Therapy Management

Approved by the Attorney General
September 25, 2012

Approved by the Legislative Regulation Review Committee
on

December 18, 2012

Received and filed in the Office of the
Secretary of the State

January 2, 2013

Effective Date: January 2, 2013

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