

Connecticut Regulations

Department of Consumer Protection

RULE ADOPTION

Regulations of Connecticut State Agencies 2022-02-22

PUBLICATION DATE: 02/22/2022

ACTION DATE: 02/18/2022

EFFECTIVE DATE: 02/18/2022

PUBLICATION TYPE: Register

CHANGES PROPOSED

REGISTER SOURCE: Regulations of Connecticut State Agencies 2021-11-24

PUBLICATION DATE: 11/24/2021

ACTION DATE: 11/23/2021

PUBLICATION TYPE: Centralized Repository

PROPOSED RULE

REGISTER SOURCE: Regulations of Connecticut State Agencies 2021-09-02

PUBLICATION DATE: 09/02/2021

ACTION DATE: 09/01/2021

COMMENT DEADLINE: 10/04/2021

PUBLICATION TYPE: Centralized Repository

PROPOSED RULE NOTICE

REGISTER SOURCE: Regulations of Connecticut State Agencies 2021-09-02

PUBLICATION DATE: 09/02/2021

ACTION DATE: 09/01/2021

COMMENT DEADLINE: 10/04/2021

PUBLICATION TYPE: Centralized Repository

Regulation of the

Department of Consumer Protection

Concerning

Shared Pharmacy Services

Regulations adopted after July 1, 2013, become effective upon posting to the Connecticut eRegulations System, or at a later date if specified within the regulation.

Posted to the Connecticut eRegulations System on **February 18, 2022**

EFFECTIVE DATE

February 18, 2022

Approved by the Attorney General on

November 29, 2021

Approved by the Legislation Regulation Review Committee on

January 25, 2022

Electronic copy with agency head certification statement electronically submitted to and received by the Office of the Secretary of the State on **February 10, 2022**

Statement of Purpose

This proposed regulation adds new sections related to shared pharmacy services, which are systems in which two or more licensed pharmacies process or dispense a prescription. The Department currently regulates the dispensing of all prescription medication within the State of Connecticut.

The new language ensures positive patient outcomes through the provision of minimum standards for (1) pharmacist care; (2) preparing, labeling, and distributing pharmaceuticals dispensed by licensed pharmacies; (3) record keeping and quality assurance; and (4) a licensed pharmacy that is located in Connecticut to participate in shared pharmacy services with any other licensed pharmacy.

Form Agency-Cert-PR-TA-ICM (Rev 11/2017)

State of Connecticut

Secretary of the State

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form is to be used for proposed permanent and technical amendment regulations only and must be completed in full.

AGENCY CERTIFICATION

Department of Consumer Protection

Proposed Regulation Concerning

Shared Pharmacy Services

eRegulations System Tracking Number **PR2021-017**

I hereby certify the following:

(1) The above-referenced **regulation** is proposed pursuant to the following statutory authority or authorities:
Conn. Gen. Stat. section 20-576

For technical amendment regulations proposed without a comment period, complete #2 below, then skip to #8.

(2) As permitted by Section 4-168(h) of the *Connecticut General Statutes*, the agency elected to proceed without prior notice or hearing and posted the text of the proposed technical amendment regulation on eRegulations System website on **N/A**.

For all other non-emergency proposed regulations, complete #3 - #7 below, then complete #8)

(3) The agency posted notice of intent with a specified comment period of not less than 30 days to the eRegulations System website on **September 1, 2021**.

(4) (*Complete one*) No public hearing held or was required to be held. **OR** One or more public hearings were held on: **N/A**.

(5) The agency posted notice of decision to move forward with the proposed regulation to the eRegulations System website on **October 6, 2021**.

(6) (*Complete one*) No comments were received. **OR** Comments were received and the agency posted the statements specified in subdivisions (1) and (2) of CGS Section 4-168(e) to the eRegulations System website on **October 6, 2021**.

(7) The final wording of the proposed regulation was posted to the eRegulations System website on **November 16, 2021**.

(8) Subsequent to approval for legal sufficiency by the Attorney General and approval by the Legislative Regulation Review Committee, **the final regulation shall be effective**

(Check one and complete as applicable)

When posted to the eRegulations System website by the Secretary of the State.

OR On _____

(Date must be a specific calendar date not less than 11 days after submission to the Secretary of the State)

/s/_____

SIGNED

(Head of Board, Agency or Commission, or duly authorized deputy)

Legal Director

OFFICIAL TITLE

11/18/2021

DATE

OFFICE OF THE ATTORNEY GENERAL

REGULATION CERTIFICATION

Agency: Connecticut Department of Consumer Protection

REGULATION NUMBER PR2021-017

This Regulation is hereby APPROVED by the Attorney General as to legal sufficiency in accordance with Connecticut General Statutes § 4-169.

DATE: November 29, 2021

Signed: /s/_____

Joseph Rubin

Assistant Deputy Attorney General

Duly Authorized

The Connecticut General Assembly

Legislative Regulation Review Committee

Senator James Maroney

Senate Chair

Representative Nicole Klarides-Ditria

House Chair

Office of the Secretary of the State

January 25, 2022

Agency: Department of Consumer Protection

Description: Shared Pharmacy Services

LRRC Regulation Number: 2021-023

eRegulation Tracking Number: PR2021-017

The above-referenced regulation has been

Approved with Technical Corrections

by the Legislative Regulation Review Committee in accordance with CGS Section 4-170.

Kirstin L. Breiner

Committee Administrator

State of Connecticut

Office of the Secretary of the State

Confirmation of Electronic Submission

Re: Regulation of the Department of Consumer Protection concerning Shared Pharmacy Services

eRegulations System Tracking Number PR2021-017

Legislative Regulation Review Committee Docket Number 2021-023

The above-referenced regulation was electronically submitted to the Office of the Secretary of the State in accordance with Connecticut General Statutes Section 4- 172 on February 10, 2022.

Said regulation is assigned Secretary of the State File Number 6357.

The effective date of this regulation is February 18, 2022.

/s/ _____

Denise W. Merrill

Secretary of the State

February 18, 2022

By:

/s/ Christopher R. Drake

Christopher R. Drake

Director, Business Services Division

Form ICM-ECOPY (NEW 6/2015)

State of Connecticut

Secretary of the State

IMPORTANT NOTICE FOR CONNECTICUT STATE AGENCIES

This form should be used only for regulations first noticed *on and after March 23, 2015*.

Electronic Copy Certification Statement

(Submitted in accordance with the provisions of section 4-172 of the Connecticut General Statutes)

Regulation of the

Department of Consumer Protection

Concerning

Shared Pharmacy Services

Approved by the Legislative Regulation Review Committee: **January 25, 2022**

eRegulations System Tracking Number: **PR2021-017**

I hereby certify that the electronic copy of the above-referenced regulation submitted herewith to the Secretary of the State is a true and accurate copy of the regulation approved in accordance with sections 4-169 and 4-170 of the *Connecticut General Statutes*.

And I further certify that in accordance with the approval of Legislative Regulation Review Committee, all required technical corrections, page substitutions and deletions, if any, have been incorporated into said regulation.

In testimony whereof, I have hereunto set my hand on **February 9, 2022**.

/s/ _____

Julianne Avallone

Legal Division Director

Department of Consumer Protection

State of Connecticut

Regulation of

Department of Consumer Protection

Concerning

Shared Pharmacy Services

Section 1. The Regulations of Connecticut State Agencies are amended by adding sections 20- 576-74 to 20-576-79, inclusive, as follows:

Shared Pharmacy Services

(NEW) Sec. 20-576-74. Definitions

As used in this section and sections 20-576-75 to 20-576-79, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Central dispensing pharmacy" means a licensed pharmacy that acts as an agent of or under contract with an originating pharmacy to dispense a prescription;

(2) "Delivery" means the process of transferring a dispensed prescription that has been through final prescription verification to a patient or patient's representative;

- (3) "Direct supervision" has the same meaning as provided in section 20-598a(b) of the Connecticut General Statutes;
- (4) "Dispense" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;
- (5) "Drug utilization review" or "DUR" or "Drug utilization review program" means an authorized and structured review of prescribing, dispensing, and utilization of drugs by a licensed pharmacist before, during, and after dispensing a prescription to ensure appropriate drug decision-making and positive patient outcomes. Such review includes, but is not limited to, the prospective and retrospective utilization reviews mandated by the Omnibus Budget Reconciliation Act (OBRA) of 1990, as amended from time to time;
- (6) "Final prescription verification" means the last review of a prescription by a licensed pharmacist prior to approving such prescription for delivery to a patient or patient's representative, after such review and approval the prescription is considered dispensed. Such review includes, but is not limited to, the original prescription, the contents of the prescription label, and the contents of the prescription container to ensure accuracy of a prescription;
- (7) "Licensed pharmacy" means a pharmacy that is either licensed pursuant to section 20-594 of the Connecticut General Statutes or a nonresident pharmacy as defined in and operated in accordance with section 20-627 of the Connecticut General Statutes;
- (8) "Licensed pharmacist" means a pharmacist either licensed pursuant to section 20-593 of the Connecticut General Statutes or licensed as a pharmacist in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States;
- (9) "Order entry" means the process by which pharmacy personnel enter prescription data into a licensed pharmacy's software system. Such data includes, but is not limited to, patient demographics, drug name and strength, drug quantity, the directions for use, the number of times the prescription may be refilled, including the use of refill terms "PRN" and "ad lib" in lieu of a specific number of authorized refills, and any required cautionary statements;
- (10) "Order entry verification" means the process by which a licensed pharmacist verifies prescription data entered in a licensed pharmacy's software system after order entry has been completed and prior to final prescription verification;
- (11) "Originating pharmacy" means a licensed pharmacy that accepts a prescription for dispensing to a patient or patient's representative, either on its own or through the use of a central dispensing pharmacy;
- (12) "Prescription" means a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient;
- (13) "Pharmacy personnel" means either a licensed pharmacist, a registered pharmacy intern, or a registered pharmacy technician;
- (14) "Registered pharmacy intern" means a pharmacy intern registered pursuant to section 20- 598 of the Connecticut General Statutes or registered as a pharmacy intern in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States;
- (15) "Registered pharmacy technician" means a pharmacy technician registered pursuant to section 20-598a of the Connecticut General Statutes or registered as a pharmacy technician in any other state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or any territory or insular possession subject to the jurisdiction of the United States;
- (16) "Remote order entry" means order entry that is conducted from a location other than the physical premises of an originating pharmacy;

(17) "Remote order entry verification" means order entry verification that is conducted from a location other than the physical premises of an originating pharmacy;

(18) "Shared pharmacy services" means a system by which two or more licensed pharmacies process or dispense a prescription; and

(19) "Shipping record" means a record that contains all shipping information for a specific shipment. Such information includes, but is not limited to, each item contained in a shipment.

(NEW) Sec. 20-576-75. Minimum Requirements

(a) Each pharmacy performing shared pharmacy services shall be a licensed pharmacy;

(b) A licensed pharmacy may dispense a prescription at the request of an originating pharmacy and return the dispensed prescription to the originating pharmacy for delivery to a patient or patient's representative, or if requested by the originating pharmacy, direct delivery to a patient or patient's representative;

(c) Each licensed pharmacy shall have a dispensing process in which order entry verification is separate and distinguishable from final prescription verification;

(d) Each licensed pharmacy shall have a secure and confidential mechanism with a licensed pharmacy or other authorized user, including pharmacy personnel, for the provision of patient demographics, prescription images, drug utilization reviews, and any other information necessary to appropriately perform order entry, order entry verification, and final prescription verification;

(e) Each licensed pharmacy shall have the ability to scan, with a minimum of a 1:1 ratio and a minimum of 200 pixels per inch, any prescription that is not electronically-transmitted to such pharmacy. Any licensed pharmacy that lacks the ability to scan with a minimum of a 1:1 ratio and a minimum of 200 pixels per inch shall only utilize shared pharmacy services for electronically-transmitted prescriptions and prescription refills pursuant to subsection (c) of this section; and

(f) Each licensed pharmacy that performs shared pharmacy services shall have prescription processing software that is capable of maintaining an audit trail that identifies, at a minimum, each pharmacy personnel or any other pharmacy staff who entered, modified, or verified a prescription during the dispensing process; approved or rejected a drug utilization review; or modified or verified a prescription after final prescription verification.

(NEW) Sec. 20-576-76. Originating Pharmacy

(a) If an originating pharmacy accepts a prescription for dispensing to a patient or patient's representative through the use of a central dispensing pharmacy, at least one of such pharmacies shall be located in Connecticut;

(b) An originating pharmacy shall notify a patient or patient's representative when a prescription may be processed or dispensed via shared pharmacy services;

(c) An originating pharmacy shall provide a patient or patient's representative with the name of the licensed pharmacy processing or dispensing their prescription. If an originating pharmacy utilizes a pharmacy network under common ownership to process and dispense prescriptions, the patient or patient's representative shall be notified that any of the network pharmacies may process or dispense their prescription. Such notification may be provided to a patient or patient's representative via a one-time written notice or signage in the originating pharmacy;

(d) Each licensed pharmacy that participates in shared pharmacy services shall have the same owner or have a written contract or agreement with a participating licensed pharmacy outlining the specific services provided by each licensed pharmacist and licensed pharmacy along with the responsibilities shared by each licensed pharmacist and licensed pharmacy with respect to complying with applicable federal and state pharmacy statutes and regulations;

(e) An originating pharmacy shall maintain each original prescription in a readily retrievable manner at such pharmacy;

(f) An originating pharmacy shall implement and maintain a quality assurance program as described in section 20-635 of the Connecticut General Statutes that documents each prescription error reported to such originating pharmacy by a patient or patient's representative or by a licensed pharmacist or licensed pharmacy participating in shared pharmacy services regardless of where such reported prescription error occurred;

(g) An originating pharmacy shall provide access to all records required by this section, section 20-576-75, and sections 20-576-78 and 20-576-79 of the Regulations of Connecticut State Agencies to the Department of Consumer Protection, Drug Control Division, within 48 hours of said department's request;

(h) An originating pharmacy shall verify, at least annually, that each licensed pharmacy utilized by the originating pharmacy for shared pharmacy services is properly licensed, and the originating pharmacy shall maintain a record of such verification on file for review by the Department of Consumer Protection, Drug Control Division;

(i) An originating pharmacy shall require pharmacy personnel to verify that each shipping container received from a central dispensing pharmacy contains each prescription listed on the shipping record. Such shipping record shall be maintained for a period of no less than three years;

(j) An originating pharmacy shall not provide any controlled substance prescriptions in Schedule II, III, IV or V of the federal Controlled Substances Act to a central dispensing pharmacy;

(k) An originating pharmacy shall perform a final prescription verification each time such pharmacy places a new prescription label over an existing prescription label or alters a dispensed prescription ready for delivery to a patient or patient's representative; and

(l) An originating pharmacy shall be responsible for reporting all dispensation data.

(NEW) Sec. 20-576-77. Central Dispensing Pharmacy

(a) A central dispensing pharmacy shall maintain a mechanism for tracking each step of the dispensing process performed by an originating pharmacy for each prescription;

(b) A central dispensing pharmacy shall label each prescription or include with the dispensed prescription the name, address, and telephone number of the originating pharmacy and the central dispensing pharmacy along with all information required in section 20-617 of the Connecticut General Statutes;

(c) A central dispensing pharmacy shall ensure that each prescription dispensed and returned to an originating pharmacy is shipped in accordance with manufacturer labeling;

(d) A central dispensing pharmacy shall provide security mechanisms that protect the confidentiality and integrity of patient information;

(e) A central dispensing pharmacy shall provide all information required by this section, sections 20-576-75, 20-576-78 and 20-576-79 of the Regulations of Connecticut State Agencies, to the Department of Consumer Protection, Drug Control Division, within 48 hours of said department's request;

(f) A central dispensing pharmacy shall provide a shipping record to an originating pharmacy listing each prescription a central dispensing pharmacy places in each container shipped to an originating pharmacy;

(g) A central dispensing pharmacy shall maintain a list of up-to-date information of all pharmacy personnel including, but not limited to, pharmacy personnel names, contact information, and credential information for the jurisdiction in which a central dispensing pharmacy is primarily licensed;

(h) A central dispensing pharmacy shall maintain and utilize adequate containers and processes to ensure drug stability and potency during storage and shipping of dispensed prescriptions. Such processes shall include, but are not limited to, (1) utilizing appropriate packaging and devices to ensure each dispensed prescription is maintained within an appropriate temperature range throughout the shipping process and (2) utilizing packaging that is tamper-evident; and

(i) Nothing in this section shall prevent a central dispensing pharmacy from shipping or delivering a prescription directly to a patient or patient's representative at a patient's or patient's representative's request after final prescription verification by a central dispensing pharmacist.

(NEW) Sec. 20-576-78. Remote Order Entry

(a) Remote order entry shall only be performed by pharmacy personnel;

(1) For the purposes of this section, direct supervision by a licensed pharmacist of a registered pharmacy technician or pharmacy intern performing remote order entry, from a location other than the physical premises of an originating pharmacy, is permitted;

(2) A registered pharmacy technician's performance regarding remote order entry, from a location other than the physical premises of an originating pharmacy, shall be evaluated at least quarterly by the pharmacist manager at the licensed pharmacy at which such pharmacy technician is registered, to determine if such remote order entry work is suitable for such pharmacy technician. A pharmacist manager's quarterly evaluation, to determine if remote order entry work is suitable for the registered pharmacy technician, shall be documented in such pharmacy technician's training record as required by section 20-576-37 of the Regulations of Connecticut State Agencies;

(b) Each licensed pharmacist, each registered pharmacy intern, and each registered pharmacy technician that performs remote order entry, from a location other than the physical premises of an originating pharmacy, shall make efforts to prevent disclosure of confidential information in accordance with section 20-626 of the Connecticut General Statutes.

(NEW) Sec. 20-576-79. Remote Order Entry Verification

(a) Remote order entry verification shall only be performed by a licensed pharmacist;

(b) Each licensed pharmacist who performs remote order entry verification shall have the ability to refuse a prescription for dispensing and the refused prescription shall be returned to the originating pharmacy;

(c) Each licensed pharmacist that performs remote order entry verification, from a location other than the physical premises of an originating pharmacy, shall make efforts to prevent disclosure of confidential information in accordance with section 20-626 of the Connecticut General Statutes; and

(d) Nothing in this section shall prevent a licensed pharmacist from working at a location other than the physical premises of an originating pharmacy.