

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

DEPARTMENT OF CONSUMER PROTECTION

Concerning

SUBJECT MATTER OF REGULATION

Nonresident Pharmacies and

Medical Practitioners

Section 1. Section 21a-254-2 of the Regulations of Connecticut State Agencies is amended to read as follows:

As used in sections 21a-254-2 to 21a-254-7, inclusive, of the Regulations of Connecticut State Agencies:

- (1) "Controlled substance" means "controlled substance" as defined in section 21a-240 of the Connecticut General Statutes;
- (2) "Department" means the Department of Consumer Protection;
- (3) "Dispenser" means "dispenser" as defined in section 21a-240 of the Connecticut General Statutes;
- (4) "Nonresident pharmacy" means a "nonresident pharmacy" as defined in section 20-627 of the Connecticut General Statutes;
- [(3)] (5) "Pharmacy" means "pharmacy" as defined in section 20-571 of the Connecticut General Statutes, or a pharmacy located in a hospital, long term care facility or correctional facility; and
- [(4)] (6) "Practitioner" means "Prescribing practitioner" as defined in section 20-571 of the Connecticut General Statutes.

Sec. 2. Section 21a-254-3 of the Regulations of Connecticut State Agencies is amended to read as follows:

A pharmacy, nonresident pharmacy or dispenser that dispenses schedule II, III, IV, and V controlled substances shall transmit the prescription or dispensing information for these controlled substances to the department. A hospital pharmacy, long term care facility pharmacy or correctional facility pharmacy shall transmit controlled prescription information for outpatients only.

Sec. 3. Section 21a-254-4 of the Regulations of Connecticut State Agencies is amended to read as follows:

- (a) A pharmacy, nonresident pharmacy or dispenser that maintains prescription or dispensing information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a person

who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Electronic Reporting Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy. A pharmacy, nonresident pharmacy or dispenser shall transmit to the department the fields listed in said reporting standard, including, but not limited to, the following:

- (1) Drug Enforcement Administration Pharmacy number;
- (2) Birth date;
- (3) Sex code;
- (4) Date prescription filled;
- (5) Prescription number;
- (6) New-refill code;
- (7) Quantity;
- (8) Days supply;
- (9) National Drug Code number;
- (10) Drug Enforcement Administration Prescriber identification number;
- (11) Date prescription written;
- (12) Number of refills authorized;
- (13) Prescription origin code;
- (14) Patient last name;
- (15) Patient first name;
- (16) Patient street address;
- (17) State;
- (18) Payment code for either cash or third-party provider; and
- (19) Drug name.

(b) A copy of the Electronic Reporting Standard for Prescription Monitoring Programs may be obtained from the American Society for Automation in Pharmacy, 492 Norristown Road, Suite 160, Blue Bell, Pennsylvania 19422. Telephone: (610) 825-7783. Website: www.asapnet.org.

(c) A pharmacy, nonresident pharmacy or dispenser that maintains prescription or dispensing information electronically shall transmit the required information by means of one of the following methods:

- (1) Electronic data transmission through a computer modem that can transmit information at a rate of 2400 baud or more;
- (2) Computer disc; or
- (3) Magnetic tape of the kind that is used to transmit information between computerized systems.

(d) A pharmacy, nonresident pharmacy or dispenser that does not maintain prescription or dispensing information electronically, and that dispenses a schedule II, III, IV, or V controlled substance to a person who is not an inpatient of a hospital, correctional institution or nursing facility, shall transmit to the Drug Control Division of the department the information set forth in subsection (a) of this section on a paper form provided by the department.

(e)(1) A pharmacy, nonresident pharmacy or dispenser shall transmit to the department the information required pursuant to this section not later than:

- [(A) The 20th day of the month for all prescriptions dispensed on and between the 1st and the 15th days of the month; and
 (B) The 5th day of the following month for all prescriptions dispensed on and between the 16th day and the last day of the month.]

(A) The first Monday of every week; and

(B) There shall be a six day grace period following each Monday.

(2) If the reporting date falls on [weekend or] a holiday, a pharmacy, nonresident pharmacy or dispenser shall transmit the required information by the next [state of Connecticut workday] business day.

(f) A pharmacy, nonresident pharmacy or dispenser shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996.

Sec. 4. Section 21a-254-5 of the Regulations of Connecticut State Agencies is amended to read as follows:

Agents of the Drug Control Division of the department, and any department employee authorized to work with the Drug Control Division, shall evaluate the controlled substance prescription or dispensing information received from pharmacies, nonresident pharmacies and dispensers. The department shall evaluate the prescription or dispensing information for the purposes of preventing controlled substance diversion, public health initiatives, and statistical reporting.

Sec. 5. Section 21a-254-6 of the Regulations of Connecticut State Agencies is amended to read as follows:

The department may provide prescription or dispensing information obtained from pharmacies, nonresident pharmacies and dispensers to:

- (a) Other regulatory, investigative or law enforcement agencies for disciplinary, civil, or criminal purposes;
- (b) Practitioners, for the purpose of education in lieu of disciplinary, civil or criminal action;
- (c) Practitioners and pharmacists, for the purposes of patient care, drug therapy management and monitoring of controlled substances obtained by the patient; and
- (d) Public or private entities, for statistical, research, or educational purposes, provided that the privacy of patients and confidentiality of patient information is not compromised.

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:** The purpose of the proposed regulations is to add nonresident pharmacies and medical practitioners to the existing groups of medical providers and pharmacies who are subject to the existing regulations concerning the Electronic Prescription Drug Monitoring Program.

(B) **Summary:** Public Act No. 13-172 amended Subsection (j) of Section 21a-254 of the Connecticut General Statutes by adding nonresident pharmacies and medical practitioners to the persons or entities required to report controlled substances information to the Department of Consumer Protection. These proposed regulations amend existing regulations concerning the Electronic Prescription Drug Monitoring Program to include nonresident pharmacies and medical practitioners.

(C) **Legal Effects:** Medical practitioners who prescribe, dispense or administer controlled substances must obtain a registration from the Department of Consumer Protection. Nonresident pharmacies that ship drugs into Connecticut must obtain a registration from the Department of Consumer Protection. If nonresident pharmacies or medical practitioners do not comply with these proposed regulations, the Department of Consumer Protection may take enforcement action against their registrations.

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 21a-254.
- b. Public Act Number(s) 2013-172.
(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 _____;
(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 _____;
(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 Commissioner Department of Consumer Protection
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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
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*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)
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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 CGS Section 4-172, as amended.

DATE	SIGNED (Secretary of the State)	BY
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(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.