

**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

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NAME OF AGENCY

**DEPARTMENT OF CONSUMER PROTECTION**

Concerning

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SUBJECT MATTER OF REGULATION

**Electronic Drug Records Maintained**

**By Medical Practitioners**

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**Section 1.** Section 21a-244a-1 of the Regulations of Connecticut State Agencies is amended to read as follows:

As used in section 21a-244a-2 to section 21a-244a-4, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Drug record” means “drug record” as defined in section 21a-244a of the Connecticut General Statutes;
- (2) “Hospital” means “hospital” as defined in section 19a-490 of the Connecticut General Statutes; and
- (3) “Licensed practitioner” means “licensed practitioner” as defined in section 21a-244a of the Connecticut General Statutes.

**Sec. 2.** Section 21a-244a-2 of the Regulations of Connecticut State Agencies is amended to read as follows:

Hospitals and licensed practitioners may create and maintain drug records using an electronic data processing system, provided they comply with the requirements of sections 21a-244a-3 and 21a-244a-4 of the Regulations of Connecticut State Agencies.

**Sec. 3.** Section 21a-244a-3 of the Regulations of Connecticut State Agencies is amended to read as follows:

Hospitals and licensed practitioners shall establish and comply with a policy in creating and maintaining electronic drug records. This policy shall be maintained electronically or in writing, shall be dated and shall accurately reflect the manner in which electronic drug records are currently created and maintained. This policy shall be readily available for inspection by the Department of Consumer Protection for a period of three years from its last effective date.

**Sec. 4.** Section 21a-244a-4 of the Regulations of Connecticut State Agencies is amended to read as follows:

Any hospital or licensed practitioner, in establishing the policy required by section 21a-244a-3 of the Regulations of Connecticut State Agencies, shall include:

(1) a description of the electronic data processing system being used to create and maintain records. This description shall include at least the following information:

- (A) the specific types of drug records being maintained electronically on the system; and
- (B) the patient populations and physical locations for which the electronic drug record system is being utilized;

(2) the specific types of electronic identifiers, including but not limited to those listed in section 21a-244a(c) of the Connecticut General Statutes, that are utilized to access the electronic system, or used in place of written signatures or initials where required. All electronic identifiers described in the system shall be unique to an individual and shall be controlled in a secure manner;

(3) the manner in which access to the electronic drug record system is controlled. This shall, at a minimum, include:

- (A) a description of the general levels of access into the system; and
- (B) the mechanism used to identify all individuals having access to the electronic system, their level of access and a description of how this access data is maintained by the hospital or the licensed practitioner;

(4) the method by which individual electronic identifiers allowing access to the system are issued, maintained and terminated. This shall include, at a minimum, the following information:

- (A) the specific individual or group responsible for issuing, maintaining or terminating electronic identifiers;
- (B) the procedure by which electronic identifiers are issued, maintained and terminated; and
- (C) the method by which the uniqueness of electronic identifiers is established and their security maintained;

(5) the system by which electronic drug records are stored on-line, archived or maintained in some other manner that ensures that they are readily retrievable for a period of not less than three years;

(6) the recovery procedure utilized to reconstruct electronic drug records in the event the system experiences unscheduled downtime;

(7) the procedure utilized to routinely backup data stored on the electronic system to prevent the loss or destruction of electronic drug records;

(8) the method employed to prevent or detect unauthorized alteration or erasure of electronic drug records maintained on the system; and

(9) the procedure employed to ensure that all information contained in electronic drug records that is deemed to be confidential is appropriately protected from unauthorized access and dissemination. Such confidential information shall, at a minimum, include the names of patients and prescribing practitioners. The electronic data processing system shall comply with all federal and state statutes and regulations pertaining to the confidentiality of patient drug records.

## **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 proposed regulations are meant to establish guidelines for electronic drug records maintained by medical practitioners.

(B) Summary: These proposed regulations amend existing regulations, Sections 21a-244a-1 through 21a-244a-4. The amendments add medical practitioners to regulations that establish requirements for electronic data processing systems that create and maintain drug records.

(C) Legal Effects: These regulations establish requirements for electronic data processing systems for the creation and maintenance of drug records by medical practitioners. Medical practitioners who violate these regulations are subject to administrative action being taken against their Controlled Substance Registrations issued by the Department of Consumer Protection.

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-244a.
- 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 \_\_\_\_\_;**  
 (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 <b>Commissioner Department of Consumer Protection</b>
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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](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.