Secretary of the State File Number

6181

Regulation of the
Department of Consumer Protection

Concerning
Electronic Drug Records Maintained by Medical Practitioners

Regulations adopted after July 1, 2013, become effective upon posting to the website of the Secretary of the State, or at a later date specified within the regulation.

Website posted on
April 13, 2015

Effective Date
April 13, 2015

Approved by the Attorney General on
December 30, 2014

Approved by the Legislative Regulation Review Committee on
February 24, 2015

Received and filed in the Office of the Secretary of the State on
April 8, 2015

Electronic copy with agency head certification statement submitted to the Office of the Secretary of the State on
April 8, 2015

Published in the Connecticut Law Journal on

Form ERS_ECC (NEW 9/2014)
State of Connecticut
Office of the Secretary of the State
Legislation and Elections Administration Division

Purpose and Legal Disclaimer: This form was designed to facilitate submission of the "statement from the department head" required by CGS 4-172(a) as amended by PA 12-92, Section 6. This form does not constitute legal advice. The Office of the Secretary of the State (SOTS) is not authorized to provide legal advice to state agencies. Consult with your agency's legal counsel before completing and submitting this form for filing

Instructions: **(1)** Save a copy of this document to your computer; **(2)** To enter data, use the Tab key to move between fields, or click-and-highlight an entire **<text field>**; **(3)** When complete, submit to your agency's legal counsel for review and approval; **(4)** After approval by counsel, PRINT and submit to your agency head for his/her original signature; **(5)** Scan the originally-signed form and submit it with the electronic copy of the regulation the statement certifies to the eRegulations System for processing and public website posting by the Office of the Secretary of the State; **(6)** retain the originally-signed copy for your agency's regulation-making record.

Electronic Copy Certification Statement

I, **Jonathan A. Harris**, **Commissioner** of the **Department of Consumer Protection**, in accordance with the provisions of Section 4-172 of the *General Statutes of the State of Connecticut,* **do hereby certify**:

That the electronic copy of a regulation concerning **Electronic Drug Records Maintained by Medial Practictioners**, which was approved by the Legislative Regulation Review Committee on **February 24, 2015**, and which shall be submitted electronically for filing to the Secretary of the State by **Tanya Washington** of this agency on **April 8, 2015**, is a true and accurate copy of the original regulation approved in accordance with Sections 4-169 and 4-170 of the *General Statutes of the State of Connecticut*.

In testimony whereof, I have hereunto set my hand on **April 8, 2015**.

(Signature of agency head)

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
DEPARTMENT OF CONSUMER PROTECTION

Concerning

SUBJECT MATTER OF REGULATION
Electronic Drug Records Maintained

By Medical Practitioners

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; [and]
(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.

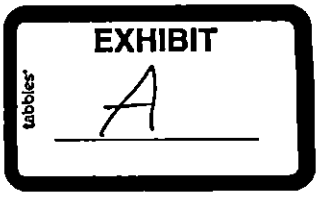
Sec. 2. Section 21a-244a-2 of the Regulations of Connecticut State Agencies is amended to read as follows:

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 [at the hospital]. 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:



[A] 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 [by the hospital] 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 [hospital's] 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 [hospital's] 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 [by which the hospital identifies] 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 [at the hospital] 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.

REGS-1 Rev. 09/2013

(Certification page—see Instructions on back)

CERTIFICATION

This certification statement must be completed in full.

I hereby certify that the above Regulation(s)

1) is/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 authorizing act has not yet been codified in the Connecticut General Statutes.)

And I further certify

2) that **Notice of Intent** to adopt, amend or repeal said regulation(s) was electronically submitted to the Secretary of the State on 08-01-2014, and posted to the Secretary's regulations website on 08-06-2014; *(Insert dates notice was (a) emailed to the Secretary of the State and (b) posted on the Secretary's website, if notice and posting were required by CGS 4-168, as amended by PA 13-247 and PA 13-274.)*

3) and that a public hearing regarding the proposed regulation(s) was held on 09-08-2014 **or** ☐ that no public hearing was held; *(Insert date(s) of mandatory public hearing(s) held pursuant to CGS 4-168(a), as amended, or other applicable statute, and/or voluntary hearing, **or** if no hearing was held, check the box for that statement.)*

4) and that notice of **Decision to Take Action** on said regulations was electronically submitted to the Secretary of the State on 11-21-2014, and posted to the Secretary's regulations website on 12-01-2014; *(Insert dates notice was (a) emailed to the Secretary of the State and (b) posted on the Secretary's website, if notice and posting were required by CGS 4-168, as amended by PA 13-247 and PA 13-274.)*

5) and that said regulation(s) is/are **EFFECTIVE** *(check one, and complete as applicable)*

   ☒ When posted online by the Secretary of the State.

   OR ☐ on *(insert date)* _____.

6) **SIGNED** *(Head of Board, Agency or Commission)*	OFFICIAL TITLE, DULY AUTHORIZED	DATE
	Commissioner of Consumer Protection	12/24/14

***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
12/30/14	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 ☒ in WHOLE **or** WITH ☐ technical corrections ☐ deletions ☐ substitute pages

☐ DEEMED APPROVED, *pursuant CGS 4-170(c), as amended.*

☐ Rejected without Prejudice ☐ Disapproved, *pursuant to CGS 4-170(c), as amended.*

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	DATE	SIGNED *(Administrator, Legislative Regulation Review Committee)*
	2-24-15	

In accordance with CGS Section 4-172, as amended by PA 13-247 and PA 13-274, one certified paper copy and one electronic copy with agency head certification statement received on the date(s) specified below.

DATE	SIGNED *(Secretary of the State)*	BY

(For Secretary of the State Use ONLY)

Date Posted to SOTS Regulations Website:

Date Electronic Copy Forwarded to the Commission on Official Legal Publications:

SOTS file stamp: