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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.