

Regulations of Connecticut State Agencies

TITLE 21a. Consumer Protection

Agency

Department of Consumer Protection

Subject

Storage and Retrieval of Prescription Information for Controlled Substances

Inclusive Sections

§§ 21a-244-1—21a-244-11

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Storage and Retrieval of Prescription Information for Controlled Substances

Sec. 21a-244-1. Computer systems requirements

(a) All prescriptions for schedule II controlled substances, and original written and oral prescriptions for schedule III, IV and V controlled substances shall be received, executed and filed in accordance with sections 21a-249 and 21a-250 of the Connecticut General Statutes and all applicable federal laws and regulations. In the case of original oral prescriptions for schedule III, IV and V controlled substances, which shall be received by a pharmacist, an individual hard copy printout of the prescription containing all required information may be used to satisfy the requirements of section 21a-249 (d) of the Connecticut General Statutes.

(b) In the case of refills of prescriptions for schedule III, IV and V controlled substances, an automated data processing system may be used for the storage and retrieval of refill information. Any such computerized system shall provide on-line retrieval for a period of at least six months from the date of the last recorded dispensing via visual display device or hardcopy printout of original prescription order information for all prescriptions including those prescription orders which are currently authorized for refilling. This shall include but is not limited to data such as:

- (1) the original prescription number;
- (2) the date of issuance of the original prescription order by the prescribing practitioner;
- (3) the full name and complete address of the patient;
- (4) the full name, full address, and Drug Enforcement Administration, United States Department of Justice, or its successor agency registration number of the prescribing practitioner;
- (5) the name, strength, dosage form, quantity of the controlled substance prescribed and quantity dispensed if different from the quantity prescribed; and
- (6) the total number of refills authorized by the prescribing practitioner.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-2. Refill history capability requirement

Any computerized system must also provide on line retrieval via visual display device or hard copy printout of the current refill history for Schedule III, IV, or V controlled substance prescription orders which are currently authorized for refilling. This refill history shall include but is not limited to:

- (a) the full name and address of patient;
- (b) the full name and complete address of the prescribing practitioner;
- (c) the name, strength and dosage form of the controlled substance;
- (d) the date of refill;
- (e) the quantity dispensed;
- (f) the date on which the prescription was first dispensed;
- (g) the original number assigned to said prescription;
- (h) the name or initials of the dispensing pharmacist for each refill; and

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- (i) the total number of refills dispensed to date for that prescription order.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-3. Documentation of data requirement

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. In order to accomplish this documentation, a pharmacy using such a computerized system must provide either:

(1) a separate hard-copy printout of controlled substance prescription order refill data for each day. This hard copy printout shall include the refill data mentioned in section 21a-244-2 of the Regulations of Connecticut State Agencies except that it need not contain the address of the patient or the address of the prescribing practitioner. Each prescription on said printout shall be reviewed by each individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document. This document shall be maintained in a separate file at that pharmacy for a period of three years from the dispensing date. This printout of the controlled substance prescription order refill data must be provided by each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed and must be verified and signed by each pharmacist who effected such dispensing as soon as possible after receipt. In no case shall the printout be verified and signed later than the pharmacist's first work period following receipt of the document; or

(2) In lieu of producing a hardcopy printout of daily refill information signed by each dispensing pharmacist, the pharmacy shall maintain a bound log book or separate file which each pharmacist involved in such dispensing shall sign in the same manner as he would sign a check or legal document. The signature of the dispensing pharmacist shall indicate that he has reviewed the refill information entered into the computer, which is attributed to him, for each date of dispensing and that it is correct as shown. Whenever possible, this log book or separate file shall be signed by each pharmacist on the date of dispensing but in no case shall it be signed later than the pharmacist's first work period in that pharmacy after such date.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-4. Information available to commissioner upon request

Any computerized system shall have the capability of producing a printout of any refill data which the utilizing pharmacy is responsible for maintaining under Chapter 420b of the general statutes and the regulations promulgated thereunder. This shall include the capability to produce a refill by refill audit trail for any specified strength and dosage form of any controlled substance by either brand or generic name or both. Said printout shall be produced within 48 hours and shall indicate the following:

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- (a) the name of the prescribing practitioner;
- (b) the name and address of the patient;
- (c) the name, dosage form, strength, and quantity of the drug dispensed on each refill;
- (d) the name or initials of the dispensing pharmacist and the date of dispensing for each refill; and
- (f) the number of the original prescription order.

Any pharmacy utilizing a computerized system and authorized to maintain records at a central record-keeping location, must be capable of obtaining the requested printout within 48 hours.

(Effective July 27, 1984; Amended January 11, 1999)

Sec. 21a-244-5. Auxiliary system provision

In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, IV or V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again. All prescriptions refilled during the down-time shall be confirmed as being authorized upon resumption of on-line service.

(Effective July 27, 1984)

Sec. 21a-244-6. When handwritten system is allowed

If an automated data processing system is used for the storage and retrieval or refill information for prescription orders as authorized by Section 21a-244 of the general statutes, and the regulations promulgated thereunder, the pharmacy may use a traditional, handwritten system only to satisfy the requirement of Section 21a-244-5 of the regulations of State agencies.

(Effective July 27, 1984)

Sec. 21a-244-7. Notice to commissioner upon commencement of use

Any pharmacy instituting an automated data processing system for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder shall notify in writing the Drug Control Division of the Department of Consumer Protection at least 30 days prior to the commencement of usage of said system.

(Effective July 27, 1984)

Sec. 21a-244-8. Compliance with federal law

Notwithstanding the provisions of Section 21a-244 of the general statutes and the regulations promulgated thereunder, there must be compliance with all applicable federal

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laws.

(Effective July 27, 1984)

Sec. 21a-244-9. Requirement of safeguards

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, it shall:

- (a) guarantee the confidentiality of the information contained in the data bank; and
- (b) be capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.

(Effective July 27, 1984)

Sec. 21a-244-10. Reconstruction of data in case of accident

If an automated data processing system is used for the storage and retrieval of refill information for prescription orders as authorized by Section 21a-244 of the general statutes and the regulations promulgated thereunder, said automated data processing system shall be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

(Effective July 27, 1984)

Sec. 21a-244-11. Discontinuance of data processing system

In the event that a pharmacy using an electronic data processing system for storage and retrieval of information goes out of business, sells out to another pharmacy that does not wish to use such a system, or discontinues use of the computer system, the pharmacy shall:

- (a) notify the Drug Control Division of the Department of Consumer Protection in writing at least 30 days prior to discontinuance of said system;
- (b) provide an up-date hard-copy printout of all prescriptions stored in the automated system for the three years immediately preceding as part of the final records of that pharmacy prior to a change over to a manual system; and
- (c) make provision for these records to be available to any nearby pharmacy in the event that the pharmacy closes, as provided in Section 20-615 of the general statutes.

(Effective July 27, 1984; Amended January 11, 1999)