

## **64B16-28.140 Record Maintenance**

**(1) For the purposes of this rule, the term signature shall include biometric authentication.**

### (2) Record Maintenance Requirements

Records may be maintained in an automated data processing system or in a manual system if the following requirements are met:

(a) All original prescriptions or orders written by a practitioner, or telephoned to the pharmacy by a practitioner and reduced to writing by a pharmacist or an intern, or sent via facsimile machine, or electronic data transmission, or by other means of communication, shall be retained. In an automated data processing system, a prescription for a non-controlled substance may be retained as an image.

(b) All transfer of prescriptions or orders must be strictly in accordance with the provisions of Section 465.026 F.S., and Rule 64B16-27.105, F.A.C, Title 21, Code of Federal Regulations (C.F.R.) Section 1306.25, incorporated by reference \_\_\_\_\_, 2008 (regulations of the Federal Drug Enforcement Administration).

(c) Controlled substances listed in Chapter 893, F.S., dispensed from the pharmacy must comply with the provisions of Section 893.07, F.S., Title 21, C.F.R. Section 1304.04, Title 21, C.F.R. Section 1306.05, Title 21, C.F.R., Section 1306.11, Title 21, C.F.R., Section 1306.21, and Title 21, C.F.R. Section 1306.22, incorporated by reference \_\_\_\_\_, 2008.

(3) The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least every 24 hours, to assure that data is not lost due to system failure.

### (4) Change or discontinuance of data processing system

(a) Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

1. Transfer the records of dispensing to the new data processing system; or
2. Transfer the records of dispensing to a paper printout which contains the same information required on the daily printout as specified in paragraph (4)(a).

(b) Other Records. A pharmacy that changes or discontinues use of a data processing system must:

1. Transfer the records to the new data processing system; or;
2. Transfer the records to a paper printout, which contains all the information required on the original document.

(c) Maintenance of purged records. Information deleted or removed from a data processing system must be maintained by the pharmacy for two (2) years from the date of initial entry into the data processing system.

(d) If multiple automated systems are utilized, all the data must be integrated and available from at least one terminal.

(e) The prescription department manager or consultant pharmacist of record shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of loss.

(5) Records of dispensing.

(a) Records of dispensing for original and refill prescriptions are to be maintained and readily retrievable for two (2) years from the date of the last filling and shall include:

1. Unique identification number of the prescription;
2. Date of dispensing and date written;
3. Patient name and address;
4. Prescribing practitioner's name, address and the federal controlled substance registration number if the prescription order is for a controlled substance;
5. Date of issuance of the prescription drug order if different from the date of dispensing;
6. Name and strength of the drug product actually dispensed and, if generic name, the brand name or manufacturer of drug dispensed;
7. Quantity prescribed and quantity dispensed if different from the quantity prescribed;
8. Directions for use;
9. Total number of refills dispensed to date for that prescription drug order;
10. Initials or an identification code of the dispensing pharmacist.

(b) A daily hard-copy print out shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(c) Each pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating, signing and including her or his license number within seven days from the date of dispensing.

(d) In lieu of producing the printout described in paragraphs (b) & (c) of this section, the pharmacy shall maintain a log book or separate file in which each individual pharmacist using

the data processing system shall sign a statement each day, certifying that the information entered into the data processing system that day has been reviewed and is correct as entered. The signature of the pharmacist shall be accompanied by her or his pharmacist license number. Such log book shall be maintained at the pharmacy employing such a system for a period of two (2) years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(e) The prescription department manager or consultant pharmacist of record and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system complies with this subsection.

(f) Failure to provide the records, either on site or within 48 hours, constitutes failure to keep and maintain records.

(g) In the event that a pharmacy data processing system is not operating the pharmacy shall:

1. Establish an auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and
2. All of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(6) Records in institutional pharmacies may be made and kept as part of the patient's medical record. The consultant pharmacist of record for the pharmacy shall ensure that a manual system, an electronic system, or a combination thereof exists to meet the requirements of this subsection.

(a) Each time a controlled substance is dispensed, issued from, or returned to the pharmacy, a record of such dispensing, issuance, or return shall be recorded in the system(s).

(b) The systems shall have the capacity to produce a list of all patient specific medicinal drug orders reviewed by the pharmacist and dispensed or issued from the pharmacy. This list shall contain the following information:

1. Patient's name and room number or patient's facility identification number
2. Name, strength and dosage form of the drug product actually dispensed
3. Total quantity of patient specific controlled substances issued from and returned to

the pharmacy.

4. Identity of the pharmacist certifying the accuracy of the medication order.

(c) Each institutional pharmacy shall compile and maintain a listing of all practitioners within the facility authorized to prescribe controlled substances listed within Section 893.03, F.S. Such listing shall include the practitioner's federal controlled substance registration number.

(d) Each institutional pharmacy shall comply with the requirements listed in Rule 59A-3.2085(2), F.A.C.

(e) A Class II Institutional Pharmacy shall require:

1. Patient specific order be checked by a pharmacist.
2. Patient specific refill orders be checked by a pharmacist;
3. Emergency Room dispensing records be checked by a pharmacist;
4. Medication Station and Departmental inspections be done monthly and reviewed by the consultant pharmacist of record; and
5. The formulary be approved by Pharmacy and Therapeutics Committee at least annually.

(f) Failure to provide records set out in this section, either on site or within 48 hours, constitutes failure to keep and maintain records.

(7) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacturer's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacturer's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

- (i) The name of the patient who received the particular compounded product.
- (8) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:
  - (a) On the original prescription; or
  - (b) Noted in the system and available via computer monitor.
- (9) Drug Enforcement Administration (D.E.A.) Inventory:
  - (a) Shall be maintained two (2) years; and
  - (b) Shall be in compliance with Title 21, C.F.R. 1304.11, initial inventory and biennial inventory requirements.
- (10) Wholesale distributor, manufacturer invoices and pedigree documents.
  - (a) Shall be maintained two (2) years from the disposition of the prescription drug;
  - (b) Shall have approval for central record keeping; and
  - (c) Shall be readily retrievable.
- (11) Schedule V Controlled Substance Records:
  - (a) A record of over-the-counter product sales shall be maintained for two (2) years
  - (b) The record shall be available for inspections by a representative of the Board or the Department.
- (12) Prepackaging Records (Unit dose or multidose)

A log shall be maintained two (2) years and shall contain the following:

  - 1. Date prepackaged;
  - 2. Number of units prepackaged;
  - 3. Drug name and strength;
  - 4. Manufacturer's lot number;
  - 5. Manufacturer's expiration date;
  - 6. Assigned expiration date; and
  - 7. Verifying pharmacist's initials.
- (13) Pharmacist Ordering Profiles and Prescriptions:
  - (a) Shall be maintained on file for two (2) years; and
  - (b) Shall maintain records in accordance with 64B16-27.210, F.A.C.
- (14) Quality Assurance Records:
  - (a) Shall be maintained on file for two (2) years.
  - (b) Product testing results shall be maintained on a log or form.
  - (c) Equipment testing shall be maintained on a log or form.
- (15) Return of medicinal drugs. No controlled substances may be returned to the pharmacy.

A record of each medicinal drug returned to pharmacy stock shall be maintained on file for two (2) years. The record shall include:

1. Prescription number;
2. Name of medicinal drug;
3. Quantity returned to pharmacy stock; and
4. Expiration date and lot number if available.

(16) An institutional pharmacy shall maintain documentation of each after-hour entry into the pharmacy and the record shall include: \_\_\_\_\_

1. The physician's order;
2. Name of the drug, strength, and dosage form;
3. Quantity of drug obtained;
4. Name of the nurse supervisor who removed the drug from the pharmacy.

(17) Automated Dispensing Machines

A pharmacy which uses an automated dispensing machine shall maintain a log to include:

- \_\_\_\_\_ 1. Name of the drug, strength, and dosage form;
- \_\_\_\_\_ 2. Manufacturer's lot number;
- \_\_\_\_\_ 3. Manufacturer's expiration date; and
- \_\_\_\_\_ 4. The initials of the pharmacist who verified the medication placed in the system.
- \_\_\_\_\_ 5. The log shall be maintained for 90 days.

(18) Methamphetamine Precursor Sales:

- (a) A record of over-the-counter product sales shall be maintained for two (2) years
- (b) The record shall be available for inspections by a representative of the Board or the Department.

Specific Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 893.07 FS. History–New