

ARTICLE XXIII RECORD KEEPING ON CONTROLLED SUBSTANCES

1. Every facility permitted by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) years.

These records shall include:

- A. A current dated and signed inventory of all controlled substances on hand on the inventory date;
- B. Complete and accurate records of receipt of all controlled substances;
- C. Complete and accurate records of disposition of all controlled substances.

These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with the controlled substances on hand and the record of disposition of controlled substances.

2. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy. A pharmacy may use a data processing system or a manual record keeping system for the storage and retrieval of all prescription order information. A hard copy of original prescriptions, whether records are maintained manually or in a data processing system, shall be maintained and filed in accordance with the provisions of ARTICLE XIII of these regulations.

All records of controlled substances in Schedule II shall be maintained separately from all other records of the registrant. All records of controlled substances in Schedule III, IV, and V, whether maintained manually or in a data processing system, shall be maintained separately or in such a manner that they are readily retrievable from the other business records. Invoices for controlled substances shall be dated and initialed by the person receiving the order.

3. If a pharmacy utilizes a data processing system it must provide immediate retrieval of original prescription order information for those prescription orders which are currently authorized for refilling and of the refill history for the past six months for controlled substances prescription orders. The data processing system must have the capability of producing a hard copy printout of this information. The data processing system must also have the capability of producing a hard copy printout of all dispensing information required to be kept by the pharmacy, including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to produce and provide this audit trail within twenty-four (24) hours, constitutes prima facie evidence of failure to keep and maintain records as defined in paragraph 1., C., of this ARTICLE.

The records of controlled substances in Schedules II, III, IV, and V, which are maintained in a data processing system shall be maintained as follows:

- A. The following information pertaining to the initial dispensing of the prescription shall be entered into the data processing system:
 - (1) Prescription number;
 - (2) Date of initial dispensing;
 - (3) Name and address of patient;
 - (4) Prescribing practitioner's name and DEA registration number;
 - (5) The name, strength, dosage form, and quantity of the controlled substance ordered and dispensed;
 - (6) Total number of refills authorized;
 - (7) The initials or identifying code of the dispensing pharmacist.
 - B. Additionally, the following information pertaining to the refilling of the prescription shall be maintained by the data processing system:
 - (1) The date of the refill dispensing, the total number of refills dispensed to date, or the total number of refills remaining for that prescription order;
 - (2) The initials or identifying code of the dispensing pharmacist.
4. A permanent record of the dispensing of all controlled substances shall be made and maintained as follows:
- A. Each time a prescription is filled or refilled a record of such filling shall be entered into the data processing system. A hard-copy printout containing only the dispensing record of original filling of Schedule II controlled substance prescriptions and the record of original filling and the refill history for Schedule III, IV, or V controlled substance prescription orders shall be produced daily, or at regular intervals, not to exceed seven (7) days. These hard-copy printouts shall be filed chronologically and stored in an orderly manner in a separate file at the pharmacy and be maintained for a two-year period from the date of the last dispensing. The hard-copy printout shall include:
 - (1) Prescription number;
 - (2) Name of the patient;
 - (3) The prescribing practitioner's name;
 - (4) The name, strength, dosage form, and quantity of the controlled substance dispensed;
 - (5) Number of refills originally authorized;
 - (6) Date of initial dispensing if an original prescription or if a refill, the date of refilling and the date of initial dispensing, and the total number of refills dispensed to date or the total number of refills remaining for that prescription order;
 - (7) The initials or identifying code of the dispensing pharmacist.
 - (8) Hard copy printouts shall only contain information regarding prescriptions dispensed.
 - B. The hard copy printout containing the information required by this paragraph shall be signed and dated by the pharmacist who produces the printout. The signature of the pharmacist on the printout shall serve as verification by that pharmacist that the information contained on the printout is complete.

5. A record of all controlled substance dispensing information shall be transmitted to the Prescription Monitoring Program, on a time basis determined by the program, by all pharmacies dispensing controlled substances (greater than a 48 hours supply) on an out-patient basis for the purpose of tracking the dispensing of Schedules II, III, IV, and V controlled substances by the Prescription Monitoring Program. Dispensers will be required to collect and transmit the following information:

- (A) The recipient's name;
- (B) The recipient's or the recipient representative's identification number;
- (C) The recipient's date of birth;
- (D) The national drug code (NDC) number of the controlled substance dispensed;
- (E) The date the controlled substance is dispensed;
- (F) The quantity of the controlled substance dispensed;
- (G) The number of days supply dispensed;
- (H) The dispenser's NABP or NCPDP registration number;
- (I) The prescriber's U. S. DEA registration number;
- (J) The method of payment of the prescription purchase.

6. Records of controlled substances in Schedule III, IV, and V which are maintained manually shall be maintained as follows:

A. A pharmacist, who fills or refills a prescription for a controlled substance in Schedule III, IV, or V, must enter on that prescription or some other uniformly maintained record system, his/her initials or identifying code as the dispensing pharmacist, the date the prescription was filled or refilled, and the quantity of the controlled substance dispensed if different from the original quantity prescribed.

If this record is maintained on the original prescription document, the original dispensing must be recorded on the face of the prescription and any refills must be recorded on the back of the prescription.

B. Original prescription documents shall be filed and maintained in accordance with the provisions of ARTICLE XII of these regulations.

For purposes of this ARTICLE, "hard-copy" means a physical document that is readable without the use of a special device (i.e., cathode ray tube, microfiche reader, etc.).