ALABAMA STATE BOARD OF PHARMACY
ADMINISTRATIVE CODE

CHAPTER 680-X-2
PRACTICE OF PHARMACY

680-X-2-.15 Record-keeping Requirements.

(1) A pharmacy's computer system shall provide for the storage and retrieval of original prescription orders and their refill histories. It must include:

(a) The original prescription number

(b) The prescribing practitioner's name, DEA registration number (if applicable), and Alabama controlled substance number (if applicable)

(c) Full name of the patient

(d) Date the original prescription was issued and dispensed

(e) Drug name, strength, dosage form, and directions

(f) Total number of refills authorized by the prescriber

(g) Quantity dispensed originally and on each refill

(h) Dates of all refills

(i) Identification of the dispensing pharmacist for the original prescription and each refill

(2) A pharmacist refilling a Schedule III-V prescription must verify the accuracy of the entered refill information using one of two methods:

(a) If such a system provides a hard-copy printout of each day’s controlled substance prescription order refill data, that printout shall be verified, dated, and signed. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he or she would sign a legal document. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed; or

(b) In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement

each day in the same manner as he or she would sign a legal document, attesting to the fact that the refill information entered into the computer that day has been reviewed by him or her and is correct as shown.

(3) Any system shall be capable of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Alabama Controlled Substances Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand, generic name, or both). The pharmacy must be capable of producing the printout within two business days. If an investigator of the Board or compliance investigator requests a copy of such printout from the pharmacy, it must verify the transmittal capability of its system by documentation (e.g., postmark).

(4) During system downtime, the pharmacy must have a backup procedure to document Schedule III-V refills, ensuring authorization, compliance with refill limits, and data retention for later online entry.

(5) Each pharmacy shall maintain its own series of consecutive numbered prescriptions. A series of numbers cannot be shared with another pharmacy.

(6) In addition to the controlled substances printout referred to in (3), a printout shall be obtained at least weekly of all new and refill prescription activity of the pharmacy for this period.

(7) All documentation required under this rule shall be retained for two years.

(8) Computer systems for the storage and retrieval of prescribes' orders for legend drugs prescribed for in-patients does not replace the requirement that the practitioners' orders be written and retained as a permanent record of the institution. The institution shall provide sufficient alternate records to maintain adequate controls and accountability.

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