

APA-3

**CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR**

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on Wednesday, June 25, 2025, and filed with the agency secretary on Friday, June 27, 2025.

AGENCY NAME: Alabama State Board of Pharmacy

INTENDED ACTION: Amend

RULE NO.: 680-X-2-.15
(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **All**

RULE TITLE: Record-keeping Requirements

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted with changes. 1 comment received in support of the changes with request to grammatically clarify (1)(f), (3), and (4)

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLIII, ISSUE NO. 7, AAM,
DATED WEDNESDAY, APRIL 30, 2025.

STATUTORY RULEMAKING AUTHORITY: 34-23-70

(Date Filed)
(For LRS Use Only)

REC'D & FILED
JUN 27, 2025
LEGISLATIVE SVC AGENCY

Anne Marie Nolen

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Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

(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 ~~and dispensed to date~~
- (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 ~~have the capability~~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).

~~(4) The central record-keeping location~~The pharmacy must be capable of ~~sending~~producing the printout ~~to the pharmacy~~ within two business days; ~~and if~~. If an ~~inspector~~investigator of the Board, ~~DEA special agent~~, or compliance investigator requests a copy of such printout from the pharmacy, it must verify the ~~printout~~ transmittal capability of its system by documentation (e.g., postmark).

~~(5)~~(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.

~~(6)~~(5) Each pharmacy shall maintain its own series of consecutive numbered prescriptions. A series of numbers cannot be shared with another pharmacy.

~~(7)~~(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.

~~(8)~~(7) All documentation required under this rule shall be retained for two years.

~~(9)~~(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.

Author: Alabama State Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §34-23-70

History: Filed June 1, 1982. **Amended:** Filed February 13, 1997; effective March 20, 1997. **Amended:** Published July 31, 2025; effective September 14, 2025.