

APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 680
Department or Agency: Alabama State Board of Pharmacy
Rule No.: 680-X-2-.15
Rule Title: Use Of Computers For Recordkeeping In Pharmacies In Alabama
Intended Action: Amend

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved? No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule? NA

Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer

Anne Marie Nolen
Anne Nolen

Date

Friday, March 28, 2025

REC'D & FILED

MAR 28, 2025

LEGISLATIVE SVC AGENCY

ALABAMA STATE BOARD OF PHARMACY

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama State Board of Pharmacy

RULE NO. & TITLE: 680-X-2-.15 Use Of Computers For Recordkeeping In Pharmacies In Alabama

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

The purpose of this amendment is to clarify requirements for record-keeping via a pharmacy computer system.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

The public hearing will be June 25, 2025 during the Business meeting beginning at 9:00 am CDT. Comments may be submitted to Anne Marie Nolen via email to anolen@albop.com by no later than June 20, 2025 at 4:00 pm CDT.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Friday, June 20, 2025

CONTACT PERSON AT AGENCY:

Anne Marie Nolen
anolen@albop.com

Anne Marie Nolen

Anne Nolen

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

~~Use Of Computers For Recordkeeping In Pharmacies
In Alabama~~Record-keeping Requirements.

(1) ~~Title 34, Chapter 23, Code of Ala. 1975, specifies the power and duty of the Board to adopt rules concerning the records and reports to be kept and made by a pharmacy.~~A pharmacy

~~(a) The computerized system shall provide for the storage and retrieval of original prescription orders as follows.~~'s computer system shall provide for the storage and retrieval of original prescription orders and their refill histories. It must include:

~~1. The original prescription number.~~(a) The original prescription number

~~2. The prescribing practitioner's name.~~(b) The prescribing practitioner's name, DEA registration number (if applicable), and Alabama controlled substance number (if applicable)

~~3. Full name and address of the patient.~~(c) Full name of the patient

~~4. (d) Date the original prescription was issued and the date it was dispensed, if different from the date of issue.~~

~~5. Name, strength, dosage form, and quantity of drug dispensed.~~(e) Drug name, strength, dosage form, and directions

~~6. (f) Total number of refills authorized by the prescriber.~~

~~7. Quantity dispensed.~~

~~8. In the case of controlled substance, the DEA registration number and the Alabama controlled substances number of the prescribing practitioner.~~and dispensed to date

~~9. Identification of the dispensing pharmacist.~~

~~(b) The computerized system shall provide for the retrieval of the refill history of all prescriptions entered into the computer. This refill history shall include:~~

~~1. The name of the drug.~~

~~2. Date of all refills.~~

~~3. (g) Quantity dispensed originally and on each refill.~~

~~4.~~ (h) Dates of all refills

(i) Identification of the dispensing pharmacist for
~~Identification of the dispensing pharmacists originally and~~
~~for each refill.~~

~~5. The total number of refills dispensed to date for that~~
~~prescription order.~~

~~(c) Documentation of the fact that the refill information~~
~~entered into the computer each time a pharmacist refills an~~
~~original prescription order 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 Schedule III, IV, or V controlled substance is~~
~~correct must be provided by the individual pharmacist who makes~~
~~use of such a system in either of two ways.~~

~~1. If such a system provides a hard-copy printout of each~~
~~day's~~ (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 ~~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.

~~(d) Any such computerized~~ (3) Any system shall have the capability
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). ~~Such a printout must~~
~~include the name of the prescribing practitioner, name and~~
~~address of the patient, quantity dispensed on each refill, date~~
~~of dispensing on each refill, name or identification code of the~~

~~dispensing pharmacist, and the number of the original prescription order.~~

~~(e) In any computerized system employed by a user pharmacy, the central recordkeeping~~ (4) The central record-keeping location must be capable of sending the printout to the pharmacy within two business days; and if an inspector of the ~~Alabama State Board of Pharmacy or~~ Board, DEA special agent, or compliance investigator requests a copy of such printout from the ~~user~~ pharmacy, it must, ~~if requested to do so by the inspectors of the Alabama State Board of Pharmacy, the agent or investigator,~~ verify the printout transmittal capability of its system by documentation (e.g., postmark).

~~(f) In the event that a pharmacy which employs such a computerized system experiences system downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedules III, IV, and V controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by original prescription order; that the maximum number of refills have not been exceeded; and that all of the appropriate data is retained for on-line entry as soon as the computer system is available for use again~~ (5) 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.

~~(g) (6) Each pharmacy shall maintain its own series of consecutive numbered prescriptions. A series of numbers cannot be shared with another pharmacy, even if they are using the same computer.~~

~~(h) In addition to the controlled substances printout referred to in paragraph (e)~~ (7) 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.

~~(i) (8) All documentation required under this rule shall be kept in a separate binder and~~ retained for two years.

~~(2) (9) 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.~~ Institution The institution shall provide sufficient alternate records to maintain adequate controls and accountability.

Author: ~~Jerry Moore~~ Alabama State Board of Pharmacy

Statutory Authority: Code of Ala. 1975, §~~34-23-92.~~34-23-70

History: Filed June 1, 1982. **Amended:** Filed February 13, 1997; effective March 20, 1997. Amended: Published _____; effective _____.