

**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, April 15, 2026, and filed with the agency secretary on Wednesday, April 15, 2026.

AGENCY NAME: Alabama State Board of Pharmacy

INTENDED ACTION: New

RULE NO.: 680-X-2-.50

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **all paragraphs**

RULE TITLE: Civil Penalties

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

Adopted with changes. The Board received 13 comments on proposed Rule 680-X-2-.50 and the related Appendix, 680-X-A. Several commenters expressed concern that the proposed Rule, as initially proposed, would allow the Board to "stack" violations and fines, contrary to the intent of Act 2025-372. The Board agrees, and has added new language to clarify that fines will be imposed concurrently, not cumulatively, when multiple legal violations are caused by the same wrongful act or occurrence. Commenters also expressed concern that the proposed Rule, as initially proposed, would allow the Board to consider factors other than "the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator" when setting civil penalty amounts. The Board agrees, and has made changes to address this concern. Commenters expressed concerns that certain provisions of the proposed Rule conflicted with recent statutory changes limiting late fees and penalty authority, and expressed concern that the proposed civil penalty structure could circumvent those limits. Upon review of these comments, the Board agreed to amend proposed Rule 680-X-2-.50 to clarify that civil penalties will not be sought or collected solely because of a licensee's failure to timely renew a license, registration, or permit. Commenters also submitted various comments relating to the rule-making process, and did not comment upon the substance of the proposed Rule. The Board follows the rule-making process outlined in the Alabama Administrative Procedure Act. Other comments were directed to the civil penalty ranges proposed in the proposed Appendix, 680-X-A. The Board has considered these comments and has decided not to certify the Appendix at this time.

REC'D & FILED
APR 17, 2026
LEGISLATIVE SVC AGENCY

APA-3

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLIV, ISSUE NO. 4, AAM,
DATED FRIDAY, JANUARY 30, 2026.

STATUTORY RULEMAKING AUTHORITY: 34-23-33

(Date Filed)
(For LRS Use Only)

Jon M Linna

Jon Linna

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.)

Civil Penalties.

(1) ~~Pursuant to the Board's authority set forth in~~In accordance with Ala. Code §34-23-33**(b)**, this Rule establishes the civil penalty fine schedule for disciplinary violations for chain pharmacies, independent pharmacies, all other pharmacy types, manufacturers, distributors, all other facility types, pharmacists, pharmacy technicians, and all other license types.

(2) The following provisions apply to civil penalties:

(a) The process for ~~executing~~imposing civil penalties shall be in accordance with the contested case provisions of the Alabama Administrative Procedures Act.

~~(b) Payment of the civil penalty must be received by the Board within ninety (90) days of notice. Failure to pay or otherwise comply with the terms of any imposed corrective action plan within the timeframe shall be considered grounds for a subsequent civil penalty, unless a request for an extension is approved by the Executive Secretary.~~

~~(c) If the person or entity wishes to contest the violation or fine, they shall notify the Board in writing within thirty (30) days of notice. In such cases, the Board shall issue a Notice of Hearing and Statement of Charges, and the matter shall proceed in accordance with the Alabama Administrative Procedures Act. Following the hearing, the civil penalty may be dismissed, upheld, modified, or replaced with disciplinary action.~~

~~(d)~~ Civil penalties imposed pursuant to this rule shall be reported to the National Practitioner Data Bank or other national reporting systems when required by applicable state or federal law.

~~(e)~~(c) If a non-disciplinary violation occurs alongside a disciplinary violation, both violations will be reviewed together. The disciplinary violation shall proceed through the formal disciplinary process, while the non-disciplinary violation may be included in the disciplinary case or addressed separately depending on whether it directly relates to the underlying conduct. The Board shall determine the most effective approach based on the nature and severity of the violations.

~~(f) If the violation is related to a failure to timely renew a license, permit, or registration, any applicable late fee shall not be imposed in addition to the civil penalty.~~

~~(g) When considering~~ (d) When determining the amount of a civil penalty for a specific violation, the Board shall consider the level and scope of misconduct, ~~including but not limited to the number of patients affected, number of days operating under a specific violation, willfulness, or negligence,~~ the level of risk to public health and safety, and the compliance history of the violator, ~~including but not limited to fines or penalties assessed and/or time since last violation.~~ The Board shall not consider whether the violator is a natural person or a legal entity, the size of the business, nor the violator's annual revenues. The Board recognizes and declares that the central purpose of civil penalty is to protect the public by incentivizing compliance with Alabama law and to deter wrongdoing.

~~(h) When a single act or omission constitutes a violation of both a statute and a rule of the Board, and the statutory provision and rule address the same~~ (e) When a Statement of Charges and Notice of Hearing alleges legal violations based on substantially the same underlying conduct, transaction, series of transactions, occurrence, or series of occurrences, the Board in its final order shall determine the civil penalties for each legal violation separately, but shall impose those civil penalties concurrently and not cumulatively.

(f) When a Statement of Charges and Notice of Hearing alleges legal violations that are not based on the same underlying conduct, transaction, series of transactions, occurrence, or series of occurrences, the Board shall not assess impose the civil penalties for the separate legal violations for each citation. In such instances, the Board shall proceed under a single statutory or regulatory citation, as determined appropriate by the Board separately and cumulatively.

(3) The civil penalty schedules set forth each disciplinary violation, the monetary amount of the civil penalty, and any possible corrective action. Civil penalty schedules are listed as individual appendices in Rule 680-X-A. Nothing in this Rule and the related appendices shall affect the Board's discretion to impose non-monetary sanctions, including license revocation, suspension, probation, reprimand, and other corrective actions, as the Board deems appropriate based on the particular facts of each case.

Author: Alabama State Board of Pharmacy

Statutory Authority: 34-23-33

History: New Rule: Published April 30, 2026; effective June 14, 2026.