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, August 19, 2026, and filed with the agency secretary on Wednesday, August 19, 2026.

AGENCY NAME: Alabama State Board of Pharmacy

INTENDED ACTION: Amend

RULE NO.: 680-X-2-.50
(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **(2), (3)**

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 without changes. I. Background
Notices of Intended Action for the above rules were filed with the Legislative Services Agency on June 17, 2026. The Board received two written comments during the comment period: a comment dated August 12, 2026 ("Commenter 1"), and a comment dated August 14, 2026 ("Commenter 2"). A public hearing was held August 19, 2026. In accordance with Ala. Code § 41-22-5(a)(2), the Board has considered all written and oral submissions received and sets forth below its principal reasons for and against adoption of the proposed rules, including its reasons for overruling the considerations urged against adoption.
As a preliminary and general observation applicable throughout this statement: Act 2025-372 substantially altered the Board's monetary penalty authority as compared to prior law. Former Ala. Code § 34-23-90(a)(12) authorized the Board to "invoke penalties not to exceed the sum of one thousand dollars ($1,000) for each violation" under a general, undefined standard. Act 2025-372 repealed that provision in its entirety and replaced it with the current framework in § 34-23-33(b), which requires that the Board adopt "dollar amount ranges based on the underlying violation," differentiated by categories of licensees including, but not limited to, chain pharmacies, independent pharmacies, manufacturers, and distributors. The Legislature did not itself define "violator," "chain pharmacy," "independent pharmacy," "level and scope of misconduct," or "level of risk to public health and safety" — terms it used and left to the Board's discretion in § 34-23-33(b)(3). The lodestar scoring methodology, the associated point bands, and the written-statement requirement for departures exceeding fifteen percent in proposed Rule 680-X-2-.50(2)(e) are not required by statute; they reflect the Board's voluntary effort to bring greater transparency, consistency, and predictability to an exercise of discretion that the Legislature otherwise

committed to the Board's case-by-case judgment. This context informs the Board's responses below.

II. Action Taken

The Board adopts proposed Rule 680-X-2-.50 and proposed Chapter 680-X-A as noticed on June 17, 2026, without change. The Board declines to make any changes to the proposed rules at this time, for the reasons stated below, while acknowledging that certain comments may warrant consideration in a future rulemaking cycle.

III. Response to Comments

A. Commenter 1 (Aug. 12, 2026)

1. Definition of "Violator"

Commenter 1 observes that proposed Rule 680-X-2-.50(d) uses the term "compliance history of the violator" without an express definition of the term “violator,” and expresses concern that the disciplinary history of a single pharmacy location could be attributed to other, unrelated locations under common ownership. The Board declines to add a definition. The Board considers the term “violator” to have its plain and commonly-understood meaning: "violator" refers to the particular permit or license holder that is found, after due process, to have committed the disciplinary infraction at issue. Compliance history accordingly attaches to that specific permit or license holder and not, without more, to other permits or licenses held by a common owner or affiliate. No amendment to the rule is necessary.

The Board also declines to implement Commenter 1's further suggestion of a fixed lookback period (e.g., five years) for prior violations. That suggestion, and the balance of Commenter 1's comments addressed below, may be considered in a future rulemaking cycle once the Board has practical experience administering the lodestar methodology.

2. Risk and Culpability Scoring Standards; Actual vs. Potential Harm (Issues #2 and #3)

Commenter 1 notes that the lodestar methodology allocates half of the scoring weight to the statutory factor of “level of risk to public health and safety” and acknowledges that the Board has established written benchmarks and point ranges to guide the Board’s decisionmaking. Commenter 1 requests that the Board add even greater specificity to these benchmarks, including more detailed “objective definitions, scoring criteria, and illustrative examples.” Section 34-23-33(b)(3) directs the Board to consider "the level and scope of misconduct" and "the level of risk to public health and safety" using the same open-textured language the proposed rule adopts, without further legislative definition. The lodestar framework in Rule 680-X-2-.50(2)(e) is designed to add a measure of structure and transparency to a discretionary judgment the statute otherwise leaves to the Board. Further codifying precise numeric definitions for every scoring band might be desirable, but also may not be feasible given the great variety of cases and fact patterns that are involved in each individual case. The Board finds these comments may have merit as considerations for future refinement after the Board gains experience applying the lodestar methodology, and may consider them at that time.

3. Written Findings for Scoring Determinations and Departures

Next, Commenter 1 argues that “the Board's transparency objectives would be significantly enhanced by requiring written findings identifying: • The score assigned in each category; • The facts supporting each score; • Any aggravating or mitigating factors considered; and • The basis for any departure from the calculated penalty amount.” Although not expressly stated in the text of the Rule, as a matter of administrative implementation, in contested cases in which a civil penalty is imposed, the Board intends to document the basis for each component score and the resulting lodestar calculation on a worksheet prepared in the particular contested case, which worksheet will be part of the administrative record in that particular case. This administrative implementation practice will provide much of the documentation Commenter 1 seeks.

4. Published Methodology for Penalty Ranges (680-X-A)

Lastly, Commenter 1 requests an explanation of the methodology used to establish the civil penalty ranges embodied in 680-X-A. The Board notes that the final proposed ranges were developed and discussed in properly noticed public meetings, at which interested persons had the opportunity to attend and to be heard. The Board discussed the proposed schedules at public meetings held on May 18 and 20, 2026, and placed the proposed civil penalty schedules on the Board's web site on June 8, 2026, all in advance of the first Board vote to initiate the rulemaking process. The present notice-and-comment process is further designed and intended to solicit public input on the ranges embodied in the schedules. The Board's Economic Impact Statement further explains, at a general level, that the schedules are designed and intended to promote "transparency (licensees can ascertain in advance the range of monetary exposure associated with any disciplinary violation), greater consistency and proportionality in penalty amounts, and deterrence of conduct that endangers public health and safety." In compliance with Act 2025-372, the schedules are further separated by license type and are therefore calibrated to structural differences among segments of the regulated market.

B. Commenter 2 (Aug. 14, 2026)

As a preliminary matter, substantial portions of Commenter 2's submission are directed at the Board's motives and general enforcement history rather than at the text of the proposed rules. Ala. Code § 41-22-5(a)(2) calls for a statement of the Board's reasons for and against adoption of the rule; the Board does not respond point-by-point to characterizations of its institutional conduct and confines this statement to the substantive points bearing on the proposed rules.

1. The Lodestar Scoring Rubric

In Contrast to Commenter 1, Commenter 2 characterizes the lodestar scoring rubric as not merely as lacking sufficient specificity, but as unauthorized and unlawful. The Board disagrees. Section 34-23-33(b)(3) prescribes three statutory factors the Board must consider in determining the amount of a monetary penalty — the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator — but leaves to the Board's administrative discretion how that directive is carried out. The lodestar methodology is simply the means by which the Board exercises that discretion: it structures the Board's consideration of the three statutory factors, assigns them defined relative weights, and creates qualitative "Advisory Anchors" to guide the Board's assignment of points. In the Board's view, a structured, transparent approach of this kind is far superior to an undefined, undocumented, and potentially arbitrary exercise of case-by-case discretion. In addition, the lodestar method focuses the Board's attention on the three statutory factors driving the imposition of civil penalties, to the exclusion of other non-statutory factors, such as the size of a business or its annual revenues.

2. Breadth of Penalty Ranges—Ranges "Far Out of Line with What the Legislature Intended"

Commenter 2 next contends that that the civil penalty ranges in 680-X-A are “far out of line with what the Legislature intended.” As discussed above, in Act 2025-372, the Legislature repealed the Board’s former authority to impose fines of up to $1,000 for each violation, and replaced it with the requirement that the Board establish civil penalty ranges "based on the underlying violation" and differentiated by license category. Act 2025-372 does not prescribe any minimum floor or maximum width. In accordance with Act 2025-372, each schedule entry sets a distinct ceiling tied to a specific violation and licensee category, which is itself the differentiation the statute requires. A zero floor for each prescribed range preserves the Board's discretion to account for genuinely minor or technical instances of a violation, consistent with the proportionality objectives Act 2025-372 was intended to serve. A zero floor in each case also explicitly preserves the Board's discretion to impose no civil penalty at all in any case in which the Board does not believe a civil penalty is appropriate.

3. Differential Ceilings for Manufacturers and Distributors

Commenter 2 contends that the Board’s penalty schedules “fail[] to honor the no-size/no-revenue statutory directive.” Section 34-23-33(b)(2) requires the Board to adopt "separate penalty schedules for specific types or categories of persons," naming chain pharmacies, independent pharmacies, manufacturers, and distributors. The differentiated ceilings among these named categories implement that express directive; they are not an unauthorized proxy for the size-of-business or annual-revenue factor that the Legislature separately removed from the case-specific scoring factors in the bill that became Act 2025-372 (see HB 123 (enrolled), lines 449-451).

4. Authority to Penalize Unlicensed Entities (§ 34-23-32(g))

Commenter 2 urges that the civil penalty schedules should not include the $4,000-per-violation civil penalty found in Ala. Code § 34-23-32(g). The referenced $4,000 civil penalty is imposed directly by § 34-23-32(g) for shipping a legend drug or device into this state without a valid Board-issued permit. Section 680-X-A-4 and -5's cross-reference to § 34-23-32(g) merely restates an existing statutory penalty, which must be accounted for in a complete civil penalty schedule regardless of whether, or against whom, the Board might ever impose it. The task before the Board in this rulemaking is to compile a schedule of potential civil penalties, not to pre-adjudicate whether any particular penalty can or will be imposed in a future case.

5. Undefined Unit of Violation; No Aggregate Cap

Next, Commenter 2 argues that “nothing in the rule or the schedules clearly defines what constitutes a single violation. . . .” The Board disagrees. The unit of violation is clearly addressed in subsections (f) and (g) of Rule 680-X-2-.50. These subsections establish that when multiple legal violations arise from the same underlying conduct, transaction, series of transactions, occurrence, or series of occurrences, the fines for multiple legal violations must be assessed concurrently rather than cumulatively. Subsections (f) and (g) are not part of the current rule amendment process; they are existing provisions of the rule that the pending rulemaking proceeding does not propose to alter.

6. Compliance History Blending Disciplinary and Non-Disciplinary Matters

Next, Commenter 2 contends that non-disciplinary administrative penalties should not be considered as part of the “compliance history of the violator.” Section 34-23-33(b)(3) directs the Board to consider "the compliance history of the violator" without qualification, and nothing in the statute forbids consideration of prior non-disciplinary administrative fines as part of that history. As discussed in Section III.A.1 above, compliance history attaches to the specific permit or license holder found to have committed the violation at issue.

7. “Undefined” Schedule Entries ("Refer to Corresponding Schedule")

Commenter 2 says that the schedule entries that read “Refer to corresponding schedule” are self-referential. These entries specify that when disciplinary action is grounded in Ala. Code § 34-23-33(a)(7) (“[v]iolation of any provisions contained in this chapter or a rule of the board”), the applicable civil penalty range is the range found elsewhere in the applicable schedule corresponding to the statute or rule allegedly violated.

8. Undefined Category Terms

Existing Board Rule 680-X-2-.05 already differentiates between chain pharmacies and independent pharmacies, and the schedules in proposed Chapter 680-X-A apply those existing, established categories rather than creating new or undefined ones.

9. Fiscal Note

Lastly, Commenter 2 argues that the fiscal note filed with the proposed rules “is internally contradictory.” The fiscal note's statement that aggregate penalties are generally expected to decline, and its separate acknowledgment that no precise empirical model of the rule's impact is feasible, address different questions: a general directional expectation informed by the Board's enforcement experience, and a recognition that the qualitative public-health benefits of deterrence cannot be quantified on the same scale as monetary penalties. The two statements are not in genuine tension. The Board does expect that aggregate fines will be lower in future years than in past years. The Board cannot empirically quantify this expectation at this time.

IV. Conclusion

The Board has considered all written and oral submissions received in this matter. For the reasons stated above, the Board adopts proposed Rule 680-X-2-.50 and proposed Chapter 680-X-A as noticed on June 17, 2026, without change.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLIV, ISSUE NO. 9, AAM, DATED TUESDAY, JUNE 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

APA-3

(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.)

680-X-2-.50 Civil Penalties.

(1) 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 imposing civil penalties shall be in accordance with the contested case provisions of the Alabama Administrative Procedures Act.

(b) 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.

(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.

(d) When determining the amount of a civil penalty for a specific violation, the Board shall consider the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator, utilizing the advisory lodestar calculation methodology described below in subsection (e). 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 imposing a civil penalty is to protect the public by incentivizing compliance with Alabama law and to deter wrongdoing.

(e) The Board shall determine an advisory lodestar civil penalty amount by scoring each case on a scale of 0-100, with 30 points allocated to the level and scope of misconduct, 50 points allocated to the level of risk to public health and safety, and 20 points allocated to the compliance history of the violator.

(i) Level and Scope of Misconduct: The Board shall utilize the following advisory anchors and guideline ranges to score the level and scope of misconduct applicable to the individual case:

Advisory Anchors	Guideline Range
Isolated Occurrence Unintentional Oversight Minimal Culpability	0-10 Points
Repeated Occurrence Negligent Oversight Moderate Culpability	11-20 Points
Systematic Occurrence Intentional Violation High Culpability	21-30 Points

(ii) Level of Risk to Public Health and Safety: The Board shall utilize the following advisory anchors and guideline ranges to score the level of risk to public health and safety applicable to the individual case:

Advisory Anchors	Guideline Range
Risk of Harm is Nonexistent, Remote, or Theoretical	0 Points
Risk of Harm is Real, but Low to Moderate in Severity	1-20 Points
Risk of Harm is Real, Meaningful, Significant	21-44 Points
Demonstrated Patient Harm	45-50 Points

(iii) Compliance History of the Violator. The Board shall utilize the following advisory anchors and guideline ranges to score the compliance history of the violator applicable to the individual case:

Advisory Anchors	Guideline Range
No Previous Discipline or Administrative Fines	0 Points
Previous Disciplines or Administrative Fines (One or Two Previous Cases)	1-14 Points
Three or More Previous Disciplines or Administrative Fines Any Repeated Occurrence of Same Violation	15-20 Points

(iv) The sum of the individual scores as determined above for the level and scope of misconduct, the level of risk to public health and safety, and the compliance history of the violator, shall be applied as a percentage to the applicable schedule range to determine the advisory lodestar civil penalty amount.

(v) The Board may depart downward in any amount, and may depart upward by up to 15% from the advisory lodestar civil penalty amount without providing any written explanation. If the Board departs upward from the advisory lodestar civil penalty amount by more than 15%, the Board, in its written order imposing the civil penalty, shall provide a brief written statement of its reasons for doing so. In no event, however, shall the Board impose a civil penalty amount in excess of the maximum applicable range set forth in the Appendix.

(f) 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.

(g) 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 impose the civil penalties for the separate legal violations 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, corrective action plans, remedial continuing education requirements, additional inspection requirements, and other non-monetary 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. **Amended:** Published August 31, 2026; effective October 15, 2026.