

APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 680
Department or Agency: Alabama State Board of Pharmacy
Rule No.: 680-X-2-.50
Rule Title: Civil Penalties
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? Yes

To what degree?: See fiscal note

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule? No

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? Yes

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

Jon M Linna
Jon Linna

Date

Wednesday, June 17, 2026

REC'D & FILED
JUN 17, 2026
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-.50 Civil Penalties

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

This rule amendment is proposed to implement a formal advisory scoring mechanism for the imposition of civil penalties.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

The public hearing will be August 19, 2026 during the business meeting beginning at 9:00 am CT at the Board of Pharmacy office, located at 111 Village Street, Birmingham, AL 35242. Written comments may be submitted to Anne Marie Nolen via email to anolen@albop.com by EOB August 14, 2026.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Friday, August 14, 2026

CONTACT PERSON AT AGENCY:

Anne Marie Nolen
anolen@albop.com

Jon M Linna

Jon Linna

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

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:

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

(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:

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

(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:

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

(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.

~~(f)~~ (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, ~~and other~~ 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: ~~Code of Ala. 1975, §34-23-33.~~

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

**ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 41-22-23(f))**

Control No: 680
Department or Agency: Alabama State Board of Pharmacy
Rule No: 680-X-2-.50
Rule Title: Civil Penalties
Intended Action: Amend

 This rule has no economic impact.

 Yes This rule has an economic impact, as explained below:

1. NEED/EXPECTED BENEFIT OF RULE:

In Act No. 2025-372, the Alabama Legislature directed that the Alabama Board of Pharmacy, "by rule, shall adopt monetary penalty schedules that shall include both civil penalties and administrative fines and shall be dollar amount ranges based on the underlying violation. The board shall adopt separate penalty schedules for specific types or categories of individuals and entities subject to this chapter, including, but not limited to, separate penalty schedules for chain pharmacies, independent pharmacies, manufacturers, and distributors. No later than the effective date of the certified rule or rules, the board shall publish the penalty schedules on the board's website." The proposed rule will implement, in part, requirements imposed by the Legislature. In addition to complying with this legislative mandate, the Board has determined that the proposed rule is needed to restore the Board's monetary penalty authority: under Act No. 2025-372, beginning January 1, 2026, the Board may not impose any monetary penalty unless the penalty is covered and addressed by a penalty schedule that has been certified and published on the Board's website. The expected benefits of the proposed rule, if adopted, include 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.

2. COSTS/BENEFITS OF RULE AND WHY RULES IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE:

The proposed rule is designed and intended to implement certain requirements outlined in Act No. 2025-372. The Legislature has

determined, and the Board agrees, that having schedules of fine ranges for particular disciplinary violations serves the public interest. The Board believes that the proposed rule faithfully implements the Legislature's intent. The proposed rule creates no new substantive duties, recordkeeping obligations, fees, or operational requirements; it only structures the monetary consequences of violating duties that already exist under existing law. The proposed rules, if adopted, will impose costs only on those licensees who commit disciplinary violations of the statutes and rules enforced by the Board, and only after due process is observed. Any such costs will help to incentivize compliance with the applicable statutes and rules, which will promote public health and safety. The proposed rule is clearly superior to known alternatives. Flat, fixed penalties or very narrow ranges for each violation would be simpler to administer, but would be disproportionate, treating an isolated, unintentional oversight the same as a systematic, intentional violation causing patient harm. Pure case-by-case discretion with wide penalty ranges would maximize flexibility, but would minimize predictability and invite inconsistency. The approach embodied in the proposed rule—published penalty ranges for each violation and licensee category, an advisory scoring methodology applied to those ranges, and bounded authority to depart from the advisory amount — balances the proportionality of individualized assessment with the predictability of a published schedule. The Board is not aware of any more effective, efficient, nor feasible means for allocating resources nor for achieving the Legislature's stated intent.

3. EFFECT OF THIS RULE ON COMPETITION:

Adoption of the proposed rule should have little to no effect on competition. Published, uniform schedules, together with a formal scoring mechanism, reduce the possibility that arbitrary or inconsistent penalty practices could advantage one competitor over another. As the statute requires, the schedules are differentiated by category — chain pharmacies, independent pharmacies, other pharmacy types, pharmacists, technicians, other license types, manufacturers, distributors, and other facility types — so that penalty ranges are calibrated to the structural differences among segments of the regulated market rather than applied identically to dissimilar actors. Within each category, all competitors would face the same published ranges and the same scoring methodology. To the extent that the proposed rule would affect competition, it would create a small advantage in favor of licensees who obey all applicable statutes and rules, and a small disadvantage for licensees who violate applicable statutes and rules. In doing so, the proposed rule would tend to incentivize compliance with Alabama laws and regulations governing pharmacy, and would thus tend to promote the public health and welfare.

4. **EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:**

The proposed rule, if adopted, would be applicable uniformly to all holders of licenses issued by the Board within and outside the State of Alabama. The proposed rule is expected to have little to no effect on the cost of living and of doing business in the State of Alabama. To the extent that there is any effect at all on the cost of living and of doing business in the State of Alabama, the Board generally anticipates that overall aggregate monetary penalties under the proposed rule will be less than the overall aggregate monetary penalties historically imposed by the Board (assuming that overall levels of legal compliance within the pharmacy industry remain constant). In addition, the Board anticipates that the proposed scoring methodology will lead to greater predictability and consistency in monetary fines imposed, which could tend to slightly decrease the overall costs of living and of doing business in the State of Alabama by slightly decreasing regulatory compliance costs.

5. **EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED:**

The proposed rule, if adopted, would be applicable uniformly to all holders of licenses issued by the Board within and outside the State of Alabama. The proposed rule is expected to have little to no effect on employment in the State of Alabama. The Board generally expects that overall aggregate monetary penalties under the proposed rule to be slightly less than the overall aggregate monetary penalties historically imposed by the Board (assuming that overall levels of legal compliance within the pharmacy industry remain constant). In addition, the Board expects that the proposed scoring methodology will lead to greater predictability and consistency in monetary fines imposed, which could tend to slightly increase employment in Alabama by slightly decreasing regulatory compliance costs.

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE:

The proposed rule implements Legislative requirements for the Board, and does not create any new regulatory mandates, reporting requirements, or prohibitions for individuals and entities licensed and/or regulated by the Board. Therefore, the Board does not expect to incur any additional material costs associated with implementing and enforcing the proposed rule. Costs associated with implementing and enforcing the proposed rule, if any, would be paid exclusively from Board funds. The Board does not receive any general fund appropriations from the Legislature and does not have any broad-based taxing authority. Instead, the Board is funded through licensing fees authorized by the Legislature and, to a much lesser extent, monetary penalties assessed on holders of licenses engaged in the pharmaceutical industry in Alabama (e.g., pharmacists, pharmacy technicians, pharmacies, manufacturers, and drug distribution facilities).

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON EFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE:

As discussed above, the adoption of the proposed regulation is not expected to have any substantial short-term or long-term economic impacts. The proposed regulation implements Legislative requirements for the Board, and does not create any new regulatory mandates, reporting requirements, or prohibitions for individuals and entities licensed and/or regulated by the Board. Any costs occasioned by adoption of this proposed rule will be borne by licensed persons and entities (e.g., pharmacists, pharmacy technicians, pharmacies, manufacturers, and drug distribution facilities) who are found, after due process, to have violated the laws and regulations applicable to the pharmacy industry in Alabama. The direct beneficiaries of the proposed rule include licensees who comply with applicable laws and regulations, who would gain predictability and protection against inconsistent penalty determinations, as well as respondents in disciplinary proceedings, who would gain published, bounded penalty exposure. Indirect beneficiaries include patients and the general public, who would benefit from the deterrence of violations that endanger public health and from continued access to pharmacy services in circumstances where a calibrated monetary penalty serves as a proportional alternative to license suspension or permit revocation.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON:

The principal benefits and burdens of the proposed rule resist precise quantification, and the Board acknowledges those limits. Factors driving uncertainty include, but are not limited to: the propensity of licensed persons and entities (e.g., pharmacists, pharmacy technicians, pharmacies, manufacturers, and drug distribution facilities) to comply with or violate laws and regulations applicable

to the pharmacy industry in Alabama; the propensity and/or ability of the Board's staff to successfully detect and investigate any such violations, if any; the potential availability of non-disciplinary administrative penalties, if any, as alternatives to civil penalties; individual investigative and charging decisions made in particular cases; the Board's ability to marshal and present evidence to support proof of disciplinary violations; evidence of any mitigating factors presented in contested cases by respondents, if any; future changes in laws and regulations, if any; and innumerable other factors. Because of these uncertainties, it is not feasible to create any meaningful empirical or quantitative analysis of the proposed rule. In addition, the principal benefits and burdens of the proposed rule are qualitatively dissimilar and difficult to compare on a common scale: monetary penalties are denominated in dollars, while the principal expected benefits of the proposed rule – violations deterred and patient harm avoided – are health and safety outcomes that cannot be directly observed or priced.

9. **THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH:**

The adoption of the proposed rule is not expected to have any substantial effect on the environment (e.g., clean air, water, and soil). The adoption of the proposed rule is, however, expected to have a positive effect on public health. The proposed scoring methodology allocates half of its total weight to the level of risk to public health and safety, so that civil penalties escalate most sharply for the conduct posing the greatest danger to patients, and the proposed penalty schedules assign the highest penalty ranges to the violations with the most serious public health consequences.

10. **DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED:**

As set forth above, the adoption of the proposed rule is not expected to have any substantial effect on the environment (e.g., clean air, water, and soil). If the proposed rule or some version of it is not implemented, however, a significant detriment to the public generally will exist because the Legislature has expressly commanded that a rule of this nature be adopted. In addition, under Act No. 2025-372, the Board may not impose any monetary penalty unless the penalty is covered and addressed by a certified and published penalty schedule. If the proposed rule is not implemented, the Board will therefore remain unable to impose monetary penalties for any violation, weakening deterrence of conduct that directly endangers public health – including the dispensing of adulterated or improperly compounded drugs, violations involving controlled substances, and the unlicensed practice of pharmacy – and leaving harsher sanctions, such as license suspension or permit revocation, as the Board's principal means of enforcement.

APA-6

Signature of certifying officer

Jon M Linna

Jon Linna

Date

Wednesday, June 17, 2026