ALABAMA STATE BOARD OF PHARMACY
ADMINISTRATIVE CODE

CHAPTER 680-X-2
PRACTICE OF PHARMACY

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
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