



Kentucky Board of Pharmacy

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FOR IMMEDIATE RELEASE

Update from the Kentucky Board of Pharmacy Regarding Medication Errors at Med Save Pharmacy in Eminence, Kentucky

The Kentucky Board of Pharmacy has reached final resolution in its administrative cases against Med Save Pharmacy in Eminence, Kentucky and against J. Drane Stephens, the owner of the pharmacy who was also pharmacist-in-charge at the time the errors occurred. These cases arose from a series of medication errors initially reported to the Board on August 26, 2024.

Upon receiving reports of three alleged medication errors all involving a compounded clonidine suspension dispensed to three separate pediatric patients, each of whom was subsequently hospitalized with serious medication complications, the Board immediately deployed its pharmacist inspection staff to conduct an on-site inspection and comprehensive investigation.

During that inspection, the Board identified significant non-compliance with state laws and regulations governing compounding, including deficiencies in preparation, oversight and quality assurance of compounded medications. Based on these findings, the Board's Case Review Panel convened an emergency meeting and directed entry of an agreed order requiring the pharmacy to immediately cease all compounding and dispensing of compounded medications. That order has remained in effect since August 28, 2024.

Following a thorough investigation, the Case Review Panel determined that the pharmacy and the pharmacist-in-charge violated multiple Kentucky statutes and administrative regulations governing the practice of pharmacy and compounding, including but not limited to violations of KRS 315.121, 201 KAR 2:205, and 201 KAR 2:076, related to professional standards, pharmacist oversight, and compounding requirements. These standards are in place to ensure that medications are prepared and dispensed safely and that patients are protected from preventable harm.

As part of the final agreed orders in these cases:

- The pharmacy has stipulated that it engaged in unprofessional or unethical conduct by selling misbranded and adulterated clonidine suspensions that were compounded incorrectly using active pharmaceutical ingredient (API) power

instead of commercially manufactured clonidine tablets, resulting in the hospitalization of three pediatric patients.

- The pharmacy has stipulated that it failed to adequately train the pharmacy technician assigned to nonsterile compounding, failed to adequately train all supervising pharmacists performing or supervising nonsterile compounding (there was no training documentation), failed to ensure that each compounding employee was continually monitored to ensure accurate compounding; failed to ensure proper storage including temperature violations; failed to ensure the master compounding formulation was followed.
- The pharmacy has stipulated that it failed to maintain proper documentation for nonsterile compounding. This failure of documentation was systemic, multifaceted and included failure to maintain the following required records in a consistent manner:
 - Critical process verification including weighing, measuring and mixing;
 - Documentation of pharmacist review of each procedure in the compounding process, including the use of the correct ingredients, assurance of correct calculations and accurate measurements;
 - Names and quantities of all components used in compounding;
 - Nonsterile compounded prescriptions dispensed to a patient;
 - Required pharmacist review of the compounding record;
 - Appropriate compounding calculations on the master formulation;
 - Description of each final compounded preparation;
 - Quality and control procedures and expected results in the master formulation;
 - Failure to update NDCs, lot numbers and expiration dates;
 - Name of the pharmacist performing quality checks;
 - Name of the pharmacist verifying the components and final preparations;
 - Failure to ensure that the compounding record included a duplicate label, description of the final preparation and when deviations from documented procedures were performed.
- The pharmacy violated KRS 315.121; KRS 217.065; KRS 217.055 and 201KAR 2:076.
- The pharmacy was issued and paid a fine in the amount of \$5,000.
- The pharmacy is on probation for a period of five years. During this term, the pharmacy must strictly comply with all terms, and any violations of the terms may result in revocation of the pharmacy's permit.
- The pharmacy is barred from compounding for a period of five years.
 - After that time, the pharmacy can only resume compounding by submitting a petition to the board, satisfactorily completing a board approved compounding inspection, strictly complying with KRS 315 and 201 KAR Chapter 2 and the pharmacist-in-charge and all designated persons compounding and having oversight of compounding shall submit documentation of specific training in compounding.
- The pharmacist-in-charge and pharmacy owner, J. Drane Stephens, has stipulated to the facts and conclusions contained within the Board's investigation.

- The pharmacist-in-charge and pharmacy owner, J. Drane Stephens has agreed to a surrender of his license to practice pharmacy, effective May 1, 2026.
 - Any future request for reinstatement of license will require a formal petition to the Board, and the Board will then evaluate the ability of the individual to safely and competently practice, with patient safety and public protection as paramount considerations.
- The pharmacist-in-charge and pharmacy owner, J. Drane Stephens has agreed to pay a \$500 fine as recoupment for enforcement costs incurred by the Board during the administrative investigation.

The Kentucky Board of Pharmacy is entrusted with protecting the health, safety, and welfare of the citizens of the Commonwealth. Medication errors involving compounded preparations, particularly those affecting vulnerable populations, such as pediatric patients, pose significant risks and will be addressed with the utmost urgency and diligence

The Board's investigation has concluded, and the agreed order represents final administrative action in the impacted cases. The Board remains committed to ensuring accountability, maintaining high standards of practice, and promoting safe pharmaceutical care across Kentucky.

To request any public record for this case, please continue to the following link and complete an official Open Record's Request and email to pharmacy.board@ky.gov:

<https://pharmacy.ky.gov/Documents/2021%20Open%20Records%20Form.pdf>