

Substantive Policy

Compliance Guideline for Pharmacist in Charge & Non-Rx drugs Expiration Dates in mercantile establishments

SUBSTANTIVE POLICY: PHARMACIST-IN-CHARGE: RESPONSIBILITY RELATED TO OUTDATED NONPRESCRIPTION DRUGS FOUND IN A MERCANTILE ESTABLISHMENT WHERE A PHARMACY IS LOCATED INSIDE THE ESTABLISHMENT

Board rule, R4-23-606(F), requires a nonprescription drug permit to sell nonprescription drugs when a pharmacist is not present. This rule targets large grocery stores and mass merchandisers who put a pharmacy inside a store, but the pharmacy hours are less than the general store hours. Nonprescription drugs sold when the pharmacy is closed are not covered by the pharmacy's permit. The establishment obtains a nonprescription drug permit and a manager is responsible for compliance with state and federal drug laws.

Over the years, chain pharmacies started keeping the main store open longer than the "pharmacy". These chain pharmacies also obtain a nonprescription drug permit for selling nonprescription drugs when the "pharmacy" is closed. It has been Board philosophy that only the nonprescription drug permittee or manager is held responsible for violations related to nonprescription drugs. Over the last few years there have been numerous incidents of violations involving outdated nonprescription drugs in establishments that also contain a pharmacy.

The Board staff has been using an unwritten 3-strike violation policy before taking the issue to the Board hoping for voluntary compliance. The large quantities of outdated nonprescription drugs found and the very liberal compliance philosophy has prompted the Board to change their policy. Under A.R.S. 32-1901.55 (paraphrased) the Pharmacist-In-Charge (PIC) is responsible to the Board for the permitted establishment's compliance with both state and federal laws and rules (regulations) relating to the practice of pharmacy and the distribution of drugs and devices. This responsibility extends to nonprescription drugs sold by self-service outside the pharmacy in mercantile establishments.

GOAL: Protect the public from potential health hazards of nonprescription drugs stocked and sold beyond their expiration date. Ensure voluntary compliance by reducing the number of violations allowed before punitive action occurs and reducing the time-frame for voluntary compliance.

POLICY:

1. It is the Board's position that the Pharmacist-In-Charge (PIC) of a pharmacy located in a mercantile establishment does in fact have a responsibility relating to removal of out-of-date nonprescription drugs from sale to the public. This does not imply that the PIC personally needs to do the work, but rather the PIC needs to ensure timely product expiration date review, prompt removal, and proper disposal of expired nonprescription drugs.
2. A nonprescription drug permittee found in violation of state or federal drug law (including stocking expired nonprescription drugs) shall receive one warning. A repeat of the same violation, within the time-frame of the next inspection, will result in an official Notice of Hearing to determine whether to fine and revoke or suspend or place on probation the nonprescription drug permit.

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