

**ARIZONA STATE BOARD OF PHARMACY**  
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**COMPLIANCE POLICY GUIDE**

**PRACTICE OF FLAVORING MEDICATIONS**

**BACKGROUND:** The practice of flavoring medications has long been an integral part of the pharmacy profession. The Board's interpretation of its rules has been that the addition of flavoring agents is compounding and requires compliance with A.A.C. R4-23-410 Current Good Compounding Practices. Recently, a few states have modified their laws or written policy statements that allow flavoring of medication without the usual recordkeeping required in compounding. The Texas Board of Pharmacy modified their rules to specifically allow flavoring on March 6, 2008. The Oklahoma Board of Pharmacy established a flavoring policy on September 22, 2009. The Connecticut General Assembly established a law allowing flavoring on July 2, 2011.

**GOAL:** To provide a guide to pharmacies and pharmacists regarding the flavoring of medications and describe the recordkeeping necessary to comply with existing rule.

**POLICY:**

1. A pharmacist may add flavoring agents, up to a maximum of five (5) percent (%) of the total volume, to a prescription at the request of a patient, the patient's care-giver, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented and maintain electronic or manual documentation of the flavoring agent and quantity added. Documentation of beyond-use-dates longer than fourteen days, including the flavoring agent and quantity added, shall be maintained by the pharmacy electronically or manually and made available to agents of the Board on request.
2. The addition of flavoring agents over five (5) percent (%) of the total volume to a prescription requires the permission of the prescriber and compliance with the requirements of the Current Good Compounding Practices rule (A.A.C. R4-23-410).
3. A pharmacist may not add flavoring to an over-the-counter product at the request of a patient or patient's care-giver unless the pharmacist first obtains a prescription for the over-the-counter product from the patient's medical practitioner.

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement.