Louisiana Board of Pharmacy **Policies & Procedures**

Title: Addition of Flavors to Medications Policy No. I.A.31

Approved: 11-13-2019 Revised:

1. The Board received a request from a representative of FlavoRx, a firm which manufactures flavoring agents used by pharmacists to customize prescription medications, to exempt the addition of flavoring agents to medications from the definition of compounding. The representative indicated his understanding that USP would include in the new update to *USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations* the guidance that the addition of flavoring agents would require compliance with the provisions of that chapter. It was suggested a requirement for compliance with USP standards might deter pharmacists from performing that service and might inhibit patient access to such services. The company requested the Board to promulgate a rule to exempt flavoring of commercially available liquid medications from the definition of compounding. The representative suggested limitations for the proposed rule such as requiring the flavoring agents to be nonallergenic and inert and for the flavoring agent not to exceed 5% of the drug product's total volume.

2. Following their review of the pharmacy law and rule, the Board determined a rule was not necessary and that an enforcement policy statement would be appropriate. The following motion was adopted after a unanimous vote in the affirmative.

> **Resolved**, that the Board adopt an enforcement policy, such that the addition of nonallergenic and inert flavoring agents to commercially available liquid oral products resulting in a change in the final product volume of less than 5% shall not require a prescriber's order or a full compounding log.