State of Utah
Utah Board of Pharmacy

Compounded Mouthwash Guidelines
Updated June 23, 2014

This document is intended to be an informal guide to pharmacies that dispense compounded mouthwashes used to treat mouth sores. Examples of compounded mouthwashes include those containing Antacid, Diphenhydramine, and Viscous Lidocaine (1:1:1) liquid ingredients. These preparations are classified as "moderate compounds" by the Utah Division of Occupational and Professional Licensing (DOPL) and the Utah Board of Pharmacy.

Under Utah Admin. Code R156-17b-614a (3), a pharmacy engaged in moderate compounding must comply with certain documentation, equipment, and training standards established in USP-NF 795. Some key provisions of USP-NF 795 are summarized in the paragraphs below; however, a pharmacy is responsible to review and comply with USP-NF 795 in its entirety. Legal advice should be obtained if necessary. USP-NF 795 governs in the case of any discrepancy between this guide and USP-NF 795. USP-NF 795 can be viewed online at www.usp.org.

- **Standard Operating Procedures.** The pharmacy must have a Standard Operating Procedure (SOP) on the premises to show how the compound will be made. This must include a description of the equipment and procedure use to make the compound.

- **Equipment.** In order to accurately measure ingredients of a Magic Mouthwash, graduated cylinders of appropriate size must be available in the pharmacy.

- **Good Compounding Practice.** The work area must be clean and orderly, including any measuring devices. Good personal hygiene must be followed and water must be distilled or purified.

- **Master Formulation Record.** Each compound must have a Master Formulation Record (MFR). Compounds must contain the following information:

    - name, strength, dosage form of the preparation;
    - calculations required to determined and verify quantities of components and doses of active pharmaceutical ingredients;
    - description of ingredients and their quantities;
    - compatibility and stability information, including references if appropriate;
    - equipment required to prepare preparation;
    - detailed mixing instructions;
    - sample labeling information including: generic name and quantity or concentration of each active ingredient, assigned Beyond Use Date

(BUD), storage conditions, and prescription or control number;
- packaging and storage requirements;
- description of final preparation; and
- quality control measures and expected results.

The MFR is a permanent record kept at the pharmacy. It is the reference used to make this version of the compound each time. If the compound is altered from the MFR, a new MFR must be created for the variation.

- **Compounding Record (CR).** This is the record for each individual compound made. The CR must contain the following information:

  - name, strength and dosage form of the preparation;
  - MFR reference for the preparation;
  - names and quantities of all components;
  - source, lot numbers and expiration dates of components;
  - total quantity compounded;
  - name of person(s) who prepared the preparation, who performed the quality control procedures, and who approved the preparation;
  - date of preparation;
  - assigned control or RX number;
  - assigned BUD;
  - duplicate label as described in the MFR;
  - description of final preparation;
  - results of quality control procedures; and
  - documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver.

  The CR may be kept either in a designated location, such as a binder, or attached to the hard copy of the prescription. It must be kept for as long as a hard copy is retained. Pharmacies may create a blank CR to fill in each time a Magic Mouthwash is made.

- **Naming the Compound.** Although the term Magic Mouthwash is commonly used, the prescription must be named with its active ingredients. For example, Lidocaine:diphenhydramine:antacid 1:1:1 mouthwash is an acceptable compound name. Abbreviations are acceptable if the abbreviation lends itself to only one drug.

- **Labeling.** The following statement must appear on all compounded preparations: this is a compounded preparation. Any appropriate auxiliary labels must be attached. For example: shake well, refrigerate.

- **Beyond Use Date (BUD).** The BUD is 30 days at room temperature for oral mucosal preparations, and 14 days refrigerated for oral preparations (swallowed). The BUD must appear on the prescription label.

- **Storage and Handling of Rx.** Any appropriate storage and handling instructions must be included with the prescription.

- **Training Documentation.** Documentation of training is required for all personnel involved in the making of the compound. Training must include familiarity with the SOP, calibration of scale (if appropriate), how the compound is made, and how the compound is documented. Training must be completed annually.

If a pharmacy making compounded mouthwash complies with standards established in Utah Admin. Code R156-17b-614a (3) and USP-NF 795, it would be in compliance with compounding standards established in Utah law.