**RESOLUTION 76-13**

**Title:** **Standard Concentrations for Compounded Oral Medications**

**Introduced by:** **Edward P. Washabaugh, III, MD, for the Washtenaw County Delegation**

**Original Author:** **Chris Dickinson, MD**

**Referred to:** **Reference Committee D**

**House Action:** **Adopted**

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**Whereas, many children are unable to swallow tablets or capsules and are written prescriptions for oral liquids, and**

**Whereas, oral liquids for many medications are not commercially available and the product must be compounded by a pharmacist, and**

**Whereas, an informal observation at the University of Michigan's C.S. Mott Children's Hospital demonstrated that approximately 60% of oral solutions that are utilized are not available commercially and require compounding, and**

**Whereas, currently there is no standardization of the final concentrations of these oral liquids, and as a result, there may be significant variation in the concentrations of compounded oral liquids and this can and does lead to medication errors, and**

**Whereas, a caregiver accustomed to administering a particular volume of medication to a child may not realize that the concentration of the drug compounded from a different pharmacy has changed and may administer the same volume of liquid, resulting in a potentially serious medication error, and**

**Whereas, the Joint Commission's Sentinel Alert on preventing pediatric medication errors noted that pediatric inpatients have approximately a three-fold increase in potential adverse drug events compared to adults, and**

**Whereas, the alert suggested limiting the number of concentrations and dose strengths of high-alert medications, and that compounded oral medications should have similar volume concentrations for inpatient and outpatient use, and**

**Whereas, on a national level, the Consumer Healthcare Products Association has reported that manufacturers have voluntarily established one standard concentration for single-ingredient liquid formulations of acetaminophen for children under twelve years of age, and this has led to the elimination of the infant acetaminophen concentration of 80mg/0.8 mL and adoption of an industry-wide standard concentration of 160 mg/5mL, and**

**Whereas, in addition, the Food and Drug Administration's Nonprescription Drug Advisory Committee and their Pediatric Advisory Committee have recommended enhanced labeling of all over-the-counter single-ingredient pediatric acetaminophen products, and while these actions promote patient safety by standardizing the concentration of single-ingredient liquid formulations of acetaminophen for pediatric**

**patients, it only addresses one of the many medications currently formulated as an oral liquid for pediatric patients, and**

**Whereas, despite initiatives to expand commercially available oral liquids for pediatric use, it is likely that compounded products will remain common practice for many years to come, and**

**Whereas, a similar problem regarding lack of standard concentrations has been documented with parenteral products, and**

**Whereas, the American Society of Health-System Pharmacists (ASHP), the ASHP Research and Education Foundation, the Institute for Safe Medication Practices (ISMP), the United States Pharmacopeia (USP), the Infusion Nurses Society, the Joint Commission, and the National Patient Safety Foundation (NPSF) held a summit in July 2008 on preventing patient harm and death from intravenous medication errors, and**

**Whereas, an important recommendation that resulted from this summit was to "implement standard infusion concentrations (dose, rate, units) based on local and national practices that are appropriate for most practice settings and allow exceptions if needed," and**

**Whereas, of equal importance is the development of widespread standard concentrations in the compounding of oral liquid medications to reduce the incidence of medication errors, and**

**Whereas, the University of Michigan Health System and College of Pharmacy, in collaboration with the Michigan Pharmacists Association (MPA) and the Food and Drug Administration (FDA), initiated a project attempting to standardize oral liquids compounded for pediatric use in the state of Michigan in order to improve patient safety, and**

**Whereas, the first step in this process was to characterize the current variation in compounding practices for oral liquids in pharmacies throughout the state, and**

**Whereas, of the 145 drugs surveyed, more than 50% had 3 or more "standard" concentrations, some medications had 5 or more concentrations, and one drug, metronidazole, was prepared in 9 different "standard" concentrations, and**

**Whereas, 8.6% of the respondents were aware of medication errors due to compounding errors; therefore be it**

**RESOLVED: That MSMS support single standard concentrations for compounded oral medications for pediatric patients; and be it further**

**RESOLVED: That MSMS ask the Michigan Department of Community Health to develop a standard concentration for all compounded medications given to children; and be it further**

**RESOLVED: That MSMS work with the Michigan Pharmacists Association to require all pharmacies to compound only the same strength for compounded oral medications.**

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**WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**