Regulation of Medication Compounding by State Boards of Pharmacy

Kelly A Reynolds, BA[1]; Sarah A Ibrahim, BA[2]; Kristin Hellquist, MS, CAE[2]; Emily Poon, PhD[2]; Murad Alam, MD, MSCI, MBA[2,4,5]

[1]University of Cincinnati College of Medicine, Cincinnati, OH [2]Department of Dermatology, Northwestern University, Feinberg School of Medicine, Chicago, IL; [3]American Society for Dermatologic Surgery Association, Rolling Meadows, IL; [4]Department of Otolaryngology, Northwestern University, Feinberg School of Medicine, Chicago, IL; [5]Department of Surgery, Northwestern University, Feinberg School of Medicine, Chicago, IL.

INTRODUCTION

- Medications are often tailored for individual use by employing a mixing process known as “compounding.”
- The compounding of medications is regulated at the state level by boards of pharmacy[1,2].
- The United States Pharmacopeia (USP) is a private organization, separate from state boards of pharmacy, that has developed compounding standards. The specific standards are USP General Chapters <795>, <797>, and <800>.
- USP compounding standards may or may not be enforced by each state board of pharmacy.

OBJECTIVE

To better understand the utilization of USP guidelines in the development of state compounding regulations.

METHODS

Study design: Open-ended questionnaire.

1. **Questionnaire respondents:** Executive directors and representatives of each state board of pharmacy, as well as Washington DC.
2. **Questionnaire content:** The survey questioned (1) whether USP standards are incorporated into compounding regulations, and (2) the process employed to incorporate the USP standards into regulations.
3. Individual responses were analyzed, and descriptive statistics were calculated from grouped thematic content.

RESULTS

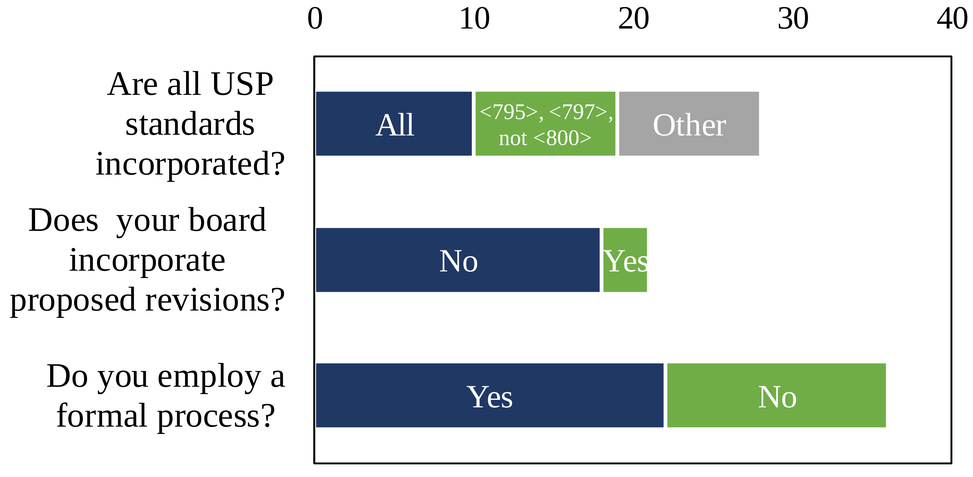
Figure 1: Number of states observing USP compounding standards

- The response rate was 71% (36/51).

Figure 2

- Twenty-eight respondents elaborated on which USP compounding standards are enforced. Ten respondents (36%) indicated that ‘all’ USP standards are enforced. Nine (32%) reported utilizing some standards, specifically ‘both <795> and <797>’, but not <800>. The rest of the respondents reported enforcing other variants of the standards (32%).
- Twenty-one responds elaborated on the incorporation of proposed USP standards. Eighteen respondents (86%) only incorporate finalized USP standards, whereas three (14%) also consider newly proposed USP chapters.
- Over half of respondents (22/36, 61%) employ a standardized process to aid the selection of specific USP standards. This process was most commonly described as a ‘formal rulemaking process’ (12/22, 55%).

Figure 2: Breakdown of survey responses



CONCLUSION

Since the passing of the Drug Quality and Security Act (DQSA)[3], state boards of pharmacy are increasingly relying on USP compounding standards in the development of their state compounding regulations.

- Pharmacy boards commonly select some standards, but not all, to be enforced, usually via a formalized process.
- Most states only consider finalized standards in the development of their regulations.
- Chapters <795> and <797> are more commonly utilized than <800>.

REFERENCES

1. The United States Pharmacopeial Convention. Compounding Standards. Available at: https://www.usp.org/compounding. Accessed June 24, 2019.
2. American Pharmacists Association. Frequently Asked Questions about Pharmaceutical Compounding. Available at: https://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding. Accessed February 1, 2019.
3. Heyward J, Padula W, Tierce JC, Alexander GC. The Value of U.S. Pharmacopeial Standards: A Review of the Literature. *Journal of Pharmaceutical Sciences.* 2018;107:2611-2617.