Role and Applicability of USP General Chapter <825> Related to Radiopharmaceuticals

Summary

On June 1, 2019, USP published a new standard on radiopharmaceuticals, General Chapter *<825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*, which describes practice and quality standards for radiopharmaceuticals. Consistent with the resolution of a recent appeal to this chapter, the Chemical Medicines Monographs 4 Expert Committee will soon determine a new official date for this chapter, granting at least another six-month implementation period. When General Chapter <825> is made official, it will be **informational** and not compendially applicable (see USP Compounding Appeals).

Compendial Applicability

USP General Chapters, monographs, and related programs are intended to help protect and improve the health of people, in part by facilitating access to high quality, safe, and beneficial medicines.

A general chapter numbered below 1000 becomes compendially applicable and thus is considered a required standard only when:

1. the chapter is referenced in a monograph;
2. the chapter is referenced in another General Chapter below 1000; or
3. the chapter is referenced in General Notices.

General Chapter <825> will not be compendially applicable because at this time it is not referenced in General Notices, a monograph, or another applicable general chapter numbered below <1000>. **This means that <825> is an informational chapter unless otherwise required by a regulatory body.**

Enforcement

State agencies (e.g., State Boards of Pharmacy), other regulators (e.g., Food and Drug Administration), and oversight organizations (e.g., The Joint Commission) may make their own determinations regarding the applicability and enforceability of <825> for entities within their jurisdiction. USP continues to engage and inform regulators, accreditation organizations, and stakeholders about the compendial status of the chapter. USP plays no role in enforcement.

USP Standards for Radiopharmaceuticals

The known risks associated with exposure to radiation present a compelling public health challenge. General Chapter <825> was developed based on public health need. Although General Chapter <797> contain some information on compounding radiopharmaceuticals, there was no public standard aimed specifically at radiation safety. The Chemical Medicines Monographs 4 Expert Committee sought to expand on the principles for compounding radiopharmaceuticals in <797> through the development of a new chapter, <825>.

- USP <825> FAQs

March 12, 2020