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USP Patient Safety CAPSLink™

PROVIDED BY THE USP CENTER FOR THE ADVANCEMENT OF PATIENT SAFETY

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USP Patient Safety CAPSLink™

This message has been sent to you as a service of the U.S. Pharmacopeia, Center for the Advancement of Patient Safety (CAPS). USP is a not-for-profit, non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies. CAPS is a component of USP's Patient Safety public health program. The USP Center for the Advancement of Patient Safety was created to encourage medication error reporting, conduct data analysis and research, develop educational programs, and propose standards, recommendations, and guidelines that ultimately improve the safety and quality of patient care.

Requirements for Compounding Sterile Preparations: Proposed Revisions to USP *General Chapter <797>*

The June 2005 issue of CAPSLink highlighted some of the patient safety issues related to the compounding of sterile pharmaceutical products for patient use. It also discussed the requirements of USP *General Chapter <797> Pharmaceutical Compounding—Sterile Preparations*, that became effective January 1, 2004 and may be enforced by the FDA, state boards of pharmacy, and accreditation organizations.

The process for revising <797> requirements has begun. USP wants input from healthcare practitioners and other interested parties regarding the proposed revisions. Historically, USP has solicited stakeholder input into the standards-setting process, which is open and transparent. This participatory approach strengthens the credibility and authority of USP standards.

USP is committed to broadly disseminating these proposed revisions to standards for sterile compounding to increase participation by healthcare practitioners and other interested parties in the revision/comment process. USP also is making the proposed revisions available online:

- [View proposed revisions to General Chapter <797> Pharmaceutical Compounding—Sterile Preparations \(with Markup\)](#)
- When interpreting revisions in the Markup version, please refer to the following editing notations:
 - Deletions are presented as a strike through
 - New content is double-spaced and presented in larger type

- Unchanged text from the official General Chapter <797> is single spaced and appears in 9-point type
- [View proposed revisions to General Chapter <797> Pharmaceutical Compounding—Sterile Preparations \(without Markup\)](#)
- [Submit your comments](#)

It is the ultimate responsibility of all personnel who prepare compounded sterile products to understand these fundamental practices and precautions, to develop and implement appropriate procedures, and to continually evaluate these procedures and the quality of the final products to prevent harm and fatality to patients who are treated with compounded sterile preparations.

90-minute webinars on Proposed Changes to USP <797>: A Dialogue with the USP

USP will be hosting a series of webinars with faculty speakers from the USP Sterile Compounding Expert Committee to publicize, review, and offer insight and rationale for the proposed changes to *USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations*.

These 90-minute webinars will:

- Highlight the significant changes to <797>
- Offer insights into the rationale for making the changes
- Provide a forum to pose questions about the proposed changes
- Describe the USP revision process and encourage submission of comments on the proposed changes

Cost: \$225 includes copy of *USP <797> Guidebook to Proposed Revisions: Pharmaceutical Compounding-Sterile Preparations* (\$79 value)

[CLICK HERE TO REGISTER](#)

DATES and TIMES: EXPERT SPEAKERS:

Wednesday June 7 9:00-10:30am [Eric Kastango, MBA and Mary Baker, Pharm.D.]

Wednesday June 7 1:00-2:30pm [Jim Wagner and Don Filibeck, Pharm.D.]

Wednesday June 14 1:00-2:30pm [Laura Thoma, Pharm.D. and Sam C. Augustine, Pharm.D.]

Tuesday June 20 9:00-10:30am [David Newton, Ph.D. and Mary Baker, Pharm.D.]

WHO SHOULD PARTICIPATE: Healthcare practitioners, particularly compounding professionals; regulatory/accrediting bodies; engineers, architects,

environmental quality certifiers; and vendors of cleanroom products and services.

FOR ADDITIONAL INFORMATION VISIT:

<http://www.usp.org/USPNF/pf/generalChapter797.html>

USP Medication Error Reporting Programs:



MEDMARX[®]—USP's comprehensive, Internet-accessible, anonymous medication errors reporting program, and quality improvement tool. The program facilitates productive and efficient documentation, tracking, trending, and prevention of medication errors.



Medication Errors Reporting (MER) Program—presented in cooperation with the Institute for Safe Medication Practices, this nationwide program makes it possible for health professionals to report medication errors confidentially and anonymously to USP.

Other USP patient safety resources:

- [MEDMARX Annual Data Summary reports](#)—provides readers with a wealth of information on reported error events including patterns in the types, causes, and level of harm associated with medication errors.
- [Understanding and Preventing Medication Errors: A Resource for Healthcare Practitioners](#)—a CD toolkit with practical guidelines, forms, and templates to help healthcare facilities improve error-reduction initiatives.
- [Advancing Patient Safety in U.S. Hospitals: Basic Strategies for Success](#)—a book in which hospitals share stories about how they reduced medication errors and promoted safer patient care.
- Medication Safety Pocket Reference—a pocket-sized reference booklet containing listings of similar drug names and dangerous abbreviations that could cause medication errors. Contact custsvc@usp.org and ask for item #3227702.
- Similar Drug Names Poster—a wall poster for easy reference listing look-alike and sound-alike drug names known to cause confusion and potential medication errors when handwritten or communicated verbally. Posters are packaged in quantities of 1 (item # 3728251) 10 (item # 3728252) and 50 (item # 3728253). Contact custsvc@usp.org and ask for the appropriate item number.

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