Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200, Horsham, PA 19044
www.ismp.org

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CONTACT: Renee Brehio, Media Relations, ISMP
704-831-8822, rbrehio@ismp.org

ISMP Releases Sterile Compounding Safety Guidelines

Horsham, Pa---New guidelines on sterile compounding from the Institute for Safe Medication Practices (ISMP) provide practitioners with input on best practices to implement. The guidelines are a result of ISMP's October 25-26, 2011 national sterile preparation compounding safety summit, which addressed frequent reports of critical intravenous (IV) compounding errors to national reporting programs, the scientific literature, and the lay press.

The completed document, "Proceedings from the ISMP Sterile Preparation Compounding Safety Summit: Guidelines for Safe Preparation of Sterile Compounds," can be found at: www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.pdf.

The summit was co-sponsored by the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) and the American Society of Health-System Pharmacists (ASHP). Participants included medication safety officers, IV safety technology experts, pharmacists, pharmacy technicians, nurses, healthcare consumers and representatives of the medical product vendor community. A representative from the U.S. Food and Drug Administration (FDA) as well as a representative of the United States Pharmacopeia (USP) Committee that is overseeing future revisions of USP Chapter <797> also were in attendance.

Summit participants comprehensively reviewed current methods used to prepare compounded sterile products, identified manual and automated safeguards to provide assurance that the proper preparation is dispensed, addressed barriers that might inhibit safe practices, and sought to identify and standardize critical quality control practices needed for preparing and verifying the quality and safety of the final compounded product.

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Core compounding processes and practices addressed in the guidelines include:

- Policies and Procedures for Compounding Sterile Preparations
- Order Entry and Verification
- Drug Storage
- Assembling Products and Supplies for Preparation
- Compounding
- Drug Conservation
- Preparation of Source/Bulk Containers
- Technology/Automation Used for Compounding CSPs
- IV Workflow Software
- Automated IV Compounding Devices
- Quality Control/Final Verification of Manually Prepared Product
- Product Labeling

ISMP is urging all healthcare organizations to review the guidelines and take appropriate action. To register for a free ISMP symposium on December 3 that will review IV admixture-related safety risks and the new guidelines, go to:www.ismp.org/pressroom/Symposium2012.asp

In addition, ISMP and ClinicalIQ, an organization headed by Eric Kastango and well respected for its expertise in sterile compounding and USP Chapter <797> education, are combining efforts to provide targeted onsite assessments of IV admixture production (see www.ismp.org/consult/oneDayRiskAssessment.pdf.) as well as simulation training.

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org

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