

Institute for Safe Medication Practices
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**ISMP Calls for Greater FDA Guidance and
Pharmacy Board Oversight of Sterile Compounding**

Horsham, Pa---The bacterial contamination of parenteral nutrition bags in six Alabama hospitals that likely led to patient deaths has caused the Institute for Safe Medication Practices (ISMP) to call for more oversight and guidance for compounding pharmacies.

A total of 19 patients were affected after receiving the contaminated parenteral nutrition, which was produced by a single compounding pharmacy. Genetic testing has confirmed that *Serratia marcescens* bacteria found in the pharmacy matched the bacteria in the patients' blood. Immediately after the outbreak was discovered, the pharmacy discontinued all production and recalled *all* of its compounded preparations. The investigation by health officials is ongoing.

ISMP believes that compounding pharmacies perform an important service, but there needs to be improved assurance that all necessary steps are followed when preparing sterile products. Therefore, better oversight and licensing and/or registration requirements should be required. Currently, sterile compounding activities must be in compliance with the United States Pharmacopeia (USP) Chapter <797>. Chapter <797> is enforceable by the Food and Drug Administration (FDA)—however, the agency defers to the individual states to perform inspections, and state boards of pharmacy vary in their adoption of USP's guidance for sterile compounding, with several not specifically requiring that the USP standard be followed.

In the April 7, 2011 issue of the *ISMP Medication Safety Alert!*[®] newsletter, ISMP issued the following recommendations to improve safety:

- **All state boards of pharmacy should expect compounding pharmacies to comply with all aspects of Chapter <797>, and survey these pharmacies regularly to enforce compliance.** To do this, state pharmacy boards must be provided with additional resources to adequately train and deploy surveyors to assess compliance.

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- **FDA should work collaboratively with the state boards of pharmacy to provide them with the necessary support and training to survey compounding pharmacies for compliance with Chapter <797>.** Compounding pharmacies that distribute sizeable quantities (to be defined by FDA) of preparations, and those operating interstate, should be registered with FDA and subject to periodic inspections. ISMP also is encouraging the FDA to move forward with plans to publish guidance documents on compounding practices and outline requirements for registration and inspection.

- **Pharmacies and pharmacists/technicians who compound sterile preparations, regardless of where they work, should know and comply with Chapter <797> to the fullest extent possible.** Whenever possible, staff should use commercially available ready-to-use products or start with sterile products if compounding sterile preparations. ISMP also recommends establishing an internal quality surveillance and review team to regularly monitor compounded preparations, the environment, compounding equipment, and personnel for compliance with key aspects of Chapter <797>.

An *ISMP Medication Safety Alert!* newsletter cover article that provides an in-depth analysis of Chapter 797 implementation and issues involved in sterile compounding is available at:

<http://www.ismp.org/Newsletters/acutecare/articles/20110407.asp>.

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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