

**ASHP** Section of INPATIENT CARE PRACTITIONERS

**ASHP LIVE WEBINAR: Compounding Outsourcing – Requirements and Emerging Safety Trends**

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*Angela Cassano, Pharm.D., BCPS (Moderator)*

Wednesday, November 2, 2011  
2:00 – 3:00 PM EDT

Planned by the ASHP Section of Inpatient Care Practitioners' Section Advisory Group on Medication Safety as a value added service for members.

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**ASHP** Section of INPATIENT CARE PRACTITIONERS

**Sterile Injectable Drug Shortages: Trends and Safety Concerns**

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**Disclosures**

Beverly Holcombe as a presenter for this continuing pharmacy education activity report no relevant financial relationships.

**ASHP**

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**A healthcare system pharmacy department provides parenteral nutrition (PN) to hospitalized neonates, pediatric patients and adult patients.**

**Over the last year the pharmacy has experienced difficulty obtaining a number of PN components due to shortages. Despite rationing and restrictions, the stock of some components will be soon be depleted. Other options for procuring PN components are being explored.**

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**American Hospital Association Drug Shortage Survey**

- 99%** experienced shortage
- 82%** delayed treatment
- 78%** reported rationing/restrictions
- 92%** reported increased drug costs
- 63%** reported strained relationships with staff

American Hospital Association Survey on Drug Shortages, June 2011. <http://www.aha.org/content/11/drugshortagesurvey>

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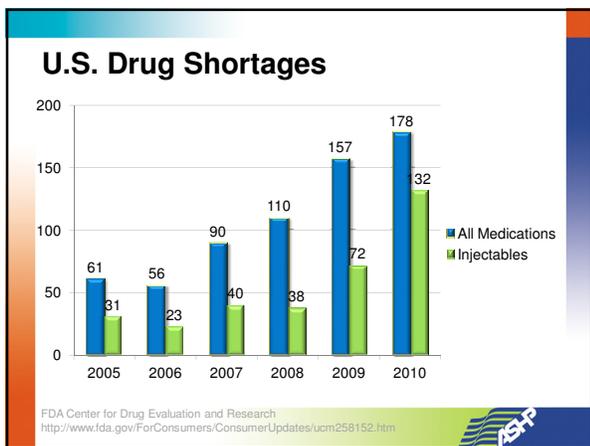
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### Parenteral Nutrition (PN) Shortages Since Spring 2010

- Amino Acids\*
- Ascorbic acid
- Calcium chloride
- Calcium gluconate
- Copper
- Cyanocobalamin
- IV fat emulsion
- L-cysteine
- Multivitamins
- Potassium acetate
- Potassium phosphate
- Selenium
- Sodium acetate
- Sodium chloride
- Sodium phosphate
- Trace elements
- Vitamin A
- Vitamin K
- Zinc

Resolved

ASHP Drug Shortages, accessed August 31, 2010



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### Effect of Drug Shortages on Patient Safety

- Institute for Safe Medication Practices Drug Shortages National Survey 2010
  - 1800 responses
  - 1000 errors and adverse patient outcomes due to shortages
    - 30% near miss
    - 25% reached patient
    - 20% patient harm
- Premier Drug Shortage Survey 2010
  - 311 pharmacy experts
  - Hospitals and other healthcare sites
  - 89% experienced shortages that may have caused a medication safety issue or error in patient care

ISMP. Drug shortages: National survey reveals high level of frustration, low level of safety. ISMP Medication Safety Alert! September 23, 2010;15(19):1-5.  
Chen C, et al. Navigating Drug Shortages in American Healthcare: A Premier healthcare alliance analysis. March 2011. <http://www.premier.com/pressroom/news/14940/usa/shortages.html>



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### Steps of Parenteral Nutrition Process



- Procurement
- Management
- Prescribing
- Order Review
- Compounding
- Administration
- Monitoring
- Patient Outcomes



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**Effect of Shortages on Patient Safety**  
Procurement

- No warning of shortages
- Increased labor and time searching market for sources of products; various vendors
- Purchase less desirable/unfamiliar products
- Purchasing outside normal channels (gray or black market, compounding facility)
- Stress on staff to find and purchase alternative products



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**Effect of Shortages on Patient Safety**  
Management

- Increased time and labor to develop and revise policies & procedures for alternative products, rationing measures, prescribing systems
- Difficult to keep all staff up-to-date on shortages, alternative products, changes in preparation, dispensing, etc.
- Strained relationships with providers, other health care staff, patients, families, etc.
- Time spent managing shortages vs. clinical care



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**Effect of Shortages on Patient Safety**  
Prescribing

- Increased prescribing errors
- Prescribe suboptimal therapy due to shortages or rationing
- Elect not to prescribe PN as unable to prevent/treat complications
- Unable to keep up with shortages, alternative products, rationing, restrictions, etc.
- Work arounds that may circumvent safety checks



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**Effect of Shortages on Patient Safety**

Order Review

- Difficulty keeping up-to-date on shortages, alternative products, etc.
- Work arounds may circumvent safety checks
- Increase number of prescribing errors
- Increase number of phone calls to correct or clarify orders
- Strained relationships with providers and health care colleagues



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**Effect of Shortages on Patient Safety**

Compounding & Dispensing

- Difficult/stressful trying to keep up-to-date on shortages, alternative products, rationing, etc.
- Work a rounds that circumvent safety checks
- Using unfamiliar products
- Using products similar in appearance
- Increased manipulation of products



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**Effect of Shortages on Patient Safety**

Compounding & Dispensing

- Prepare PN's without data to support stability, compatibility (Ca chloride, Mg chloride)
- Frequent changes in configuration of automated compounding device (ACD)
- Increase in manual additives when alternative products cannot be configured for ACD



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**Effect of Shortages on Patient Safety**

Patient Outcomes

- Vitamin deficiencies
- Deaths due to *Serratia*-contaminated PN when amino acids prepared from source powders and water
- Electrolyte, acid-base and fluid abnormalities
- Unable to provide neonates with adequate calcium and phosphorus for bone accretion due to lack of L-cysteine used to enhance solubility
- Hyperglycemia when increasing dextrose intake to meet energy needs when IV fat emulsion not available



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**Effect of Shortages on Patient Safety**

Patient Outcomes

- Increased catheter-related blood stream infections when ethanol locks unavailable
- Increased infection risk when accessing intravascular access to administer supplements
- Increased hospitalizations for electrolyte abnormalities or catheter-related infections
- Unable to transfer patients from acute care hospitals to SNF's or LTACH's due to increased cost of PN's



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**When the cupboard is bare . . .**

- **Purchase from gray market**
  - ❖ Increase expense; average increase 650%
  - ❖ Difficult to follow supply chain
  - ❖ Under investigation
- **Purchase from outsource compounding facilities**
  - ❖ Increase expense
  - ❖ Concerns for sterility, stability
- **Import products from foreign countries**



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**Summary**

- Drug shortages have significant financial, safety and emotional implications for the health care system and patients.
- PN product shortages pose safety risks throughout the entire PN process.
- Procurement of PN components from alternative sources should be carefully evaluated and assessed for safety.
- Providing PN therapy during product shortages requires vigilance and continuous assessment of the entire PN process to optimize patient care quality and avoid patient harm.



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 Section of  
INPATIENT CARE  
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**Compounding Outsourcing:  
Requirements and Emerging  
Safety Trends**

*Eric S. Kastango, MBA, RPh, FASHP*  
President/CEO  
Clinical IQ, LLC

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**Faculty**



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### Disclosures

Eric S. Kastango as a presenter for this continuing pharmacy education activity report no relevant financial relationships.



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### Learning Objectives

- Describe the history of compounding.
- Differentiate between pharmacy compounding practices and manufacturing.
- Summarize the regulatory quandary associated with outsourcing sterile compounding operations.
- Explain UPS <797> compounding requirements and their application to the inspection of outsourcing sterile compounding operations.



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### Disclaimer

"Although I am a member of the 2010-2015 USP Compounding Expert Committee, I am speaking today in my individual capacity and not as a member of the Committee or as a USP representative.

The views and opinions presented are entirely my own. They do not necessarily reflect the views of USP, nor should they be construed as an official explanation or interpretation of <797>."



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## History of Compounding

- **All states license pharmacists to compound**
  - ❖ States laws vs. Federalism
  - ❖ The federal government through the FDA is arguing that patient safety is in jeopardy
- **Schools of pharmacy do not often teach sterile compounding skills**
  - ❖ Only 1 in 6 graduates prepared for sterile work\*
- **Compounding is an essential component of pharmacy practice**

\*Helmus M, Alverson, SP, Morik-Tutor, MR. Instruction on compounded sterile preparations at U.S. schools of pharmacy. AJHP. Volume 64, Nov 1, 2007: 2267-74.



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## History of Compounding

- **Pharmacy compounding is simply the art and science of preparing customized medications for patients.**
- **Compounding is legal under state law.**
- **Non-patient specific compounding is permitted by some state boards of pharmacy in certain circumstances:**
  - ❖ Shared Services
  - ❖ Central Fill Operation
  - ❖ Outsourcing



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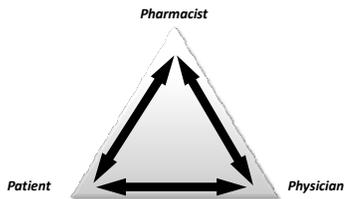
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## Pharmacy vs. Manufacturing



The Patient-Physician-Pharmacist triad (IRON TRIAD) is one of the critical elements of pharmacy that is **not** present in manufacturing.



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## History of Compounding

- The government (essentially FDA) argues that the compounding of drugs is in violation of the 1938 Food Drug and Cosmetic Act and that compounding was essentially legalized in 1997 with FDAMA.




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## Value of Responsible Compounding

- "...the government recognizes that traditional pharmacy compounding historically has and continues to serve an important public purpose - allowing physicians and pharmacists, working together, to develop customized therapies for patients for whom commercially manufactured drugs are not suitable for various medical reasons."

❖ U.S. Government response: Medical Center Pharmacy, et al. v. John Ashcroft, et al.




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## Comparison of Practitioner Compounding vs. Industrial Manufacturing

Attribute	Compounding	Manufacturing
Quantity, duration, and distribution of medication	small, short, and local (patient-MD-RPh triad)	large, long, and nationally to wholesalers and pharmacies
Approximate history	-from unrecorded BC era -A USP founding purpose	Since late 1800s
Main legal regulation	State Pharmacy Boards	FDA
Quality and performance testing	little or none	pre-, in-, and post-process
Therapeutic paradigm	matches drug to patient	matches patient to drug

United States Pharmacopeia (USP) Compounding Pharmacy Stakeholders Forum, August 21, 2001, USP Headquarters, Rockville, MD  
David W Newton, PhD, Chair of USP Parenteral Compounding Expert Committee




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### Level of Compliance

- There IS a statistically significant difference between the “red” and “green” states even as they are adjusted for the differences in the size and variability of the populations.
- There IS and between the “yellow” and “green” states even as they are adjusted for the differences in the size and variability of the populations.
- There is NOT a significant difference between the “yellow” and “red” states.



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### Outsourcing

- Outsourcing pharmacies may be required by state boards of pharmacy to register with the FDA as a manufacturer.
  - ❖ Several states do not permit licensed pharmacies to prepare and sell or dispense non-patient specific (NPS) doses to another pharmacy for future dispensing.



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### Outsourcing

(continued)

- States that permit NPS compounding typically require:
  - ❖ Registration/Notification to the State Board of Pharmacy
  - ❖ Clear delineation of responsibilities
  - ❖ Written contract
  - ❖ Shared computer system



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## Outsourcing

(continued)

- **Registration with the FDA is voluntary**
  - ❖ Pharmacy Manufacturing<sup>1</sup>
  - ❖ Regional Admixture Pharmacy<sup>1</sup>
- **Currently there is NO clear guidance from the FDA re: pharmacy compounding operations**
  - ❖ New guidance document expected by end of 2011
- **FDA expects these operations to comply with 21 CFR 210 and 211.**

<http://www.fda.gov/Drugs/Compliance/RegulatoryInformation/DrugRegistration/Listing/compounding2011.pdf>



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## What are the cGMPs?

- **A set of current, scientifically-sound methods, practices or principles that are implemented and documented during product development and production to ensure consistent manufacture of safe, pure and potent products.**
- **In place to prevent**
  - ❖ Sub-potency or super-potency
  - ❖ Contamination
  - ❖ Unpredictable safety or efficacy
  - ❖ Misbranding



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## Approved or Unapproved Drugs

- **FDA *approves* drugs, packaging, labeling and their marketing material (claims)**
- **FDA *inspects* facilities of manufacturers who manufacture approved drugs to ensure compliance with 21 CFR 210 and 211.**
  - ❖ The FDA *does not approve or certify* manufacturing operations
- **Outsourcing pharmacies are technically creating a “new drug entity”**



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### CSPs from Outsourcing Pharmacies

- These compounded doses have not been approved by the FDA and have not been evaluated for safety or efficiency.
- CSPs from FDA registered outsourcing pharmacies are not the same as drugs from “big pharma.”
- A compounded medication with a NDC number does not mean that the drug is approved.



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### Patient Safety Risks

- Some compounded/manufactured TPN additives and pharmacy bulk packages are unapproved, without formal FDA review of safety and efficacy.
- Components of compounded preparations may be at greater risk for economically-motivated adulteration- lack of component testing.
- Consider the relative lack of process validation and end-product testing.



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### US Food and Drug Administration

- In lieu of a detailed ANDA or NDA submission to the FDA, outsource vendors are expected to have the ability to link its CSPs to the specific patient to whom the CSPs are ultimately dispensed.\*
- The outsource vendor is responsible for assuring that the hospital have in place the necessary controls to link vendor prescription products, by lot, control numbers, or otherwise, to specific patients (to ensure that CSPs can be traced to patients in the event of a recall).

\*<http://www.fda.gov/CDER/Enforcement/Actions/Warnings/etes/2006/Letters/075928.htm>



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### Reflection Point



*"Doverai, no proveryai"  
"Trust but verify"  
Former President Ronald Reagan*



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### Contracting with Outsourcing Vendor

- **What are your and your hospital's responsibilities?**
  - ❖ Do know what is in your contract?
  - ❖ One contract detailed the following requirements:
    - "Customer shall be responsible for determining whether any compounded solution provided under this Vendor Agreement is clinically correct, appropriate or accurate for prescribing to any particular patient and for any particular disease or condition, and for determining and recording the individual patients that receive the medications."



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### Contracting with Outsourcing Vendor (continued)

- **Most if not all outsourcing pharmacies claim to meet or exceed <797> requirements**
  - ❖ Ask for a crosswalk on how the vendor matches up against USP Chapter <797>
  - ❖ Areas often misaligned:
    - Use of sterile alcohol
    - Use of sterile gloves
    - Sterility testing methods (direct inoculation vs. membrane filtration)
    - Speciation of CFUs



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## BUD and Sterility Testing

- In addition to “relevant” sections of 21 CFR 210 and 211, the FDA has required registered outsourcing pharmacies to comply with USP Chapter <797>
- Areas of interest relate to:
  - ❖ Sterility testing
  - ❖ Beyond-use dating



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## BUD and Sterility Testing

(continued)

- Since compounded drugs from outsource pharmacies have not been approved, how do you know if their assigned BUDs are valid?
  - ❖ You have the right to demand documentation and substantiation of stability and dating of drugs!
    - Offer to sign a non-disclosure agreement if necessary.
    - Stability data should be based on studies that utilized stability indicating methods vs. a simple drug strength test.



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## BUD and Sterility Testing

(continued)

- How does the vendor ensure that the drugs are sterile?
  - ❖ Per batch testing, process validation or some other means?
  - ❖ USP requires sterility testing of *each batch* of drug!



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## BUD and Sterility Testing

(continued)

- **How does the USP statement get used by the vendor?**
  - ❖ "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."




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## Quality of Ingredients

- **Insuring the quality of APIs (active pharmaceutical ingredients)**
  - ❖ National drug shortages are challenging the ability to source APIs.
- **Quality of Bulk Substances**
  - ❖ "Food" or "Un-graded" bulk substances have been used in TPN compounding.




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## Quality of Ingredients

(continue)

Grade of Chemical	Description
Technical (commercial)	Commercial or industrial quality, generally of indeterminate quality
CP (chemically pure)	More refined than technical grade, but still of unknown quality; only partial analytical information available
USP/NF*	Meets standards set by the USP/NF
FCC	Meets specifications of Food Chemical Codex
ACS reagent	High purity; meets specifications of the Reagent Chemicals Committee of the American Chemical Society
AR (analytical reagent)	Very high purity
HPLC	Very high purity; used in high pressure liquid chromatography
Spectroscopic grade	Very high purity
Primary standard**	Highest purity; used in standard solutions for analytical purposes

\* Minimal requirement    \*\* Ideal ingredient

Used With Permission By The International Journal Of Pharmaceutical Compounding, Allen, L.V., Jr. General Guidelines for the Use of Chemicals for Prescription Compounding, International Journal of Pharmaceutical Compounding 1:46, 1997




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### Quality of Ingredients (continued)

- **Where is your outsourcing vendor getting the drugs they are using?**
  - ❖ Commercially available?
    - Primary vendors or brokers?
  - ❖ Prepared from non-sterile ingredients?
    - Demand notification if APIs are compounded from non-sterile ingredients



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### Insist on the following information!

- Is *USP/NF* grade material used - review to current *USP-NF* specifications?
- Does the vendor buy from FDA-registered suppliers?
- Do they know the origin of supplier and manufacturer?
- Are labeling and accompanying certificate of analysis (COA) of API reviewed?
- Does the vendor determine the impact of component's bioburden on sterilization process ?
- Does the vendor quarantine components until tested/examined?
- Does the vendor randomly test finished drug products compounded from bulk ingredients?



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### Vendor Qualification

- **Conduct an onsite visit (preferably unannounced) of operation at least annually.**
- **Review the following information during audit:**
  - ❖ Summary of any regulatory inspection reports from SBOP or FDA
  - ❖ CAPA (corrective and preventive action) program, employee training records, sterility and stability data
  - ❖ Assurance and measurement of operational control and fitness
  - ❖ Observe personnel work practices and compare against vendor policy and procedure.



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### Summary

- State BOP laws form the foundation of compliance for pharmacies
- BUT pharmacies that voluntarily register with the FDA are required to comply with *additional* regulation which plainly stated means that:
  - ❖ There are comprehensive, detailed written SOPs;
  - ❖ There is ZERO gap between what SOP says and what staff actually do;
  - ❖ The written documentation demonstrates ZERO gap 100% of the time; and
  - ❖ The manufacturer demonstrates that their processes are "in control" through consistent and routine monitoring to identify and close gaps as well as identify potential changes to improving patient safety.
- Accrediting organizations such as TJC have no relevance to FDA operations.



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Section of  
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### Review of ASHP Guidelines on Outsourcing Sterile Compounding Services

*James R. Rinehart, RPh, MS, FASHP*  
Medication Safety Officer  
Indiana University Health

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### Disclosures

James Rinehart as the presenter for this continuing pharmacy education activity reports no relevant financial relationships.



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### Learning Objectives

1. Provide an overview of the ASHP Guidelines on Outsourcing Sterile Compounding Services
2. Describe key elements within the guidelines

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### Polling question #1

Prior to hearing of this webinar have you read the ASHP Guidelines on Outsourcing Sterile Compounding Services?

1. Yes
2. No

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### Polling question #2

Have you referred to the ASHP Guidelines on Outsourcing Sterile Compounding Services when considering the outsourcing of sterile compounded products?

1. Yes
2. No
3. Not applicable - I am not involved with these discussions
4. Not applicable - We have not considered outsourcing sterile product compounding

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### Publication citation of the guidelines

**ASHP Guidelines on Outsourcing Sterile Compounding Services**

*American Journal of Health-System Pharmacy*  
May 1, 2010 Volume 67, pages 757-765



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### Purpose of the guidelines

**To provide an overview of factors and processes for health care organizations to consider when exploring outsourcing of pharmacy sterile compounding.**

- ❖ Strategic planning
- ❖ Drafting contract provisions for compounding pharmacies
- ❖ Negotiating a compounding pharmacy contract
- ❖ Evaluating a compounding pharmacy's performance



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### Reasons to consider sterile product outsourcing

● **Operational**

- ❖ Limited technological resources to provide the desired services
- ❖ Financial constraints
- ❖ Consolidation of services across integrated health systems
- ❖ Efficiencies of preparation e.g., batch compounding



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**Reasons to consider sterile product outsourcing**

- **Operational**
  - ❖ Being able to provide specific compounded products that are outside of the routinely prepared products
  - ❖ Minimize facility remodeling costs e.g., to meet USP 797 requirements
  - ❖ Consistent product availability to meet patient needs



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**Reasons to consider sterile product outsourcing**

- **Staffing**
  - ❖ Limited staffing resources
  - ❖ Limited staff with compounding technological expertise
  - ❖ Complex or rarely compounded items
  - ❖ Staffing inefficiencies due to variable compounding workload



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**Reasons to consider sterile product outsourcing**

- **Competition among healthcare providers**
  - ❖ Being able to provide specialized products for unique patient needs



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### Reasons to consider sterile product outsourcing

- **Quality assurance**
  - ❖ Consistency with compounded items
  - ❖ Documented / validated beyond use dating
  - ❖ Assist with and ensure compliance with legal, regulatory and accreditation requirements



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### Reasons organizations **DO NOT** consider sterile product outsourcing

- **Operational**
  - ❖ Internal sterile preparation operations are cost effective, well managed , and efficient
  - ❖ Negative experiences with outsourcing
  - ❖ Concern about time delays, product interruptions



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### Reasons organizations **DO NOT** consider sterile product outsourcing

- **Operational**
  - ❖ Concern about loss of control over sterile preparation operations or expertise with sterile compounding
  - ❖ Concern about reversing the decision to outsource



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**Reasons organizations DO NOT consider sterile product outsourcing**

- **Staffing**
  - ❖ Concern about unacceptable staff reductions due to outsourcing



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**Reasons organizations DO NOT consider sterile product outsourcing**

- **Quality assurance**
  - ❖ Concern about conflicting values between the organization and compounding pharmacy
  - ❖ Concerns about qualifications and competencies of compounding pharmacy staff



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**Examples of services provided by compounding pharmacies**

- Implantable and external pump cartridges
- Cardioplegia solutions
- Ophthalmics
- Chemotherapy preparations
- Analgesic preparations



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**Contents of RFPs**

- Organizational demographics
- Process used to select the compounding pharmacy
- Organization's standard terms and conditions
- Specific services required by the organization



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**Contents of RFPs**

- Compounding pharmacy characteristics
  - ◆ Address, business hours, contact numbers
- Assurances the pharmacists are licensed as required
- Registration /verification that pharmacy technicians are in good standing on file if applicable



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**Contents of RFPs**

- Licensure, accreditation as applicable
- Proof of liability insurance
- Ability to review standard operating procedures
- Listing of services the compounding pharmacy can provide
- Listing of services the compounding pharmacy cannot provide and the reasons why the compounding pharmacy cannot provide them.



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### Contents of RFPs

- Examples of batch reports, quality control reports, stability documents
- Delivery cycles (routine, after hours and emergency)
- Listing of all fees and charges
- A copy of the standard or proposed contract
- The process for requesting new products from the compounding pharmacy

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### Other information to obtain from the compounding pharmacy

- Has the compounding pharmacy had liability lawsuits filed against it for preparations it compounded? (Description of the lawsuit, date, and outcome)
- Has the compounding pharmacy had formal recalls and how are recalls conducted?
- Other information regarding the delivery process e.g., severe weather.

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### Evaluating the RFPs

- Collaborative effort amongst disciplines
  - ✦ Involve as appropriate governing board, CEO, COO, CFO, P&T Committee, DON, legal counsel
- Products meet applicable state and federal labeling and packaging requirements
- If high risk products are prepared then applicable end product testing documentation to be provided.

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### Evaluating the RFPs

- Organization's and compounding pharmacy's policies on compounding practices
- Beyond use dating documentation support
- Compliance with rules and regulations
- Use of USP- NF ingredients or FDA approved products in accordance with the organization's intended use



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### Evaluating the RFPs

- Products are delivered in containers that ensure proper storage conditions
- Provide upon request batch records for any compounded sterile preparation
- How to handle special situations when a patient presents with the need for a compounded medication that neither the organization's pharmacy or the compounding pharmacy can prepare under the existing agreement



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### Contract negotiation considerations

- Review the proposal and clarify any unclear provisions
- Term and length of the agreement
- Billing and payment terms
- Prescription order communication methods (including considerations for controlled substances as applicable)



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### Contract negotiation considerations

- Recall processes
- Method for resolving preparation, delivery, and other performance issues
- Establish the right of the organization's pharmacy to inspect the compounding pharmacy with reasonable notice

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### Evaluation of the compounding pharmacy's performance

- Improved quality of patient care
- Responsiveness to organization's needs
- Improved pharmacy productivity and staff performance
- Reduced / controlled pharmacy costs without compromising patient care
- Effective interaction between compounding pharmacy staff and organization's pharmacy staff

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