Outside the Mix: Outsource Compounding in Rural Hospitals

Matthew Eberts, Pharm.D., MBA
Director of Pharmacy
Allegheny Health Network

Objectives
1. Demonstrate how CSP facilities are beneficial to small and rural hospitals.
2. Determining when the use of outsourcing CSP facilities is appropriate.
3. Discuss obstacles that small and rural hospitals might face with outsourcing CSP operations.

Canonsburg General Hospital
- Average Daily Census: 50
- Pharmacy FTE’s: 10
- Pharmacy Drug Budget: $1M

Canonsburg General Hospital
- IV Operations
  - Antibiotics “Snaps”
  - LVP
  - Pre-mixed TPN’s
  - SVP
  - 1 Batch/day

IV Operations
- CSP Production by hospital size
<table>
<thead>
<tr>
<th>Hospital Size</th>
<th>Number of Doses of CSPs Administered in Hospitals Mean (95% CI)</th>
<th>Number of Doses of Sterile-to-Sterile CSPs Administered in Hospitals Mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer than 50 Beds (n=82)</td>
<td>0.065 (0.316–1.252)</td>
<td>67 (10–124)</td>
</tr>
<tr>
<td>50–99 Beds (n=40)</td>
<td>18,000 (6,980–29,096)</td>
<td>Unable to project masculine due to 95% CI</td>
</tr>
<tr>
<td>100–299 Beds (n=69)</td>
<td>45,378 (33,823–56,952)</td>
<td>49,222 (33,658–56,785)</td>
</tr>
</tbody>
</table>

- 16% of hospitals < 50 beds doing non-stereile to sterile compounding

Source: American Society of Health-System Pharmacists

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Benefits of Outsourcing CSP’s

Drug Shortages

National Drug Shortages: New Shortages by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortages</td>
<td>120</td>
<td>73</td>
<td>120</td>
<td>207</td>
</tr>
</tbody>
</table>

Benefits of Outsourcing CSP’s

Longer Expiration Dating

- USP 797 Beyond Use Dating

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Room Temp</th>
<th>Refrigerator</th>
<th>Freezer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use</td>
<td>1 hour</td>
<td>1 hour</td>
<td>N/A</td>
</tr>
<tr>
<td>Low</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium</td>
<td>30 hours</td>
<td>15 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

• USP 71 Sterility Tests

Source: USP 797

Benefits of Outsourcing CSP’s

Limited Department Resources

- Physical Requirements
  - Cost for clean room in < 100 bed hospital over $100,000

- Human Resources
  - May 2013-Hospital Cut 9,000 jobs
  - Sequester cuts to Medicare-$9.9 Billion

Benefits of Outsourcing CSP’s

Ability to produce High Risk CSP

- Pain Syringes
- Electrolytes

Benefits of Outsourcing CSP’s

Other

- High amount of time required
- Need for specialized equipment
- Cost of producing in-house
- Need for ready to administer form of CSP
- Testing requirements
- Labeling requirements

What is the biggest reason your organization has decided to outsource CSP?

A. Drug Shortages
B. Longer Expiration Dating
C. High Risk Compounding
D. Other

Source: US News and World Report

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Determining when the use of outsourcing CSP facilities is appropriate
- New Cardiac Service Opening 9/2013
  - Key drug not available
    - Drug shortage
    - High Risk CSP

- Magnesium Bags
  - Wholesaler unable to provide on short notice
    - Drug shortage
    - Save Supply for Parenteral Nutrition
    - Longer Expiration Date

Injectable Narcotic
- PCA’s
- Drips
- IV Push

Case Study #1
- Outsource OR/Anesthesia Syringes
  - Situation: ABC Hospital is a 78 bed community hospital that provides care to adult patients in the community. The hospital has a steady and significant OR volume. In the past two years two incidents have occurred in the OR related to medications. Eighteen months ago a patient had unexplained issues with blood pressure during surgery and while the issue was resolved during the RCA it was found that the CRNA administered phenylephrine instead of the intended ondansetron at the end of surgery. One month ago during a routine regulatory survey, the surveyor found an unlabelled syringe in the OR and issued a citation. The organization CEO has charged the pharmacy director with solving this problem.
  - Background: Pharmacy currently provides a tray of medications primarily in vials to be used by anesthesia staff. Med tray is stored in a locked anesthesia cart.

Case Study #1
- Assessment: Pharmacy director has decided to provide medications in a more ready-to-use delivery system in the form of pre-filled syringes with commonly used medications at standard volumes and concentrations. The pharmacy director is now decided if this process should be in-sourced or out-sourced. The pharmacy director has put together a financial assessment and list pro/con list for these options.
  - Financial Assessment:

<table>
<thead>
<tr>
<th>Cost Driver</th>
<th>Insourcing</th>
<th>Outsourcing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Acquisition</td>
<td>$7,000</td>
<td>$11,500</td>
</tr>
<tr>
<td>Supply Acquisition</td>
<td>$650</td>
<td>$0</td>
</tr>
<tr>
<td>Waste</td>
<td>$800</td>
<td>$150</td>
</tr>
<tr>
<td>Labor</td>
<td>$9,200</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$13,650</td>
<td>$11,650</td>
</tr>
</tbody>
</table>

Recommendation-If you were the decision maker for this facility would you outsource?

A Yes
B No
Case Study #2

- Outsourcing Oxytocin bags for L&D service
  - **Situation:** XYZ General Hospital is a 120 bed community hospital that includes a Labor and Delivery service. The pharmacy department had a long time technician retire and due to budget changes in the hospital they are not able to get an FTE approved to replace the position. This brings the total technician FTE for the department to 7.3. The pharmacy director is looking for ways to decrease the workload on the current technician staff. The pharmacy director had a meeting with the outsourced CSP company which handles the pain syringes used in the outpatient pain clinic. The sales rep shared their catalog that included oxytocin bags which are used in the L&D area. In addition the medication is stored in the fridge on the unit that is not connected to the ADC. It is not always correctly decremented and results in stock outs.

- **Background:** XYZ General Hospital currently mixes these bags daily. The pharmacy makes the bag as 10units/ml in 500ml of NSS. The medication is given a 7 day BUD and stored in the fridge.

### Case Study #2

**Insourcing**
- Less Expensive
- More Waste
- Store in refrigerator
- More Labor
- Drug has been shorted by wholesaler couple times but no major shortage

**Outsourcing**
- More Expensive
- Decrease Waste-45 day expiration
- Can store at room temp, load in ADC
- Labor Savings
- Protection Against Shortage

### Recommendation

- **If you were the decision maker for this facility would you outsource?**
  - A: Yes
  - B: No

### How to Ensure the Safety of Outsourced CSP’s

**Initial Assessment**
- Regulatory Compliance
  - Where is company located?
- Quality and Safety Measures
- Medication Safety and Product Information
- Labeling Options
- Hazardous Drug Requirements
- Availability of reports and technical summaries
- On-site review

**On-Going Assessment**
- QA reports
- Hold outsourced CSP provider accountable
- Periodic Review
- Develop P/P for managing outsources CSP’s
- On-site visits

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**Financial Assessment:**

<table>
<thead>
<tr>
<th>Drug Acquisition Cost</th>
<th>Insourcing</th>
<th>Outsourcing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Acquisition Cost</td>
<td>$675</td>
<td>$6,000</td>
</tr>
<tr>
<td>Supply Acquisition Cost</td>
<td>$50</td>
<td>$0</td>
</tr>
<tr>
<td>Waste</td>
<td>$50</td>
<td>$0</td>
</tr>
<tr>
<td>Labor Cost</td>
<td>$1,040</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$1,815</td>
<td>$6,000</td>
</tr>
</tbody>
</table>
How to Ensure the Safety of Outsourced CSP’s

Contract Best Practices
- Define types of quality assurance activities and how frequently they will be available
- Specific quality indicators that will be monitored and shared
- Confidentiality statement
- Conditions for termination of contract
  - Avoid evergreen clause

Obstacles in Outsourcing CSP’s

Concerns over outsourced CSP’s
- Fungal meningitis outbreak
  - Case Count: 750
  - States: 20
  - Deaths: 64
- Since 1990-71 compounded products linked to hundreds of adverse drug events

Obstacles in Outsourcing CSP’s

Establishing contracts/agreements
- Commitments
- Contract approval process
- Lack of organizational expertise
- Regulatory agencies
  - Outsourced CSP-Hot topic during surveys
  - Contracting Services-Hot topic during surveys

Obstacles in Outsourcing CSP’s

Resources Required
- Resources to vet CSP facilities
- Legal Expertise
- Increase contracting
- Increase purchasing

Obstacles in Outsourcing CSP’s

Other Concerns
- Putting labor at risk
- Regulatory Compliance

Sources:
CDC
Sterile compounding tragedy is a symptom of a broken system on many levels. ISMP Medication Safety Alert. October 18, 2012
Conclusion

Canonsburg Model

Mixed In House
- Antibiotics-snaps
- Large Volume
- TPN-premixed
- Small Volume

Outsourced Products
- PCA
- Narcotic Drips
- OR Syringes

Questions?