Outsourcing Sterile Product Preparation: Using the ASHP Contractor Assessment Tool

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Topic areas

- History and Purpose
- Principles for Use
- Overview of evaluation criteria
Evolution of the assessment - 1

- Upward trend in outsourcing

Table 10. Preparation Activities That Are Either Partially or Completely Outsourced, Excluding Services Through a Contract Pharmacy Services Provider

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>% Hospitals Outsourcing Preparation Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient-Controlled Analgesia and Epidural Analgesia Preparations</td>
</tr>
<tr>
<td>All hospitals—2011</td>
<td>441</td>
</tr>
<tr>
<td>All hospitals—2008^1</td>
<td>270</td>
</tr>
<tr>
<td>All hospitals—2005^2</td>
<td>186</td>
</tr>
<tr>
<td>All hospitals—2002^a</td>
<td>137</td>
</tr>
</tbody>
</table>

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A While outsourcing is widespread, there has been a decline in the number of facilities using this approach.
Evolution of the assessment - 2

Emergence of new business model

- Large volumes of sterile injectables
  - High demand for repackaging
- Sold for subsequent dispensing and administration
- Extended beyond-use dating
- Off the shelf fulfillment
New outsourcing business model

- Unclear delineation of oversight: State (BoPs) vs and Federal (FDA) laws
  - Lack of uniform regulations in States
  - State resource constraints
  - Challenges to FDA authority
- USP 797 not intended for bulk manufacturing
- How to assure patients receive safely compounded preparations?
Evolution of the assessment - 3

ASHP Guidelines on Outsourcing Sterile Compounding Services

- Developed by stakeholder panel that included external experts, sterile compounding pharmacists and pharmacy leaders
- Focused on considerations for contracting with vendor
- Used to develop tool
There are choices...
Accessing the tool

http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool
Downloading

- Online version calculates scores for each section and saves data
- Can save changes and print
Principles for Use - 1

- Based on best understanding of (then) current regulations and standards
- A useful checklist; not a practice standard
- Use in tandem with site visits
- A group effort
- Not applicable to nuclear pharmacies
How to Use this Tool

Step 1. Minimum Requirements for a Vendor
A vendor simply meets the minimum requirements or they are disqualified.

Step 2. Vendor Assessment
The questions in this section are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering each question, the Assessment Tool provides a score for the vendor and a table to interpret the score.

Step 3. Vendor Comparison
The vendor scores and score legend provided in the Assessment Summary can be used to compare potential outsourcing vendors.
Minimum Standards

Step 1: Minimum Requirement Questions

Part 1: Regulatory Compliance

1. Does the outsourcer have a state pharmacy license available where the compounding center resides?
   - Yes
   - No

2. Is the outsourcer licensed to ship to my state?
   - Yes
   - No
   - N/A

3. If the outsourcer prepares a significant number of non patient-specific preparations (e.g., >5% of the outsourcer’s volume), is the outsourcer registered as a drug manufacturer with the FDA, if required?
   - Yes
   - No
   - N/A

4. If an FDA-approved product is commercially available (not on backorder), does the outsourcer compound the same drug formulation using non-sterile powders or other components?
   - Yes
   - No
Minimum standards - continued

17. If a positive media fill occurs, does the outsourcer institute corrective and preventive action?
   - Yes
   - No

18. Does the outsourcer provide customers with substantial evidence that supports extended expiration dating for compounded sterile preparations when BUD limits in USP <797> are exceeded?
   - Yes
   - No

19. Does the outsourcer perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists?
   - Yes
   - No

20. Does the outsourcer verify that staff members are complying with gowning, gloving, and glove-tip processes that are consistent with USP chapter <797> standards?
   - Yes
   - No
Vendor Assessment

- Part 1. **Regulatory compliance** – follows all relevant regulations and standards
- Part 2. **Quality and patient safety** – staff competency, QC
- Part 3. **Medication safety** – labeling, tamper-evident closure
- Part 4. **Service excellence** – scope of services, turnaround time, preparation information
Summary and Next Steps

- Implications of the Drug Quality and Safety Act
- Revision of ASHP guidelines/assessment tool
- “In-sourcing” tool