Conduct a Value Assessment for Insourcing vs Outsourcing TPNs

To accurately assess whether to outsource or compound TPNs in-house, it is important to consider the pros and cons of each approach in relation to the needs of the organization. Although cost always is a concern, additional factors to consider include physical space requirements, expected turnaround time, waste reduction, staffing concerns, and product quality.

Piedmont Hospital in Atlanta is a 488-bed, private, not-for-profit, tertiary care hospital in Georgia and the flagship hospital of the five-facility Piedmont health care system. Piedmont contracts with an outsourced vendor for TPNs, using approximately 20-25 TPNs for adults and 5-10 TPNs for neonates each day at the Atlanta campus. When investigating the options for obtaining TPN, multiple issues were considered:

- **Space.** While sufficient, Piedmont’s pharmacy space is limited, and expanding our physical space was deemed cost-prohibitive. Outsourcing TPNs streamlines pharmacy operations and allows us to appropriate space in the pharmacy and cleanroom for other purposes.
- **Staffing.** Meeting our daily TPN needs via in-house compounding would have required additional FTEs, which was not an option at the time the decision was made. By outsourcing TPN compounding, we can assign staff to other important tasks.
- **Additional Equipment.** Compounding TPNs for a hospital of this size requires the use of compounding technology, as well as sterile sets that must be routinely replaced. Consider the cost of purchasing these sets in relation to TPN compounding volume when comparing in-house vs outsourced compounding costs.
- **Drug Shortages.** Ongoing drug shortages, many of which affect nutrition products, may impact the decision to outsource TPNs. Due to their high volume purchasing power, outsourcing vendors often have better access to medications on shortage.
- **Quality Assurance.** Clearly, quality and safety are top considerations. Our outsourcing vendor does frequent, extensive testing that is well beyond our in-house capabilities, including weekly particle counts, bioburden testing, and fingertip testing. They also provide a quarterly quality assurance report that is readily retrievable.
- **Alternate Products.** Another option is purchasing commercially available premixed nutritional products, which can be a cost-effective solution. Any decision about sourcing TPNs should include an assessment of these products. Piedmont Hospital periodically examines premixed nutritional products, as well as the clinical literature associated with them.
- **Cost.** In today’s hospital environment, cost always is a factor in medication purchasing decisions. Because we require a relatively large quantity of TPNs, the health system is able to take advantage of volume pricing. After a quick glance, producing TPN in-house may appear more cost-effective than outsourcing; however, factoring in cost and quality requirements made it clear that outsourcing was the best fit for our organization.

Choose an Outsourced Vendor

The first step in choosing a vendor is verifying the vendor’s licensure status. While registration with the FDA as a 503B compounding pharmacy is still voluntary, 503B registration should be the starting point for inclusion in any analysis. After confirming FDA registration, any decision must take state law into consideration. Licensure became an issue at our hospital recently when we considered engaging a new compounding vendor; because the vendor was not licensed in our state, we could not move forward.

To evaluate an outsourcing vendor, consider the vendor’s reputation, its ability to meet daily TPN needs in a timely manner, reporting capacity, and its internal quality control procedures. Piedmont’s physicians and pharmacists write TPN orders in the morning, and the vendor delivers the medications twice daily. Be sure to choose a vendor that is centrally located to ensure prompt delivery. One question to ask when evaluating compounding pharmacies is whether the pharmacy compounds sterile products from non-sterile sources. Due to reported problems with some of these products, our policy is to avoid them. To assess the vendor’s reporting capability, request samples of their quality assurance reports.

Investigate the vendor’s compounding practices with a site visit. Factors to consider include their rigor of compliance with rules related to sterility, training and assessment of personnel, and their willingness to discuss the results of FDA inspections. The vendor we chose invited us to their facility to evaluate their practices. Upon visiting, we were impressed by their level of commitment to, and compliance with, USP <797>.

Contracting is another important consideration. Typically, the vendor proposes a standard contract specifying the services they will provide, including delivery times (eg, overnight or 2 business days); the reports they will provide, along with the frequency and method; and their quality assurance measures. Some TPN vendors email quarterly reports, while others provide online access to quality data.

Be sure to adjust the contract as necessary to suit the needs of your organization. Also, it is prudent to have the hospital’s legal department review the contract prior to signing. The contract should address quality considerations and service level expectations, which are standard in most contracts. Each health system’s legal counsel may have specific requirements regarding liability and indemnity. For TPNs or any other patient-specific compounding, the agreement must address the fact that HIPAA-protected health information is being exchanged, and that a strategy exists for protecting this information.

Maintaining ongoing communication between the organization and the vendor is necessary to ensure appropriate oversight of the vendor’s compounding operations. Moreover, access to the vendor’s quality reports assists in documenting vendor oversight. During an audit, regulatory bodies, such as The Joint Commission and DNV, may want to review quality reports.
Consider Establishing a System-wide Compounding Pharmacy

In certain situations, TPNs can be produced in-house with great efficiency. For example, a large health system may be equipped to create an in-system compounding service for compounding most drugs used within the system, including TPNs. For this arrangement to work, a health system must be able to replicate fully the compounding practices of a 503B compounding pharmacy. To pursue this approach, begin by evaluating what additional quality testing will be required, as well as the cost and time required for this testing.

Applicable state laws also must be examined to guide decision-making. For example, does state law permit one hospital to compound medications for use by other facilities within the system under their hospital pharmacy license, or is it necessary to open a separate pharmacy or obtain a wholesaler license? If this approach is feasible, and the volume of TPNs required is sufficient to support such a centralized compounding service, then insourcing may be a viable option.

WHERE TO FIND

Outsourced Compounding Services

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<tr>
<th>Suppliers</th>
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<tr>
<td>AnazaoHealth Corporation</td>
<td>LDT Health Solutions, Inc</td>
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<tr>
<td>Cantrell Drug Company</td>
<td>Medistat</td>
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<tr>
<td>CAPS (A B. Braun Company)</td>
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<td>Healix, Inc</td>
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