



Evaluating Outsourced Compounding

There are many factors that figure into the decision to outsource compounded products. Making the right call is a highly complex decision for pharmacy directors, as it extends well beyond the question of whether outsourcing will simply cost less than keeping the process in-house. Rather, the goal in outsourcing should be to determine the mix of products that works best for your particular operation. The various product types available, including ready-to-use, outsourced, and in-

goal for utilizing outsourcing. In our case, the goal was to take time out of the compounding and dispensing processes. We were looking for a solution that would save us time, allowing our pharmacists to be more involved in clinical activities. Outsourcing is not the only answer to this common challenge. It is important to consider other solutions, in addition to outsourcing, to achieve the most economical processes. Alternate products from different suppliers should be reviewed as well as the possibility of replacing certain products altogether and instituting new systems.

There are certain products we always try to outsource, such as large volume solutions containing oxytocin, premixed epidural solutions, high-volume IV piggybacks, critical drips when possible, and PCA pump syringes. Not only is the compounding of these products very labor-intensive, but more importantly, the process can be very time-interruptive. These products often are ordered as STAT or ASAP and require a fast turnaround. The cost to outsource some of these products may not always be less than the actual time and cost to compound them in-house, however, I am often forced to spend that time and money when the department is least able to do so. For example, when a critical drip is ordered, stopping what we are doing to prepare the needed product is often difficult. Furthermore, staffing our third shift to always have someone available for this compounding is not a good use of our resources. By outsourcing these products on a consistent basis, there is more control over the allocation of staff time.



Photo courtesy of PharMEDium

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house compounded products, each fill a need. Because there are many hidden costs involved in compounding, ranging from supply costs and wastage to available staff time, it is important to fully understand the total costs before making a decision.

Establishing Goals

Yuma Regional Medical Center is a 333-bed acute care facility in Yuma, Arizona, with modern facilities that include a Women and Children Services Center and a Level II neonatal ICU. The facility also boasts a cardiopulmonary care unit, a cancer center and a freestanding outpatient surgery center. Our pharmacy department is staffed with 28 full-time employees, including 13 pharmacists and 15 pharmacy technicians.

When deciding what products to outsource, the first step is to establish a

Cost Evaluation

Conducting a cost analysis of each product being considered for outsourcing is a key step. For example, with diltiazem drips, we analyzed the cost of the drug, bag, syringe and needle. We estimated the time required to compound it in-house and considered that staff may not be readily available at the time compounding was required. We compared this against the cost of outsourcing the product and made our determination based on whether the price difference favored outsourcing or if the cost was something I was willing to pay to accrue time-savings during peak work times or low staffing times. Volume is also a consideration in price comparisons; justifying a more expensive outsourced product for high volume items is often more difficult than for key products we use less often.



Cover Story

Establishing a price difference percentage point at which it makes sense to purchase an outsourced product is not an approach I would recommend. Rather, each product under consideration for outsourcing must be evaluated on its own merits, including how outsourcing will affect your control over staff allocation.

Bar Coding and Labeling

Another consideration, the quality of bar codes and labels, can favor outsourced products. For example, when you purchase a pre-mixed product, the NDC code on that product represents the combination product, making inventory and charge control much easier. When you compound these products in-house, the bar code has to cover the combination of drugs included within the end product. Many of the current pharmacy systems do not have a method to provide bar codes at all. Of course, the flip side of this argument is that by compounding in-house you are not limited to just the products and concentrations that are available from outsource vendors.

If your facility is performing bar coded medication administration (or planning to do so in the near future), it is important to evaluate the outsourcer's bar coding capabilities before making a final decision. Some vendors offer a variety of bar code options, while others have more limited capabilities. Also, consider that your outsourcing partner must be able to provide a label that meets the needs of both pharmacy and nursing staff. Have the vendors under consideration submit samples for your nursing and pharmacy staff to review.

Quality Issues & Reporting

Generally speaking, outsourced products meet a high quality standard. This is because outsourcers often develop products in a more controlled environment than current hospital pharmacy practice, and as a result, the likelihood for error appears to be greatly reduced. In the hospital pharmacy, the staff's compounding responsibilities are just one of many other tasks they are responsible for. At a compounding facility, the staff person is responsible for completing a single process in a defined time frame. Nonetheless, the risk of contamination exists in any compounding practice.



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Photos courtesy of PharmMEDium

The value of quality reports depends on whether you are outsourcing patient-specific or non-patient specific products. For patient-specific products, the quality reports will be very similar to those in your own pharmacy; you probably won't see a significant improvement. The quality control records for non-patient specific products, however, should provide much more in-depth data, such as compounding logs, traceable lot numbers, and clearly defined "do not use after" times and dating.

Addressing <797> Issues

USP <797> raised the bar for all hospitals. In the past, there were many hospitals that quite frankly did not do a very good job of maintaining a clean environment and performing the testing and training necessary to support sterile compounding. USP <797> established standard practices and requirements throughout the compounding process, from prescribing how to gown and glove and how to clean the compounding

areas and laminar flow hoods, to determining what must be monitored and how often. Achieving USP <797> compliance should improve a hospital's overall compounding processes and result in fewer problems with compounded products. Of course, achieving compliance has a cost ascribed to it. Staff must be sufficiently trained and dedicated to cleanroom policy and procedures, for example, and all training and cleaning processes must be monitored and documented. All of this takes time and available equipment in addition to a proper environment. Meeting USP <797> requirements may be an added cost to consider when comparing outsourcing costs, particularly if you are facing staffing constraints or require cleanroom modifications.

Inventory Management

At Yuma, we are highly automated and use a perpetual inventory system that works quite well. In our experience, inventory management is much simpler with outsourced products versus those compounded in-house. When purchasing from an outsourcer, especially a larger player, I am confident the product will be available when I need it in the form I expect. To compound in-house, I have to be sure I not only have the products available, but I also need to have the bags, bottles, and other compounding supplies on-hand. Most importantly, I need to have the time (i.e. available staff) to do the compounding when I need it.

In addition, because of USP <797> guidelines, I am limited in the number of products I can make ahead of time and store for later use. To do so requires a significant amount of documentation and raises concerns about product waste. Because outsourced products generally have longer beyond use dating (BUD), there is more order flexibility. Product waste issues are less of a concern as is the need to staff around the clock to manage compounding needs.

The ideal approach – from a safety, as well as an inventory and resource management perspective – would be to purchase all IV products in a ready-to-use format. Until that option becomes reality, working with an outsource partner provides many similar benefits.



Survey Preparation

While Yuma is currently a CMS-certified hospital only, we were certified by The Joint Commission two years ago. Interestingly, the first question the inspector asked in pharmacy was, “Who made your large volume IVs containing oxytocin: nurses, pharmacy, or is it outsourced?” The inspector followed up with nursing, asking them how they would make an oxytocin IV. The inspector was satisfied when we shared our documentation and when nursing showed that their practice was to retrieve the pre-mixed oxytocin from the automated dispensing cabinet. It is highly likely that a survey will include questions about outsourced products, therefore it is key that your documentation always be up-to-date.

Choosing an Outsourcer

The first step in the process of choosing an outsource provider is a due diligence review of the company. Examine their history of product availability and on-time delivery. Have they experienced shortages and how have those been handled? How often have they had product recalls? Have they faced any regulatory actions?

Once you determine a company to be both acceptable and reliable, you should review the depth of their product line. I am a big proponent of streamlining systems within pharmacy. In my opinion, it is not advisable to provide a product (or similar products) in multiple delivery systems, such as supplying the first dose of a product as frozen or premix, the next dose as a vial admixture system, and another as a syringe or other bag-based system. A lack of standardization in the delivery system can lead to confusion in the patient care area and result in medication errors at the time of administration. Nursing needs to know where the product is stored, how to use it properly, be familiar with the labeling, and have an overall confidence in the delivery system. Similarly, I prefer the consistency of providing a product from a single source, not purchasing some concentrations pre-mixed, outsourcing others, while also compounding some in-house. Therefore it is key to determine the depth of the outsourcers’ available product line. Ordering multiple products from the same supplier ensures nursing will develop a familiarity with the labeling and pharmacy can take advantage of streamlined ordering and inventory management processes.

Resource Allocation

In an ideal world, where staffing, financial, and space constraints are not factors, compounding all products in-house may be the best choice. However, we are all faced with resource constraints that must factor into decisions to get the most efficiency out of our systems. Our primary decision point for moving to outsourcing is staffing; I want our pharmacists working on clinical activities, not serving as high-priced checkers of technician’s work.

Our pharmacists serve in a decentralized role and are valued members of the clinical staff. On average, 85–90% of all interventions are pharmacist-driven. Rather than primarily managing distribution processes, our pharmacists are serving very important clinical roles. To support this approach, 60–70% of our compounded IV product inventory is currently sourced as pre-mixes from the manufacturers or supplied by an outsourced provider. This is a percentage we would like to increase to further improve our efficiency. However, premixed or outsourced products cannot totally replace compounding in hospital pharmacy practice, especially given the short stability of some products and the need for very patient-specific dosing.

Of course when the inventory relies on such a high percentage of com-

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pounded products from outside suppliers, a back-up plan to handle product shortages, delays, or other emergencies is also necessary. In our case, we are nearly 180 miles from the next nearest, large acute care hospital, so planning for shortages has always been important for us. We make a point to order sufficient inventory to withstand short-term outages or dosage changes.

Final Recommendations

Be sure you are outsourcing for the right reason; outsource because you are going to utilize the time saved for more efficient activities, such as clinical interventions. Do not outsource simply because a product is available. Rather, do your homework so you can quantify how much product you are using and determine your total production costs, including staff time. A flowchart of your processes or simply collecting data on a simple stroke sheet of your compounding activities for a few weeks should give you sufficient data to analyze. To better understand your actual practices, be sure to do this analysis with your own cost data; do not accept an outside analysis. Flexibility is key, as you will need to continually monitor your inventory, usage patterns, and costs and then make adjustments based on these constantly changing factors.

Outsourcing just one product may not make sense, as it will not significantly affect staff assignments, training, equipment needed, etc. However, as additional products are outsourced, the incremental savings will accrue and the resulting timesavings will allow you to refocus your staff on other activities. Like automation technology, outsourcing does not need to be a replacement for your current system, rather it should be a step toward improving the overall performance of your system. ■

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WHERE TO FIND: Outsourced Compounding Services

Vendor	Reader Service Number
AnazaoHealth Corp	12
CAPS/B.Braun Medical Inc	13
LDT Health Solutions, Inc	14
PharMEDium Services, LLC	16
Safecor Health, LLC	17