Consolidation of Pharmacy Compounding Services: *An Alternative to Outsourcing*

Kate Douglass, CCNS, MS, AOCN, CRNI
Coram Healthcare Corporation
Totowa, New Jersey

Eric S. Kastango, RPh
Clinical IQ, LLC
Madison, New Jersey

Today's healthcare environment is changing dramatically as a result of reduced reimbursement, point-of-care shifts from inpatient to outpatient treatment, shorter lengths of stay, and shorter authorized episodes of home healthcare and home infusion service. More organizations are focusing on the identification of their core competencies, and an increase in the outsourcing of noncore functions has resulted. Hospital and home healthcare providers are challenged to manage the clinical and economic effects of rapid and significant changes, which are driving many providers into buyouts and mergers. In the 1990s, the home healthcare industry experienced significant consolidation. Today, only a handful of national providers of home healthcare providers exists, but 5 five years ago, there were many more.

The mergers of hospitals and those of hospital systems have outpaced all other industry mergers. In 1996, more than 760 hospitals (an increase of more than 5% since 1995) announced plans of merger or acquisition.[1] Almost 40% of the nonfederal hospitals in the nation were involved in merger or acquisition from 1994 to 1997.[2] Consolidation has occurred in the home healthcare market as well. From 1997 to 1999, there were 298 fewer hospital-based home healthcare agencies, and there were 2697 fewer Medicare-certified home healthcare agencies nationally.[3] The number of mergers of other healthcare providers and related entities such as physician groups, nursing homes, health maintenance organizations, drug companies, and vendors is also increasing. Because of hospital mergers and consolidations, the number of empty hospital beds has risen to levels of 50%.[4]

When planning, implementation, and overseeing operations are part of the process of merging, many potential benefits can be realized. Efforts to consolidate services within an organization or a strategic partnering between organizations can achieve many of the same benefits. According to Carolyn Merriman, president of Corporate Health Group in Omaha, Nebraska, those advantages include internal benefits (to operations and fiscal components) and external benefits (which are customer driven).[5]

Internal benefits include:

- Increased economies of scale. The Balanced Budget Act has had a significant short-term negative effect on the financial status of healthcare organizations in the United States. As a result of pressure to improve profit, there is now a mandate to strive relentlessly to deliver more services more efficiently and with fewer resources.
- Decreased expenses as a result of opportunities for aggregate group purchasing and debt consolidation.
- Increased access to capital, investments, and benefits.
- Potential to improve the provision and use of human and financial resources.
- Competitive marketing advantages resulting from excellence in delivered care.

External benefits include:

- Increased customer satisfaction from focused services delivered in an optimal manner.
- Increased market share from satisfied customers.

In addition to the number of empty hospital beds, duplicate services are often provided by a hospital in the areas of finance, laundry, clinical laboratory, medical or diagnostic procedures, utilization review, performance improvement, and pharmacy. For more than two decades, those areas have been consolidated successfully as shared hospital services, which are performed at one location and delivered to multiple locations.[6-8] Operational redundancies in areas such as cognitive or production pharmacy activities, purchasing, billing, pump maintenance, and delivery of products and/or services often occur in national or regional home infusion providers with multiple locations.

These areas of duplication provide a variety of prospects for entrepreneurial managers who can flourish in the process of consolidation. Creative thinkers can seize the opportunity to redefine traditional paradigms associated with the delivery of products and services. The key to capitalizing on this opportunity is in the ability of managers to streamline and simplify redundant systems and to enhance the coordination of capital and human resources. Another factor critical to success is that of identifying and managing the "cultural differences" among merging businesses or facilities that are consolidating various services. Overlooking the sensitivities of staff members in merging organizations can cause an otherwise successful consolidation to fail. However, the prospect of enhancing quality while increasing efficiency and reducing costs is tantalizing.

Models of Consolidation of Pharmacy Compounding Services

In the remainder of this article, strategies for regionalizing pharmacy compounding services are presented. Successful consolidation of pharmacy compounding services (which is much like the strategy used to outsource services successfully[9]) depends on the development of a detailed plan and on choosing a model that is aligned with the goals and mission of the organization. During and after a merger, new groups of people must work together to provide services. Relationship management can be challenging, and program objectives, goals, and operational issues must be methodically and proactively identified. All parties must have opportunities to express their concerns, expertise, and desired outcome. Participating in the planning of the consolidation furthers confidence among team members as well as an understanding of the reasons for the merger.

As the stress and complexity of today's market increase, business leaders are identifying new approaches to regionalization. The following three models for the consolidation of pharmacy admixture services have been used successfully in the United States. The best model can be selected according to its alignment with the organizational mission and goals and with the participants' ability to manage change.

Model 1. Vertical integration of hospital or home infusion pharmacy admixture services within an organization.

This model provides for the consolidation of all or some pharmacy compounding services within an existing organizational structure. In the case of a regional hospital system, it may involve creating one large-scale operation that will provide service for its own and its affiliated hospital locations. The scope of services provided from a hospital hub location can include sterile-product preparation, unit-dose cart filling, purchasing, and the distribution of narcotics (depending on local and state pharmacy practice acts). The regionalization of compounding centers within specified geographic regions may be an option for the national home infusion company that serves multiple locations, each of which has a pharmacy. Because pharmacy services can be provided by phone within the home infusion model, pharmacy cognitive services (in addition to sterile-product preparations such as total parenteral nutrition, antibiotic, and intravenous immunoglobulin formulations) can be delivered from regional centers.

In April 1992, four affiliated health care facilities (three hospitals and one home healthcare agency), which are part of the Carilion Health System in Virginia, consolidated their inhouse sterile-product preparation services to an offsite dedicated compounding center. That center was dedicated to the preparation of hospital-based, sterile-product preparation needs and also offered the daily compounding of home healthcare preparations. From October 1992 to October 1994, staff at that center compounded almost 700,000 sterile-product preparations.

Advantages gained from that consolidation resulted in significant benefits. Physical plant space for the preparation of sterile-product preparations was increased, key staff at the healthcare facilities and the compounding center were retained, the instances of duplication of supplies and waste in the preparation of compounds were reduced, standardization of product ordering was achieved among the facilities, and the overall quality of services improved. The shared offsite compounding center was a successful undertaking that resulted in a savings of $437,000 over 21 months.[10]

Model 2. Integration of hospital pharmacy admixture services by establishing an alternate site location, which, though part of the hospital system, is managed as a separate entity apart from hospital pharmacy operations.

This model involves the horizontal integration of healthcare system resources. An alternate-site location is established or acquired and is run as a division of the healthcare system but is managed as a separate entity that is independent of hospital pharmacy operations. This organizational model exists at the MedStar Health System in Baltimore, Maryland, where staff at an offsite admixture pharmacy (extenCARE, Inc) are available to support the system's home healthcare program and to prepare and deliver patient-specific parenteral nutrition solutions and small-volume parenteral admixtures, antibiotics, and other therapeutic medications every day of the year to five area hospitals. The staff of extenCARE, Inc, have prepared more than 35,000 bags of total parenteral nutrition and 1,000,000 small-volume parenteral (SVP) doses since February 1998 (S. Weintraub, oral communication, November 2000). The operational focus of the sterile-product preparation pharmacy is based on systematic process control and uses operating policies and procedures that are modeled after the US Food and Drug Administration's Current Good Manufacturing Practices (cGMPs).

Model 3. Consolidation of hospital or home healthcare pharmacy admixture services via another entity that has entered into a joint venture or a general partnership.

The third model involves working with a third-party provider of sterile-product preparations. The focus on "best-of-class practices" is one of the advantages of working with a third-party provider. This model most closely resembles outsourcing but is defined by the services undergoing consolidation.

In 1995 and 1996, HILLMED Home Medical Systems of Ashland, Virginia, compared a hospital sterile-product preparation program with an alternate-site home healthcare pharmacy to determine the differences in compounding costs and in the frequency of errors in medication administration. The comparison indicated a statistically significant reduction in the frequency of medication errors of omission in addition to a cost savings in the hospital program during the first year of operation totaling more than $86,000.[11] Some of that reduction in cost was achieved by reassigning the hospital technician to performing sterile-product recycling, which involved reclaiming sterile products from the nursing units before medications had expired and reusing them.

This experiment has been continued. It demonstrates the opportunities for home healthcare pharmacy operations to expand their base of services and to identify other avenues of revenue.

Effective Cost Assessment

Before the implementation of any plan, all direct and indirect costs associated with a service targeted for consolidation must be identified and analyzed. The decision to proceed with consolidation should be made only when a careful, comprehensive cost analysis demonstrates that regionalization will very probably generate significant cost savings, will improve the efficiency of operation, and will not significantly affect quality or customer service. The cost analysis should include intradepartmental and extradepartmental considerations and long-term cost implications. Extradepartmental considerations can be determined by answering the following questions:

■ **Hospital-Related Effects**

Is the hospital using 8-hour or 12-hour total parenteral nutrition units versus 24-hour total parenteral nutrition units?

Must nursing staff alter the traditional times at which they hang 24-hour infusions?

Must physicians change the times at which they perform patient rounds because of reassigned cutoff times? Did cutoff times exist? If so, were they ever enforced by the pharmacy?

Must the lab require phlebotomists to draw blood earlier so that

results will be available to physicians at the times at which they need to write orders?

■ **Home-infusion related effects**

Must the hours of operation be extended to meet the demands of a hospital-based customer?

Are the medications for homecare patients prepared 24 to 48 hours before use so that the increased volume can be integrated into the daily operation without the addition of staff?

How will deliveries be made to patients?

Who will interact with physicians? Who will perform clinical monitoring?

Who will manage supplies?

Will the consolidation affect insurance billing?

Will preparing sterile-product preparations for other licensed pharmacies violate state or federal laws?

Will the labels be accurate and will they meet the requirements of the state Board of Pharmacy?

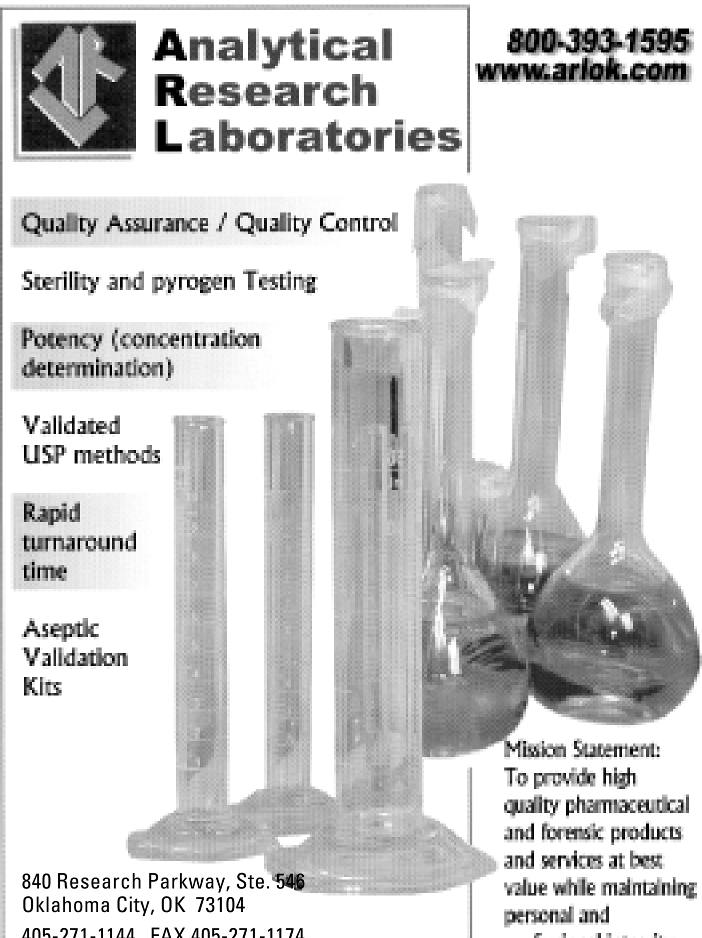
Will the compounding pharmacy have the appropriate medications and diluents?

■ **General effects of consolidation**

How will new admissions or "stat" changes be accommodated?

Will the new compounding facility be as good as the old one was?

Will there be more waste?



How will inventory control and purchasing be accomplished?

Even when consolidation occurs within an organization, the real and imagined concerns of the staff are significant. When the consolidation occurs as a result of another entity (either a different part of the parent company or an entirely new organization), turf issues can become more complex. All hospital-related issues must be considered if an entity that is within an organization but is run separately (such as a home infusion pharmacy that is part of a hospital-based home healthcare agency) is responsible for the hospital pharmacy compounding.

Although it might seem like a straightforward activity, a true baseline cost should be established to enable the comparison of costs before and after the consolidation. Having a baseline cost also helps to identify and establish break-even point projections, and it can be used to present the overall effect of pharmacy decisions on other healthcare departments in the system.

Several indirect costs within sterile-product preparation practice, such as waste management, equipment maintenance and recertification, employee training, didactic and skills-based competency of aseptic processing, routine aseptic technique validation, environmental and microbiologic monitoring, and inventory handling and carrying costs, are not routinely considered when inhouse expenses are calculated.

It might be thought that some indirect costs can be completely eliminated because they are not being performed or are of no value. Many organizations minimize the importance of validating aseptic technique by means of media fill (a method used to test an operator's aseptic technique through the manipulation of tryptic soy broth [a lab culture medium]), environmental monitoring, and rigorous skill-based competency evaluation because patient injury has rarely resulted from the failure of a pharmacy operation or activity. However, it is more likely that no formal indicators or monitors are used to detect deviations in product quality.

Even if monitoring agents are established, there are far too many variables beyond the control of the pharmacy to make identification of the causes of such problems possible.[12] However, several initiatives pertaining to pharmacy compounding practices are under way at state and federal levels. The American Society of Health-System Pharmacists (ASHP) recently reissued its guidelines on quality assurance for pharmacy-prepared sterile products. Those guidelines and other references such as *USP* chapter <1206> and the National Association of Boards of Pharmacy (NABP) model regulations, which are published as a series of regulations for improving the practice of pharmacy, enable pharmacists and technicians involved in sterile-product preparation to understand the risks to patients who receive ill-prepared products and to adhere to technically sound processes and techniques during sterile-product compounding.[13] Some states are significantly upgrading their requirements with regard to sterile-compounding practices.

Pursuing a consolidation strategy within a system that has an outside provider or uses multiple pharmacies would reduce or eliminate the need to make capital improvements (such as modifications to clean rooms, facilities, and equipment) to comply with new standards, such as evolving state Board of Pharmacy regulations, increased capacity needs, and/or modernization necessary for

adherence to the ASHP guidelines mentioned above. In a multisite healthcare system or a national home infusion company, those costs can be reduced easily by consolidating some operations to achieve economies of scale.

Plan the Work and Work the Plan

To ensure success, any project requires planning. An effective plan must clearly present overall objectives and action-plan strategies for each department. All departments, business activities, and staff affected by the consolidation must be identified. The implementation of the plan, criteria for success, and desired outcomes should be measurable and tactical (immediate results should be noted operationally and financially). Identifying key staff members who will champion and manage the plan is essential.

Employee support is a critical part of any successful plan. Communication, requests for input, ownership, honesty, and addressing the "what's in it for me" syndrome are very important. Having a clear plan that is understood and embraced by employees who feel a sense of ownership ensures success. Employees must have value-oriented, measurable vision to focus on during the process of change.[4]

Building a Solid Foundation

A significant amount of the work in any plan of consolidation involves business logistics. Without a solid financial foundation, the stability and function of the program are affected negatively. The components of a robust and stable program plan include:

■ **Establishing a project management team.**

Members of that team should include representatives from all functional departments. Those representatives can communicate and champion the program to their respective departments and can act as rumor-control agents.

■ **Focusing on the following activities.**

A clear definition of objectives, desired outcomes, and criteria for success.

Coordination of and communication with all departments (nursing, laboratories, pharmacy, medicine, purchasing, warehouse, finance, reimbursement).

An impact analysis prepared by representatives from the medical and nursing staffs and from departments such as utilization review, reimbursement, delivery of products and services, inventory, performance improvement and risk management, sales and marketing, and contracting, as well as those listed above.

■ **Developing conflict resolution and communication mechanisms.**

Effective methods of resolving conflict and communicating ensure the continuous improvement and refinement of processes and ultimately, the desired outcomes. All participants must know how to identify, address, and resolve undesired results without backstabbing or other unprofessional behaviors.

■ **Addressing therapy-related sterile-product preparation issues. The following issues should be considered carefully:**

Identification of specific sterile products involved; a phased approach should be used.

Standardization of components used in the sterile-product preparation process and standardized drug, dose, or diluent combinations and/or formulas.

Sterile-product order forms.

Order cutoff times.

Sterile-product hang times.

Sterile-product expiration dating.

Accommodation of custom preparations.

Final product label format per end-user specification and state Board of Pharmacy regulations.

Safety concerns and error reduction.

Mechanisms for new admissions and/or "stat" orders that are not on the normal schedule.

Delivery schedule (daily or other).

Inventory issues (consignments, drop-ship orders, other orders).

Marketing to internal and external customers.

■ **Integrating performance improvements into a new, consolidated system plan.**

■ **Creating contingency plans and alternatives to pharmaceutical needs for "after-hours" situations.**

■ **Identifying methods of order transmission.**

Use of methods that decrease or prevent the introduction of additional elements of risk (eg, fax versus electronic order entry).

Implementation of connectivity systems with sites of service, such as faxing written orders or the use of MOS (Baxter Clintec, Deerfield, Illinois) or TPN-PC Plus (Baxa Corporation, Englewood, Colorado) for total parenteral nutrition or RxTRIEVE (CDA Technologies, LLC, Florham Park, New Jersey) for small-volume parenterals, cardioplegia, narcotics, and antineoplastic chemotherapy.

■ **Redeploying critical resources to achieve increased valued and additional cost savings.**

Intravenous drug recycling program.

Pharmaceutical care models.

Right sizing.

Innovations via Strategic Partnering

In addition to the direct cost savings associated with consolidation of services, additional benefits can be gained by regionalization. The professional and technical pharmacy staff and other staff members can be reduced dramatically in number. Often, however, some reduction in staff can occur while other staff members are redeployed to perform other activities that will further reduce costs by different or creative means, result in new services that can be marketed to managed care customers, and provide additional opportunities for program development and potential business opportunities.

Costs in a hospital-based program can be reduced by redeploying some technicians as part of a system-wide, dose-recycling program. During this effort, costly errors of drug omission and product waste can be addressed internally. Omission of doses occurs frequently and inadvertently in some hospital settings. Using a dose-recycling program facilitates the tracking of those types of errors.

Reasons for the errors can be identified, strategies can be developed, and staff can be educated to reduce the incidence of error. Missed doses increase product waste, become a billing issue, and can significantly reduce the effectiveness of treatment. Outcomes are altered, and prolonged hospital stays can result. Potential product wastage can be identified before it happens (eg, when an anti-infective, narcotic, or antiseizure medication or parenteral nutrition is discontinued, but doses previously mixed will be wasted). Those situations can be identified swiftly, and medications can be returned to the satellite or centralized pharmacy for relabeling in accordance with pharmacy regulations. This recycling saves the cost of the base component products and the associated costs of inventory and compounding.

It has been reported that 12% of emergency room visits and 5% of hospital admissions (which total $14.4 billion) are directly related to issues of drug management.[14] Johnson and Bootman[14] estimated that more than 198,000 patient deaths in 1995 were attributable directly to drug-related problems such medication errors. The paradigm shift that promotes the use of pharmacists on the patient care unit can affect those statistics positively. The use of a pharmaceutical care model significantly improves medication use practices within any healthcare system and differentiates an organization from its competitors.

A pharmaceutical care model used in a hospital differs from that used in a home healthcare organization. Regardless of the differences in setting, the direct involvement of a pharmacist as a clinical team member can benefit both the quality and the cost of care. Over the years, pharmacists have developed many integrated processes that help to ensure patient safety in all dimensions of medication use. The pharmacist can participate in product selection, acquisition, and the development of drug formularies; implement systematic process controls for sterile-product preparation; monitor and report adverse drug reactions; implement the safe handling of cytotoxic or hazardous drugs; review individual patient drug regimens; provide patient education and counseling about the use and side effects of prescribed drugs; educate medical, nursing, and other staff about specific pharmacologic aspects of disease management; review overall drug-use patterns and strategies to enhance prescribing practice, and provide pharmacokinetic dosing services for drugs with a narrow therapeutic index. Unfortunately, many organizations have limited the role of pharmacists to that of production, and clinical activities have been limited. The role of the pharmacist is crucial in the significant reduction of serious medication errors.[15] Other data[16,17] indicate that the increased use of pharmacists in overseeing prescriptions and drug administration processes and their role as collaborative interdisciplinary team members can be very beneficial to patients and to the healthcare organization.

The Future Is Here

The models described above may suggest new opportunities for improvement. Perhaps the partnering of hospitals, satellite operations, branch facilities, or related organizations will enable the identification of additional areas for consolidation. Consider the following questions when consolidation is an option: Can clinical, operational, financial, or sales expertise be leveraged for the common good of all? Do you or does your organization follow "best-in-class" practices every day? Where do problems occur? Is there anyone in your organization who could help? Can you partner with another facility to consolidate a service that is not performed effectively by your organization? The possibilities for success are endless!

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Eric S. Kastango, RPh, is the president of CDA Technologies, LLC, a company that specializes in identifying and correcting inefficiencies in the preparation of sterile-product preparations. Rx-TRIEVE, *which is produced by CDA Technologies, is a pharmacy management software tool that facilitates the delivery of patient-specific small-volume parenteral compounds to customers who choose to outsource those products to regionalized compounding operations.*

Address correspondence to: Eric S. Kastango, RPh, Clinical IQ, LLC, 21 Madison Avenue, Suite 149, Madison, NJ 07940-1410. E-mail: ekastango@clinicaliq.com