ASHP Guidelines on Medication Cost Management Strategies for Hospitals and Health Systems

Because medication costs comprise the majority of health-system pharmacy budgets and continue to increase faster than other health care expenditures,[1] drug costs are a constant target for cost containment initiatives. The purpose of these guidelines is to provide guidance on medication-cost-management strategies.

These guidelines recommend techniques to manage drug costs in hospitals and health systems. The guidelines focus on drug use in inpatient settings and hospital clinics, where health-system pharmacies typically have responsibility for purchasing and distributing drugs. Strategies for other settings, such as managed care and ambulatory care settings, and strategies for revenue optimization are beyond the scope of this document. Although revenue optimization and medication cost management are complementary approaches to improving the financial performance of pharmacy departments, revenue optimization is best addressed through literature specific to that topic[2,3] and is not extensively reviewed in this document.

These guidelines examine methods for nonlabor pharmaceutical cost containment, focusing primarily on variable costs (costs dependent on patient volume) and direct drug costs. Fixed and indirect costs, such as labor to prepare or administer medication, nonpharmaceutical materials, and overhead, are also beyond the scope of these guidelines. There is also not an attempt to consider the impact of drug costs and drug-cost-management strategies on other hospital departments (e.g., laboratory, respiratory care) or on the total health care costs once the patient leaves the acute care setting. Although not discussed here, these shifts in drug costs are important to consider as drug therapies influence other health care costs, and pharmacists should lead efforts to promote the value medications provide across the hospital and health care system.

A broad range of drug-cost-management strategies exist throughout hospitals and health systems. Some approaches are relatively straightforward and can be implemented within the pharmacy. Other approaches are more complex and require high-level strategic planning and extensive collaboration throughout the hospital. Successful drug cost management requires systematic attention to and integration of both approaches. Because of the different nature of various drug-cost-management activities, these guidelines present information at different levels of complexity appropriate to the approach being described.

When selecting and implementing drug-cost-management strategies, it is essential that pharmacists remain mindful of patient safety and the quality of patient care.

Drug-cost-containment initiatives must never compromise the department's ability to provide the best possible care to patients. In many cases, it is prudent and necessary to monitor and evaluate the safety and outcomes of drug-cost-management projects. Fortunately, many drug-cost-containment strategies have little or no potential for detrimental effects on patient care, and efforts to improve the quality of drug use often coincide with cost-containment initiatives.

Trends in Medication Expenditures

Senior hospital administrators have recognized the importance of drug costs to the fiscal status of health systems. For example, a health care consultancy reported that in 1996, "managing hospital drug utilization and expenditures" was not ranked in the top 20 concerns for hospital CEOs.[4] When the survey was repeated in 2000; however, hospital CEOs ranked drug costs as their seventh most important concern. The 2000 survey also reported that among hospitals' greatest financial challenges, drug and technology costs were second only to decreased reimbursement, and hospital CEOs said that drugs offered the single greatest opportunity for cost savings.[4] Although somewhat dated, these data illustrate that drug-expenditure management presents health systems with an important challenge that is recognized by senior hospital administration.

Four primary factors drive growth in overall drug expenditures: price, utilization, mix, and innovation.[1]

Price inflation is an increase in the unit price of existing medications. Utilization is an increase in use of a drug, such as an increase in number of users, days of therapy, or dose per day of therapy. Mix changes when newer, more expensive therapies are used in place of older, less expensive but equally effective drugs. Finally, a blend of the utilization and mix factors increases drug expenditures when expensive, new medications become available to treat conditions previously untreatable with drug therapy (i.e., innovative therapy).

The United States spent over $250 billion dollars on prescription drugs in 2005, but total drug costs represent a relatively small portion of total U.S. health care spending (approximately 11%).[5] However, double-digit increases in prescription drug expenditures have been common (e.g., 15% in 2000, 18% in 2001, 12% in 2002, 11% in 2003, and 9% in 2004).[1,4,6] The rate of drug-expenditure growth has frequently been higher than inflation, increases in wages, and other health care spending, including spending for hospitals, physician services, and total health care expenditures. However, with the exception of 26% growth in 2001, the recent rate of growth in hospital drug expenditures has been less than the growth of total drug expenditures. Hospital drug expenditures grew 4.9% in 2000, 26% in 2001, 9.7% in 2002, 6.3% in 2003, 7.9% in 2004, and 5.7% in 2005.[1,5–7] However, the rate of growth in clinic drug expenditures has consistently exceeded the growth of total drug expenditures. Clinic drug expenditures grew 24.6% in 2000, 23% in 2001, 21.3% in 2002, 22.2% in 2003, 13.5% in 2004, and 12.4% in 2005.[1,5,7]

While the rate of increase in prescription drug expenditures moderated somewhat between 2004 and 2006, drug-expenditure growth remains substantial. Long-range forecasts suggest that the rate of increase in total prescription drug expenditures will continue to exceed the rate of increase for total health care expenditures through 2014. Because drug expenditures are the largest component of every health-system pharmacy's operating budget and often a meaningful portion of the entire hospital operating budget, drug expenses

attract significant attention from hospital leaders. For these reasons, it is apparent that drug-expenditure-management will remain an area of focus and responsibility for health-system pharmacists for the foreseeable future.[8]

Systematic Approach to Medication-Cost-Management Measures

A systematic approach to planning and prioritizing specific drug cost management strategies is essential when implementing initiatives that will influence drug expenditures in a health system. Annual financial planning (i.e., budgeting) is the most common planning approach, and specific drug-cost-management strategies should be considered a part of the budgeting process. However, longer-term strategic and programmatic planning activities also have an important role in managing drug expenditures.

A systematic approach to drug-cost containment requires specific and detailed data on both health-system drug purchases and actual drug-use patterns. Data must underlie all types of planning to manage medication expenditures. Systems should be established to have ready access to the data and continually review and monitor these data.

It is essential to interact and collaborate consistently with physician leaders from various specialties to successfully plan, prioritize, and implement medication-cost management efforts. Physician involvement must be sought during the annual financial planning process and when doing strategic or programmatic planning related to drug expenditures. Appropriate physician representatives must also be engaged in specific drug-cost-management initiatives. During the annual financial planning process, physicians can provide important information related to drug costs, such as anticipated use of key drugs in the pipeline, programmatic or new service implementation, anticipated recruitment of specialists who may require high-cost agents, projections for use of high-priority drugs, and insights for drug cost containment. Pharmacy leaders can also use this opportunity to update physicians on the pharmacy department's recent accomplishments and goals for the future.

Drug Budgeting. Although a complete discussion of the drug-budgeting process is beyond the scope of this document, several important suggestions are provided below. A general approach to systematically developing the annual drug budget is outlined in Table 1.[7] At the beginning of each calendar year, the *American Journal of Health-System Pharmacy* publishes a projection of drug expenditures for that year.[1,5–7]

Annual drug budgeting is a challenging exercise. Unanticipated situations that result in extreme increases in drug expenditures will likely occur and the pharmacy director should be prepared to explain those situations. Better data and more experience will improve a department's ability to forecast institutional drug expenditures. Regardless of the drug budget's accuracy in forecasting the institution's drug expenditures, a well-planned drug budget should help the department understand drug use patterns and identify opportunities for drug cost management. Specific reports that can be helpful in understanding drug use will be described below.

During the annual financial planning process, it is important to identify and focus on key drug expenditures. The Pareto Principle, or 80/20 rule, applies to drug budgeting and states that in nearly all cases, a few vital factors are important and many are trivial. A relatively small number of drugs (50–60) typically account for 80% of most hospital drug budgets. Therefore, budgeting and cost-containment efforts should focus on those drugs, and the cost-management plan should especially concentrate on those top drugs for which it is feasible to influence prescribing patterns. Much of this document focuses on the need to develop a cost-containment plan after initial estimates of drug costs are completed (Table 1).

Table 1.
Steps for Developing Annual Drug Budget[7]

Collect and review data (e.g., drug purchase data, drug utilization data, workload and productivity data, other financial statements).
Develop budget for high-priority agents (top 50–60 drugs).
Identify relevant new drugs and build new agent budget.
Budget for nonformulary drugs and lower-priority drugs.
Establish a drug cost containment plan (identify drugs going off patent, opportunities for therapeutic interchange or protocol development).
Finalize and present the total drug budget.
Continue the budgeting process throughout the year through constant vigilance and monitoring of drug use.

Medication-cost-management projects should be carefully selected and prioritized as part of an ongoing financial planning process. Because drug-cost containment strategies must be customized to each health system's unique characteristics, a global assessment of the pharmacy department and the hospital must be conducted to identify opportunities for drug-cost-management. This assessment must go beyond a qualitative assessment of opportunities and must include retrieval and analysis of both drug purchase and drug-utilization data. Pharmacy departments may need to obtain and develop resources, such as personnel and software, to analyze these data.

Despite the need to customize the strategy and tactics to fit the needs of different hospitals and health systems, a systematic approach to identifying, prioritizing, and implementing medication-cost containment initiatives is necessary and can be applied in any setting. A clearly defined list of cost-containment targets should be established during each financial planning cycle. To be successful, the number of initiatives should be manageable and should focus on the institution's top expenditures. In many situations, multiple approaches for cost containment will be necessary.

The foundation for effective cost-management strategies, and the first stage of the systematic approach, begins with determining current costs of medications, both as ongoing expenses and those held as assets in inventory. Understanding and tracking key medication-cost indicators on an ongoing basis is necessary to determine the opportunities for medication-cost reduction. Examples of these indicators may include:

- Medication inventory per adjusted patient day
- Medication inventory turnover rate
- Contract coverage percentage
- Contract compliance percentage
- Intravenous-to-oral dosage ratio
- Volume-adjusted total medication costs (e.g., cost per adjusted patient day, discharge, etc.)

- Volume-adjusted drug category costs (e.g., antibiotics, anesthesia-related drugs, etc.)
- Descending-order total purchase histories, tracked over time

In addition, the use of external benchmarks may provide assistance in identifying medication-cost-reduction opportunities. External benchmarks may be available as a component of services provided by consulting organizations, the pharmacy's drug wholesaler or group-purchasing organization (GPO), or from professional published data. Benchmark data should be used with care; however, because there may be important limitations to the applicability of the data to a specific site. For example, difficulties may exist in adjusting the data for the specific pharmacy practice, such as models and intensity of services, and in finding an appropriate peer group.[9]

After cost-management opportunities are identified, they need to be quantified. Dollar values should be assigned to each opportunity, including inventory reduction, improvement in inventory turns, improving contract compliance, therapeutic interchange of various agents, and others. A specific goal and action plan should be set for each drug-cost-management target. For example, one goal might be to reduce expenditures for a drug class by 8% by establishing a contract for a new, preferred agent and implementing a therapeutic interchange program to shift use to the new agent. Alternatively, the goal might be to slow the rate of increase in use of a particular drug or drug class (e.g., based on current patterns, use of this drug class is expected to grow 15% in the next fiscal year, but the goal of interventions is to limit the rate of increase to 10%). Monitoring is essential, so drug cost containment targets should be consistently measured and evaluated. Identifying and quantifying the opportunities must be completed before prioritization and in-depth evaluation begins.

Assessment and Prioritization. Once opportunities for cost management have been identified and quantified, assessment and prioritization can occur. There are many methods of prioritization, but most of them contain two key elements: determining the potential benefit and estimating the relative ease or difficulty of attaining the benefit. Even though potential benefit may be clear-cut, the degree of difficulty is often hard to establish. Important points to consider when determining the relative degree of difficulty and likelihood of achieving benefits from a given drug-cost-management opportunity include (1) the amount of time pressure (the time available until the cost reductions occur), (2) key stakeholder (e.g., nurse, physician) sensitivity and willingness to collaborate, (3) extent of leadership support for the initiative, (4) resources required, and (5) existing level of expertise within the organization for the specific cost-management opportunity.

Drug-cost management strategies that are under the direct and exclusive purview of the pharmacy department (e.g., purchasing, inventory management, and waste reduction approaches) are generally easier to implement and provide more immediate benefits. These activities, however, often provide smaller or one-time financial benefits. Utilization management tactics (e.g., clinical practice guidelines and therapeutic interchange) generally provide greater financial benefits, but these efforts have correspondingly higher degrees of difficulty and complexity.

Because of the relative ease of implementation, cost-containment opportunities in areas that are primarily under the department's control will usually be pursued first. After these initiatives are underway, more complex techniques that require collaboration with the medical staff and others should be pursued.

These guidelines are structured so that the cost-management techniques are presented in the order in which health systems often implement them. Components of a cost-management program are listed in Table 2. An appendix that lists specific cost management opportunities is also provided. It is important to note that although these guidelines are separated into sections on purchasing and inventory management and medication-use management, both activities are integral and indivisible to drug-cost management planning and the practice of pharmacy in hospitals and health systems.

Purchasing and Inventory Management

When selecting drug-cost-containment initiatives, purchasing and inventory management procedures should be considered first.

Drug Product Costs and Procurement. At the most fundamental level, drug costs are a function of unit costs and

Table 2.
Components of a Cost-Management Program[a]

Pharmacy-Directed Activities
Purchasing
GPO contracts
Facility contracts
Wholesaler contracts
Inventory management
Wholesaler ordering programs
Storage
Waste reduction
I.V. product waste
Returns
Interdisciplinary Activities
Medication utilization program
Clinical pharmacy services
Assessment of drug costs
Medical staff support
Formulary management
Therapeutic interchange
Guideline (protocol) development
Pharmacist interventions
Plan implementation and analysis
Reimbursement & Charging
Reimbursement
340B programs
CMS (DRG class)
Commercial insurance (payer mix)
Outpatient infusion center
Charging
Coding and processing
Indigent care programs

[a]GPO = group purchasing organization, CMS = Centers for Medicare and Medicaid Services, DRG = diagnosis-related group.

utilization. Drug-unit costs are a function of acquisition costs (contracted or non-contracted), the external (in-bound) distribution fee, inventory management costs, and internal distribution costs.

Contracting. There are three main avenues for purchasing pharmaceuticals at discounted rates: GPO contracts, facility contracts, and wholesaler own-use contracts. All facilities should seek to maximize savings available from use of generic products, and some may have other considerations, such as use of 340B or indigent care programs.

GPO contracts. GPOs utilize the aggregate purchasing power of many facilities in negotiating pricing agreements with manufacturers. Most hospitals are members of a GPO. While there are GPOs that focus exclusively on drugs, the majority of GPOs offer contracts for medical and surgical supplies, food, and other support products and services in addition to pharmaceuticals. Most GPOs make their contract portfolio available to members via hard copy, and some GPOs have contract portfolios available on secure internet sites. Considerations in contracting with a GPO are listed in Table 3. It is also important to have routine surveillance, preferably an automated service, that ensures that contract prices are applied to all purchases.

GPOs are funded by one of two means. First, most, if not all, GPOs collect a contract administrative fee (CAF) from the manufacturers or distributors with which they contract. The CAF is rarely greater than 3% of the dollar volume of product purchased through the contract. Some GPOs return a portion or all of the CAF to its members. If any or all of the CAF for a particular drug product is returned to the facility by the GPO, it should be taken into account when calculating the net cost of the drug. The second method by which GPOs are funded is direct payment of fees by members to the GPO. In this arrangement, all of the CAF is returned to the facility.

Contracts through GPOs consider not only the unit cost of the pharmaceutical but also include the allowable distribution methods for the pharmaceutical, payment terms, returns policies, and supplier performance requirements. Many GPO contracts, especially those for multi-source generics, include simple line-item pricing, which only requires the purchaser to buy and pay for the product. Other contracts are more complicated, with incentive rebates for all purchases or rebates for achieving volume or market share targets.

Typically, market share agreements are utilized when two or more products can be used to treat the same disease and no generic equivalent exists. The incentive, such as a rebate, a lock-in of a current discount, or achievement of a higher discount, is contingent upon attaining a given market share for a particular product in the institution's market basket. To achieve the greatest financial advantage from the contract (lowest net drug cost), the pharmacy must work with the medical staff. This process requires a careful evaluation of comparative efficacy and safety of the product and its alternatives.

Some GPOs have multiple products on contract within categories of pharmaceuticals, allowing the facility to receive discounted pricing on similar agents when prescribing practices are not standardized to one agent. More aggressive GPOs will sometimes contract for a single agent within a particular class (e.g., for one fluoroquinolone or one liposomal amphotericin B product to the exclusion of others) in order to gain the maximum value for its members.

Successful use of GPO contracts requires a constructive and collaborative relationship between the member, the GPO, the manufacturer, and the distributor (i.e., wholesaler). Potential advantages of GPO contracts are listed in Table 4.

In addition to the contracting portfolio, GPOs offer services such as lost savings and compliance reports, rebate and contract administrative fee reports, clinical utilization management programs, and letters of commitment.

Lost savings and compliance reports. These reports provide data and analysis of missed savings opportunities in the user's purchase history (e.g., items purchased off-contract when a generically equivalent alternative item was on-contract). These reports may also indicate the compliance level, or the amount of purchases on-contract versus the amount of purchases that could have been made on-contract (drugs purchased on-contract plus the value of drugs purchased off-contract when alternatives were on-contract). These reports should be reviewed monthly to determine if purchasing practices are effective.

Rebate and contract administration fee report. These reports tally the amount of rebates and contract administration fees generated by the facility's purchases of specific products under contact. When evaluating the costs of two or more equivalent products, it is important to include any applicable rebates to arrive at net cost.

Clinical utilization management programs. These programs assist facilities in managing the utilization of various drug products and classes, often through evaluation and

Table 3.
Considerations in Group Purchasing Organization (GPO) Contracting

Fees (e.g., contract administrative fee)
Allowable distribution methods
Payment terms
Return policies
Supplier performance requirements
Rebates
Market-share agreements
Single-agent contracts
GPO services (e.g., lost savings and compliance reports, rebate and contract administration fee reports, clinical utilization management programs)
Letters of commitment

Table 4.
Potential Advantages of Group Purchasing Organization Contracts[10,11]

Standardization of products
Reduction of contract labor costs for institutions
Enhancement of member institution's purchasing program
Enhancement of information sharing
Enhancement of purchasing expertise
Protracted periods of price protection
Coordination of contracting and budgeting process
Reduction of duplication of purchasing efforts among institutions
Assistance identifying alternative or secondary products during drug shortage

comparison of product efficacy, safety, and cost, as well as therapeutic interchange programs.

Letters of commitment. Letters of commitment (LOC) available through GPOs should be evaluated and taken advantage of when appropriate. The LOCs usually contain requirements for the pharmacy to do one or more of the following in order to gain lower pricing or rebates:

- Declare that a particular drug is on formulary.
- Declare that a particular drug will be on formulary and will not be restricted.
- Achieve a target periodic volume.
- Achieve a target market share relative to competitive drugs for a given period of time.

The LOC may not require significantly more purchasing of the drug. If LOC requirements do not conflict with formulary and utilization management strategies, the LOC should be signed if there is a reasonable chance of meeting the requirements.

Facility contracts. The alternative to GPO contracting is individual contracting. This type of contracting may be done at the facility or the health-system level. In some cases, equal or better pricing than GPOs can be obtained by individual facilities when contracting, especially large facilities or integrated delivery networks (IDNs). Opportunities for better pricing through individual contracting may exist for specialized health systems (e.g., those focused on oncology or transplantation), that purchase a large volume of a selected drug and are able to commit to maintaining a market share for the drug.

It is important to carefully evaluate the benefits of individual contracting and its influence on the collective bargaining power of the GPO. Continual use of individual contracts that are in contravention to GPO contracts, in theory, will eventually erode the GPO's ability to consistently contract aggressively for its members. Because of larger GPO volume, manufacturers often will not offer the same pricing or other terms to individual facilities or IDNs that they offer to GPOs. Another factor to consider with individual contracting is that a facility may require contracts to be reviewed by attorneys, whereas the GPO acts as the contracting agent of the facility, obviating the need for legal review of each contract by the facility's counsel. Finally, the amount of time required to negotiate, write, and maintain an individual contract should be weighed against the incremental value gained over what a GPO contract would offer. In many situations, it may be more efficient and productive to voice contract concerns to GPO representatives and become involved in GPO committees rather than write multiple, individual contracts outside the GPO.

Some drug contracts, especially for sole-source awards to generic manufacturers, call for the manufacturer to reimburse the pharmacy for the difference in cost when the pharmacy must purchase a product off-contract because the manufacturer was not able to supply the contracted product. The manufacturer-unable-to-supply reimbursement process is time-consuming and the requirements can be rigid, but submitting reimbursement to manufacturers under these provisions can return additional funds to the pharmacy.

Wholesaler own-use contracts. Wholesalers are also able to take advantage of special pricing on certain branded and generic drugs and offer those products to their customers in the wholesaler's proprietary contract portfolio. This creates margin for the wholesalers that can be used to fund distribution discounts. Wholesalers also take advantage of cash discounts and quick-payment terms from manufacturers to increase their margin and to offer discounts to customers.

Generic Drug Savings Maximization. The expiration of patents on widely used branded drugs can result in large reductions in drug expenditures. It is important to be mindful of the opportunities presented by the first-time introduction of generics on high-spend branded drugs, both in budgeting and implementing rapid and effective uptake of generics when they are introduced.

Budgeting. There are several sources for monitoring patent expiration dates (off-patent dates) for branded drugs, including www.drugpatentwatch.com and the GPO. The GPO may also be able to estimate the potential initial savings from contracting for generic drugs that are first-time introductions. It is also important to determine when the first-time generic product will be available from multiple manufacturers. The initial savings differential between the branded and generic versions may be small because a single generic manufacturer often has a period of exclusivity before the generic drug becomes available from multiple sources. In some cases the savings may be so insignificant that health systems will choose to remain with the branded drug for safety reasons and consistency in product supply. Changing products several times within a short period of time could confuse caregivers, so pharmacy managers should weigh the benefits and risks of making such changes.

Operational considerations. Swift uptake of the generic product is necessary to maximize the savings after a branded drug comes off-patent and multiple generic versions are available. The following steps should be taken during any product conversion, but they are particularly important when converting from a brand name product to a first-time generic equivalent product.

- Contracting. Be sure that the health system has access to contract pricing on a generic product on the first date that the drug is available as a multisource item. The contract pricing will usually be through the health system's GPO, but in some cases, the health system may write its own contract for the generic product.
- Contract Price Loading. The contract pricing for the product must be loaded at the wholesaler with enough notice to become effective. Up to 30 days notice may be required before the contract pricing becomes effective through the wholesaler. Although the manufacturer or GPO typically send the contract information to the wholesalers, when the hospital or health system directly contracts for the generic drug, the contract information should be sent directly to the wholesaler by the hospital or health system.
- Demand Matching. Work with the wholesaler to ensure that there will be a sufficient supply of the generic product at the local wholesaler distribution center to match current purchases of the branded product, a process called demand matching. Wholesalers will need at least 30 days notice on demand matching to ensure sufficient stock of the generic product on the off-patent date. Working with the wholesaler on demand matching also improves overall supply chain management

by allowing the wholesaler to draw down inventory of products that will be in less demand.

- Autosubstitution. Some wholesalers allow pharmacies to institute autosubstitution rules in the wholesaler ordering system to substitute a preferred generic product for a branded product or non-preferred generic products. This process maximizes savings and contract compliance. Care must be exercised in creating autosubstitution rules to ensure correct product-to-product substitution in chemical entity, dosage form, package size, package form (unit dose, bulk oral, liquid), and so forth, especially in cases in which a brand-name drug goes off-patent. Autosubstitution rules may also be implemented in the wholesaler ordering system for medication safety reasons (e.g., reduction of sound-alike and look-alike drugs) in addition to savings optimization or contract compliance.

Other Considerations. Pharmacy managers should explore whether the hospital can obtain pharmaceuticals at advantageous pricing using 340B (disproportionate share) programs. Because hospitals and health systems must meet specific criteria to be designated as a 340B facility, pharmacy managers should collaborate with the chief financial officer and financial services department to determine if they can access 340B pricing for pharmaceuticals. Detailed descriptions of the qualifications and benefits of 340B programs are also available through the Health Resources and Services Administration Office of Pharmacy Affairs www.hrsa.gov/opa/; the Pharmacy Services Support Center, pssc.aphanet.org/; the Safety Net Hospitals for Pharmaceutical Access, safetynetrx.org; and ASHP 340B Information Site www.ashp.org/s_ashp/cat1c.asp? CID=3813&DID=6225.

Pharmaceutical manufacturers also continue to offer indigent patient care programs for select drugs for qualified patients on an individual basis. Although substantial savings can be realized through replacement drugs at no charge, the process can be arduous and complex. There are independent consulting services that specialize in assisting with coordination of the program for hospitals and typically require payment as a percentage of the savings. Patients eligible for Medicaid and other regional or local low-income health insurance do not usually qualify for the indigent care programs sponsored by the pharmaceutical industry.

Wholesalers and Distribution Fees. Most hospital pharmacies purchase 80% or more (by dollar volume) of their pharmaceutical needs from a drug distributor (wholesaler). Hospital pharmacies can lower their costs by ensuring that the distribution fee mark-up is as low as possible. To understand the cost that wholesalers charge for drugs, and the distribution fee charged to hospital pharmacies, it is necessary to understand wholesalers' revenue streams and expense drivers.

The adoption of the prime-vendor system, in which a pharmacy procures a very large portion of its pharmaceutical needs from one supplier, has led to great efficiencies in the pharmaceutical supply chain. Through these efficiencies, wholesalers are able to offer low incremental fees to their customers for distribution of pharmaceuticals. In many cases, they are able to offer discounts to the contracted price of the drug or "cost-minus" discounts to the wholesale acquisition cost of the drug if it is not contracted.

Through automated inventory, stock replacement, and order fulfillment, wholesalers have streamlined the delivery process and lowered pharmaceutical costs in the supply chain. In the past, wholesalers increased their margins through speculative buying, which is buying pharmaceuticals in large quantities and holding them past the date of future manufacturer price increases. The products would then be sold to customers at the higher price. These practices have reportedly decreased since 2004.[12] However, at the same time that speculative buying decreased, the wholesale drug industry instituted inventory management agreements with manufacturers, who in return for agreements regarding product supply and demand, pay the wholesalers a negotiated fee based on the percentage of the volume that the wholesalers purchase from them. These methods of creating margin through increasing revenue and decreasing expenses can be translated into a cost-minus fee structure for the hospital that is purchasing from the wholesalers.

Individual hospital factors that influence wholesaler fee structure. Several characteristics of individual hospital-pharmacy purchasing can affect a wholesaler's revenue and expenses and result in higher or lower distribution fees. To some degree, a higher purchasing volume results in a lower distribution fee. However, other factors, including deliveries per week, dollars per drop, dollars per line extension, numbers of delivery sites per location, payment terms, and special services, must also be considered. These factors should be considered collectively and not in isolation. In addition, most major wholesalers have supply, automation, and other service and equipment divisions, and an institutional contract with multiple divisions can provide additional savings.

Deliveries per week. The fewer deliveries from the wholesaler per week, the lower the expenses for the wholesaler, which can reduce the wholesaler distribution fee to the pharmacy. Some large hospitals have up to 11 deliveries per week, but other large hospitals are able to manage inventory so that patient care can be well-maintained with only 5. Inventory and patient care can be well maintained at less than five deliveries per week at small hospitals. Fewer deliveries may require additional purchasing discipline, but some wholesalers have programs to help pharmacies improve their purchasing practices.

Dollars per drop. This factor is important to wholesalers because the higher the number of delivery locations (drops), the higher the wholesalers' cost, and vice versa. For a given dollar value of pharmaceuticals purchased, a wholesaler's expenses are lower, and margin is higher, for a lower number of delivery points. This margin can be translated into lower distribution fees for the pharmacies, particularly for IDNs of multiple pharmacies.

Dollars per line extension. For each line of products on an invoice that a wholesaler fills and delivers to a pharmacy, there is an associated cost. The dollars per line extension is the total dollars purchased by a pharmacy over a given period of time divided by the number of lines of products ordered over the same period of time. Pharmacies with higher dollars per line extension purchased can sometimes have lower distribution costs than pharmacies with lower dollars per line extension because it costs relatively less for the wholesaler to service the pharmacy with the higher dollars per line extension.

Secondary wholesalers. Secondary wholesaler relationships should be avoided if inventory levels meet patient

care needs. Purchases from secondary wholesalers usually carry a much higher distribution fee. Such purchases also result in a higher primary wholesaler distribution fee because there are decreases for the pharmacy in its dollars per drop, dollars per line extension, and total volume. Wholesalers are increasingly requiring pharmacies to meet a minimum monthly volume to maintain an account, and the costs of maintaining the minimum volume at a significantly higher distribution fee can be prohibitive.

Expanding the use of the wholesaler within the health system may offer additional opportunities for cost savings. Hospital departments such as radiology, the clinical laboratory, interventional cardiology, and anesthesiology may procure pharmaceuticals directly from the manufacturer through the purchasing or materials management departments. Utilizing the pharmaceutical wholesaler for these products through a separate purchasing account does not change the process of procurement or distribution but reduces the unit cost through application of the wholesaler discount. Because some of these products may be relatively costly (e.g., contrast agents, blood factors, or anesthetic gases), there is a potential for additional savings if these purchases push the hospital into a higher tier of the wholesaler cost structure. Pharmacy directors should communicate with other department managers to determine how pharmaceuticals are purchased, and it is usually best if all drug purchases are managed by the pharmacy.

Payment method and frequency. Payment method and frequency can also affect the distribution fee. Many wholesalers offer a lower distribution fee to hospitals that pay by electronic fund transfer (EFT). Pharmacy managers should work with their accounts-payable departments to establish EFT, which is usually a more efficient method of payment for both the hospital and the wholesaler. In addition, the more frequent the payment, the lower the wholesaler distribution fee will generally be. Since 2004, the amount of speculative buying has waned and large discounts for more frequent payments have decreased. However, many wholesalers offer terms based on prepayment, or placing funds on deposit with the wholesaler, and then paying invoices on a go-forward basis. The advantage in lower distribution fee is clear, but this gain must be balanced against the time value of money for having the funds on deposit with the wholesaler rather than drawing a return for the health system.

Most GPOs have wholesaler-distribution agreements for use by their members. However, because of higher-than-average dollars per drop, dollars per line extension, and discipline in number of deliveries per week, large hospitals and health systems can often get better pricing and terms by dealing directly with wholesalers rather than through GPO wholesaler agreements.

Other wholesaler tools. Most wholesalers provide pharmacies with access to computer software or Web-based solutions for product ordering, reporting, and inventory management. The programs will allow the buyer to check for lower-priced alternatives and contract compliance prior to placing orders. Pharmacy managers should work with their wholesaler representatives to be sure that these features are available and utilized.

Some wholesalers produce contract compliance reports. These reports can be used to gauge the effectiveness of purchasing practices. Pharmacy managers should check with their wholesalers to determine if these reports are available. If they are, they should be reviewed monthly for opportunities to improve contract purchasing.

Some wholesalers have automatic substitution programs to assist pharmacy buyers in selecting the correct product when multiple generic alternatives exist. These programs allow the pharmacy manager to direct purchases of less-preferred products (as determined by the pharmacy management) to more-preferred items. For example, if one brand of unit dose acetaminophen 325-mg tablet is on contract as a sole-source award, the autosubstitution program can allow for inadvertent orders for noncontract unit dose acetaminophen 325-mg tablets to be substituted with the preferred version. Such programs may not be available from all wholesalers, and they should receive careful consideration before being implemented.

Inventory Management. Inventory management is a balancing act. It involves meeting patient and internal customer needs while committing the least amount of dollars possible to drugs on the shelves or in automated cabinets. The rate of inventory turnover (defined as total annual drug expenses divided by the dollar value of the inventory assessed on an annual basis) is dependent on many factors. Typically, the pharmacies of smaller hospitals will have a lower drug inventory turnover (8–10 turns per year) than the pharmacies of larger hospitals (12–18 turns per year or higher) and some specialty hospitals.

Many wholesalers' ordering programs provide systematic methods for asset management (i.e., inventory value optimization and increasing turnover). Wholesaler representatives can assist in the initial setup of these programs. Inventory items should be divided into high-, medium-, and low-value products, and the minimum and maximum inventory levels for at least the high- and medium-value products should be established. At the same time, reorder points and reorder quantities should be established for at least the high- and medium-value products. Systematic use of these programs can decrease the time required for the ordering process and increase inventory turns. The minimum and maximum levels, as well as the reorder points and reorder quantities, should be reviewed on a routine schedule and revised when necessary.

When seeking to increase inventory turns, storage in the central pharmacy and automated dispensing cabinets should also be considered. Configuring pharmacy storage locations so that each drug product has only one storage location in the central pharmacy sometimes helps to free capital by reducing inventory. Automated cabinet inventories should be regularly reviewed for appropriate turnover. Most cabinet systems have report capabilities to optimize both the products and the quantities that should be in a particular cabinet based on the dispensing philosophy devised by pharmacy and nursing departments. Cabinet manufacturers have product specialists that consult with pharmacy management to optimize use of the cabinets.

I.V. product waste. Many pharmacies waste a significant quantity of drugs, particularly unused IV solutions, and many do not have an accurate valuation of the amount of waste because it is only sporadically monitored. Table 5 lists strategies for reduction of IV product waste.

Returns. Most pharmacies use a third party (reverse distributors or returns companies) to process wasted and expired drugs. However, not all pharmacies completely track

Table 5.
Strategies for Reducing I.V. Product Waste

Establish policies that are based on the most recent literature for maximum i.v. bag hang-times and i.v. set change frequency.
Institute an i.v.-to-oral switch program for both cost reduction and patient care benefits.
Periodically audit the amount of i.v. admixtures being wasted and log the date and time of waste, date and time of preparation, the i.v. fluid type and drug admixed, quantity of products, and the cost of the products. Review the log and determine the most common occurrences.
Reduce i.v. batch sizes (creating more, smaller batches) and reduce the amount of time between preparation of the i.v. dose and the actual administration time.
Routinely monitor the status of i.v. drips that are adjusted.
Routinely return all unused i.v. admixtures to the i.v. preparation area as soon as possible.
Consider the use of manufacturer premixed products where advantageous, both economically and for patient care.
Compare the quality, economic, and regulatory (e.g., *USP* chapter 797) differences within your practice site between different administration methods such as i.v. syringe infusion, i.v. intermittent infusion (i.v. piggyback), and volumetric drip chambers.
Establish standard concentrations, dosages, and base solutions for i.v. admixtures.
Ensure that there is an efficient process for communicating changes in i.v. admixtures (e.g., rate, fluid, dosage) or discontinuation.
Reduce total parenteral nutrition use by employing enteral nutrition when possible, and establish standardized total parenteral nutrient base solutions, hang times, and related policies and procedures.

and trend the drugs that are most commonly wasted, the dollar value of the expired and wasted drugs, or whether credits were received. The pharmacy manager and pharmacy buyer should work together to utilize reports from the reverse distributor to determine the opportunities for reducing the amount of expired and wasted drugs and insuring that all credits due to the pharmacy from the manufacturers are received.

Medication Utilization Management

Planning and Developing a Medication Utilization Management Program. An effective plan for medication utilization management must provide the health system with a road map for continuous improvement in pharmaceutical expense management, with specific goals and outcome measures of success. It is important to acknowledge that although one purpose of medication-utilization-management is to add economic value, the quality and safety of patient care are foremost in the mission of pharmacy services and should never be compromised for cost. Medication-utilization-management must integrate evidence-based science with the standards of medical practice within the health system.

Before embarking on a comprehensive medication-utilization-management plan, goals must be established, a reporting structure delineated, roles identified, measurement tools developed, and implementation procedures established. The successful plan is dependent on many levels of commitment, including commitment to administrative and clinical pharmacy management, the medical staff, and senior health-system management. The director of pharmacy provides leadership by facilitating the efforts of the medical staff, setting priorities for the clinical pharmacy staff, and cultivating the support of senior leadership. Clinical pharmacists with advanced training and education must have dedicated time to develop and implement the cost management initiatives. They must also be empowered to monitor the program and educate other staff to participate in therapeutic interchange, medication utilization review, and other interventions while encouraging the infusion of fresh ideas for pharmaceutical cost management.

Role of Clinical Pharmacy Services in Drug Cost Management. Clinical pharmacy services, activities in which pharmacists provide direct patient care, are an important foundation for a successful medication-utilization-management program that is focused on managing drug costs. Clinical pharmacy services have demonstrated an overall positive financial impact. In a systematic review of original assessments of clinical pharmacy services from 1988 to 1995, Schumock et al.[13] reported that 89% of 104 studies reviewed reported positive financial results. In the seven studies of clinical pharmacy services where sufficient information was available to calculate a benefit-to-cost ratio, the median benefit-to-cost ratio was 4.09:1. Therefore, in these studies, every dollar invested in clinical pharmacy services returned four dollars. The systematic review was updated in 2003 to review published assessments of clinical pharmacy services from 1995 to 2000, and once again, the value of clinical pharmacy services was demonstrated.[14] For this five-year period, benefit-to-cost ratios could be determined from 16 studies, and when these studies were combined, the median benefit:cost ratio was 4.68:1.

Some specific types of clinical pharmacy services have also been associated with decreased drug costs. Bond et al.[15] have used an extensive database of the outcomes of clinical pharmacy services to show that drug information services, medication admission histories, and drug protocol management are associated with lower drug costs.

In addition, clinical pharmacists' active involvement is crucial to the success of many drug-cost-management ini-tiatives. Many of the drug-cost-containment techniques can only be successful with diligent and often daily support from clinical pharmacists. For example, successful implementation of a clinical practice guideline as a drug-cost-management technique will require the expertise of the department's clinical pharmacists to develop the guideline, and will also require the pharmacy staff's consistent enforcement of the guideline in their interactions with prescribers. Similarly, it will often be the clinical pharmacist's responsibility to routinely carry out the hospital's therapeutic interchange policies.

Assessment of Drug Costs

A successful pharmaceutical-cost-management program must be data driven. GPOs, wholesalers, distributors, pharmaceutical manufacturers, and supply-chain divisions of multi-hospital systems need to track costs in a variety of ways. Advances in information technology have made drug usage data more accessible and sophisticated, and effort should be spent to manage and analyze these data. Pharmacy management must also take advantage of the data available in its own facility

through the materials management department, purchasing department, and finance department. Internal and external data sources are the foundation for the decision-making process for medication-utilization-management and must be examined closely prior to setting goals for cost-management initiatives.

Because each health system has a unique mix of patients, services, and centers of excellence, the drug-cost-assessment process must be customized to create a priority list of initiatives that will provide the greatest value. Key reports that should be considered are listed in Table 6. Once the formulas for denominator data are established as consistent across many facilities, a multihospital health system can effectively benchmark drug costs.

Medical Staff Support. Any program that involves altering prescribing patterns to improve the cost-effectiveness of drug therapy requires the support and engagement of the medical staff. Although health systems have the ability to negotiate discounted unit prices for pharmaceuticals, the efforts of the GPOs and the increased availability of generics have leveled the expense of many high-cost drug products used in hospitals. Cost-management programs have therefore become increasingly dependent on the hospital's ability to manage utilization and prescribing, which will ultimately influence market share and drug pricing. Several effective strategies that can harness physician knowledge, cultivate a collaborative relationship, and facilitate ownership of the process by the medical staff are described in Table 7.

Once the medical staff is engaged and there is a commitment from senior management for the medication-utilization-management program, a detailed procedure for initiative generation can be established. Key steps include the following:

- Designating clinical sub-groups based on categories of the initiatives.
- Identifying the lead physicians, clinical pharmacists, and other key practitioners for each group.
- Using evidence-based studies and the drug assessment data to make decisions.
- Defining the types and categories of the initiatives.
- Creating a dashboard and a clear and concise reporting format for communicating progress.
- Facilitating the infusion of ideas through brainstorming and other effective meeting and group techniques.
- Defining measurable outcomes and benchmarks for evaluation.

Table 6.
Key Reports to Consider in Assessing Drug Costs

Report	Considerations
Wholesaler purchasing reports	For 80/20 analysis, by therapeutic class, and of top 200 drugs; drugs with multiple strengths and sizes need to be aggregated; wholesalers can also provide monthly trending reports and benchmarks from their customers.
Direct (nonwholesaler) purchase reports	Available from the purchasing or finance departments.
Interdepartmental purchasing reports	Available from materials management or other departments that have internal transfers.
Cost (total drug costs or specific drugs) per medical service or hospital area	Drug-utilization data will be needed to produce this report.
Cost per drug-related group reports	Available from internal sources (ideally) or fee-based external vendors; distinction must be made between using cost or charge data.
Cost per occupied bed, adjusted patient day, admission, discharge, or case mix index adjusted patient day	Adjusted patient days are calculated with a standard financial formula that modifies patient days with a ratio of outpatient to inpatient revenue to correct for volume changes and severity of illness.[16] External and internal benchmarking is dependent on these kinds of reports.
Pharmacy-adjusted patient days	Calculated using the same ratio of outpatient to inpatient revenue but for drugs only, and may also add specificity and value to comparative data.
Cost per case, procedure, or admission (e.g., surgical case, cardiac procedure, dialysis admission)	These are important based on the patient mix and the drugs that comprise the greatest costs within the health system. Physician participation in the dissemination of the data is essential.

Formulary Management. The guiding principles of a sound formulary management system are well described in two documents,[17,18] and are concisely summarized in the following statement: a well-managed formulary system ensures a close relationship between the organization's medication-use policies, the therapies offered by the organization, and the medication routinely stocked by the pharmacy.[18] Although the primary goal of a formulary system is to promote safe and effective drug therapy, it can be a valuable cost management tool and has inherent medical staff support through the actions of the pharmacy and therapeutics (P&T) committee. The medication-utilization-management program is highly dependent on an effective formulary system. Key aspects of formulary management in cost-management efforts are described in Table 8. Once again, the efforts of clinical pharmacists are crucial to successful implementation of the formulary system.

Methods of Pharmaceutical Cost Management. Pharmaceutical cost-management initiatives are typically categorized by therapeutic class or group or by method of implementation. The latter is usually subdivided into three or four different types: therapeutic interchange (therapeutic substitution), guideline (protocol)

Table 7.
Strategies to Involve Medical Staff in Cost-Management Efforts

Enlist the pharmacy and therapeutic (P&T) committee to review medication-utilization management issues as a standing agenda item.
Identify the centers of excellence and work with individual chiefs of service to gain support.
Meet with key medical staff departments and divisions, including infectious diseases, anesthesiology, cardiology, and oncology, as well as intensivists, hospitalists, and interventionalists as appropriate.
Develop prescriber reports on the targeted high-cost drugs and discuss methods for cost reduction.
Provide continuous feedback to the P&T committee and individual departments and divisions on cost management successes.
Provide hospitalwide expenditure data on the top 50 items to the P&T committee.
Utilize evidence-based research to propose changes in medication utilization.
Identify physician champions for specific initiatives.
Create a consistent procedure for developing prescribing guidelines, protocols, care paths, and preprinted orders.

Table 8.
Key Aspects of Formulary Management in Cost-Management Efforts

Policy for formulary drug addition and deletion through evidence-based product selection, including efficacy, safety, and pharmacoeconomic assessments
Policy for the use and monitoring of non-formulary medications
Policy for medication-use evaluation
Limitation on combination, sustained-release, and long-acting products
Policy for therapeutic interchange and prescribing guidelines
Reduction of drugs in the same therapeutic group or class
Periodic house cleaning to reduce under-used and discontinued line items
Policy for drug restriction
Procedure for consistently monitoring the use of new agents particularly if there are specific guidelines for use
System to provide the formulary electronically with timely updated information
Off-label or ad hoc use of medications
Restricted use (by indication, prescriber, patient care area, patient)
Dose adjustment or discontinuation based on clinical triggers or end points
Injectable to oral conversion
Therapeutic equivalence

development, and pharmacist interventions (clinical and operational), such as parenteral-to-oral conversions, renal-dose adjustments, drug restrictions, repackaging, dosage-form changes, waste reduction, and others. Although the terms are sometimes used interchangeably, therapeutic group refers to a broad classification (e.g., anesthetic agents, anti-infectives, or chemotherapeutic agents), whereas therapeutic class is a narrower designation (e.g., beta-lactam antibiotics, volatile anesthetic gases, serotonin antagonists). If the decision is made to use therapeutic class, then each of the methods of implementation are used as appropriate within the medication categories. An example would be selecting third-generation cephalosporins utilizing a therapeutic interchange for cefotaxime and ceftriaxone (therapeutic interchange method). Third-generation cephalosporins may also be the preferred class of antibiotics within a pneumonia protocol (guidelines method). Examples of using the implementation method rather than the therapeutic class would be to select several drug classes for therapeutic interchange, some for guideline development, and some for other intervention types.

Therapeutic interchange. ASHP defines therapeutic interchange (TI) as "an authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines or protocols within a formulary system."[17] This definition stipulates that the interchange is between two or more drugs that are not generic equivalents. Although FDA defines the term *therapeutic equivalent* to include generically equivalent products, therapeutic interchange or substitution in the hospital setting generally refers to drugs that are not generically identical.

The American College of Clinical Pharmacy (ACCP) Guidelines for Therapeutic Interchange[19] contain a more recent definition of TI:

> Therapeutic interchange is defined as the dispensing of a drug that is therapeutically equivalent to but chemically different from the drug originally prescribed. Although usually of the same pharmacological class, drugs appropriate for therapeutic interchange may differ in chemistry or pharmacokinetic properties, and may possess different mechanism of action, adverse-reaction, toxicity, and drug interaction profiles. In most cases, the interchanged drugs have close similarity in efficacy and safety profiles.

The ACCP guidelines also describe a comprehensive five-part process for health-system TI implementation, with an emphasis on patient safety; an extensive review of drug classes appropriate for therapeutic interchange, including specific evidence-based examples; discussion of legal and regulatory issues; viewpoints of other professional organizations, including the American Medical Association, the American College of Physicians, and the Pharmaceutical Research and Manufacturers of America; and medical and pharmaceutical literature references.

The health system, through the action of the P&T committee, must decide on the general policy for a TI program, particularly regarding the authority and autonomy of the pharmacy staff. The committee may define TI as an automatic conversion by the pharmacist, may require contact with the prescriber before the change can occur, or may employ a combination of both. The prescriber may be informed orally before the drug is dispensed or through written communication in the medical record. Most commonly, TI implies pharmacist autonomy once the P&T committee has sanctioned the policy, but there may be exceptions based on the level of clinical judgment required. A survey of the prevalence of TI conducted in 2002 revealed that the vast majority (88%) of hospitals use TI programs, and most of those did not require the pharmacist to contact the prescriber before making the conversion.[20]

Categories of drugs that offer modest savings with minimal challenge include various non-prescription groups,

such as antacids, vitamins, nonsteroidal antiinflammatory drugs, topical products, and cold and cough remedies. To make significant gains in pharmaceutical cost savings, the health system must consider the drug classes that comprise the greatest proportion of drug expenditures, such as colony-stimulating factors, antiinfectives, cardiac agents, and drugs used in critical care settings. An abundance of literature supports the success of TI programs, both in terms of quality patient outcomes and economic benefit. Based on the literature, therapeutic classes offering the most opportunity for success with the medical staff, as well as significant cost savings, include histamine-2 antagonists, fluoroquinolones, hydroxymethylglutaryl–coenzyme A reductase inhibitors, serotonin antagonists, colony-stimulating factors, low molecular weight heparins, and proton pump inhibitors.[20–27] Although it is not the intent of these guidelines to delineate an exhaustive list of all potential TI opportunities, the appendix contains examples of the TIs that have proven successful.

Most of the evaluative studies on TI initiatives focus on the economic value and quality improvement related to standardization and formulary management. As the popularity of TI programs increases in the acute care, managed care, and ambulatory settings, an associated risk may also increase due to substitutions along the continuum of care and patient confusion regarding drug classes and duplicative therapy.[28,29] The Joint Commission standard requiring medication reconciliation can be partially traced to anecdotal reports of the potential for medication errors as a result of TI programs in various health care settings.[29] Pharmacists can play a vital role in supporting medication-reconciliation activities through medication history assessments and discharge counseling.[30,31]

Guidelines. A variety of terms are used to describe these tools, including prescribing guidelines, therapeutic position statements, therapeutic guidelines, clinical practice guidelines, protocols, or pathways. There may be subtle differences beween these tools, but they all seek to enhance patient safety, reduce variation in medical practice, and increase standardization.

Guidelines can focus on a disease state, a therapeutic class, or a specific drug.[32] Published guidelines are available for many drugs and drug classes.[33,34] The Agency for Health Care Research and Quality maintains an extensive online collection of published guidelines at www.guideline.gov. A 2004 ASHP survey found that 83% of U.S. hospitals use guidelines that include medications.[35] Successful implementation of such general guidelines often requires customization to meet the needs of individual health systems, however. For example, local guidelines should be developed that reflect the best available evidence, incorporate the opinions of local prescriber experts when necessary, and are applicable within the context of the individual health system.

Guidelines are also an important step leading to rules-based computerized prescriber order entry (CPOE), which is recommended by NQF in its 2006 Safe Practices.[36] CPOE facilitates guideline adherence during the ordering process.

Steps to implementing an effective pharmaceutical cost-containment program using drug-specific or drug class guidelines mirror those for TI and include:

- Utilization of evidence-based criteria.
- Adoption of published, evidence-based, and peer-reviewed guidelines from national organizations.
- Solicitation of thought leaders and clinical experts (e.g., physician specialists, chiefs of service, chief medical officers).
- Review and approval of the P&T committee.
- Education of clinical staff.
- Ongoing support from front line clinical pharmacist staff.
- Use of quantifiable measures.
- Utilization of medication-use evaluation (MUE) to determine compliance.

The last step is an important distinction between TI and guidelines because what is approved by the medical staff and what is done in practice may differ. Conducting periodic MUEs with the approved criteria can determine the thoroughness and consistency of the guidelines and ultimately the success of this component of cost management. It should also be emphasized that although guidelines can be used to reduce drug costs, improving quality of care may require more spending rather than less.

When guidelines reduce inappropriate prescribing, drug costs will also be reduced. Due to the complex uses of some drugs and drug classes, such as low-molecular-weight heparins, guidelines may be more practical and effective in managing drug costs than TI and other approaches.[37] Drotrecogin alfa was one costly agent for which guidelines became the standard of care in most acute care settings.[38–40] Other successful guideline efforts have been demonstrated with a number of drugs and drug classes, such as third-generation cephalosporins,[41] statins,[42] antifungals,[43,44] albumin,[45] and serotonin-receptor antagonists.[46] Drug shortages can also be an impetus for the development and implementation of guidelines, as was the case with the use of parenteral pantoprazole, which may be used inappropriately and at a much higher cost in place of histamine-2 antagonists for stress ulcer prophylaxis.[47] Although volatile anesthetic agents are often a top-20 item in the pharmaceutical budget and offer a unique challenge for guidelines or TI implementation, accurate evaluation of cost savings can be accomplished by using the hourly cost to maintain a minimum alveolar concentration.[48]

Implementation of Medication Utilization Management Initiatives. Careful thought and attention to the implementation is required to successfully influence drug expenditures through medication utilization initiatives, and multifaceted interventions are often necessary. The active involvement and support of clinical pharmacists and the medical staff are crucial to effective implementation of these initiatives. It is necessary to seek out ways to integrate or hard-wire initiatives such as guidelines and TI into the care provided at the bedside. For example, passive guideline dissemination (e.g., simply posting to the hospital's intranet site) is rarely successful. Protocols, order sets, and pathways that reflect the evidence in the guideline should be used to integrate the guideline into daily patient care. The growing use of CPOE systems and other technologies can also be leveraged to implement medication-utilization-management endeavors. CPOE can be used to guide prescribing in such straightforward ways as leading prescribers to select formulary products or recommended dosing frequencies.[49] CPOE can also promote efficient medication use through more complex scenarios such as prompting therapeutic interchanges or requiring prescribers to follow interactive prescribing guidelines. For

example, one institution established guidelines for activated protein C use and utilized an interactive computer order entry algorithm to implement the guideline.[50]

Data Analysis. To ensure the validity of the medication-utilization-management program, regardless of the method of implementation, the estimated and actual cost savings calculations must be grounded in accurate and consistent data analysis. Unfortunately, there is no standard regarding a method to determine the pharmaceutical cost savings with programs such as TI. Hospitals have struggled for years to balance practical considerations while striving for accuracy and completeness.[20] Hospitals have to decide early in the process whether to consider indirect costs such as devices and other non-pharmaceuticals, price changes during the review period, general drug price inflation, volume changes, and labor costs.

Equivalent doses for all drug alternatives for each TI must be established based on scientific evidence and current practice standards, which may not be the same as FDA-approved manufacturers' recommendations. Most of the references cited for TI above list the therapeutic equivalence for the drugs in a specific class. *Days of therapy* is the common method to compare equivalent costs of drug therapy within a therapeutic class, particularly for antibiotics and other classes that include scheduled drugs that are dosed multiple times per day. For classes that include drugs with extended half-lives and durations of action, weeks of therapy or cost per course of therapy may be more appropriate. Examples include colony-stimulating factors (e.g., epoetin versus darbopoetin and filgrastim versus pegfilgrastim). Correcting for equivalent strengths, sizes, and units of packaging is another important step in cost-savings calculations, particularly for liquid and parenteral products. The number of standard doses available from a container of liquid medication or a large volume parenteral medication varies based on the size of the container. Medical staff input is important in determining equivalent doses, particularly if there is a divergence between manufacturer's recommendations and published literature on dosing.

Once the methodology of data analysis is established, a drug savings matrix should be developed. This becomes the primary monitoring document that tracks the progress of each initiative based on the changes in utilization. Purchase data is the typical source for maintaining the cost savings matrix, but it is essential to adjust and scrub the data before matrix input. It is important to maintain a consistent common denominator. Utilization increases in certain targeted drugs may be due to patient volume and may be appropriate. Correcting for volume with denominator data and using effective MUE programs will assist with determining actual cost increases. The elements of a standard drug-savings matrix spreadsheet include the initiatives (TI and guidelines), savings targets, baseline purchase dollars corrected for volume, current purchase dollars (after implementation) corrected for volume, and actual savings monthly and year-to-date. It is important to be accurate and include both wholesaler and direct purchases, rebates, and wholesaler discounts.

To maintain commitment to and focus on the process, it is paramount to provide consistent feedback regarding the changes in the cost savings matrix to the P & T committee. Some health systems also establish a reporting structure to another oversight committee, such as a value analysis group or similar body that has overall responsibility for non-labor cost management.

Conclusion

Medication costs continue to rise and will continue to be a target for cost management. Drug costs make up a majority of health-system pharmacy budgets, and budgeting for these expenses is an important function, but longer-term programmatic and policy planning is also essential for successful cost management. An effective plan for medication utilization management must provide the health system with a road map for continuous improvement in pharmaceutical expense containment with specific goals and outcome measures of success. Gathering the data to understand drug expenditures and drug-use patterns is a prerequisite for cost-savings efforts, and constant vigilance and monitoring of these data are required.

A relatively small number of drugs usually makes up the majority of the drug budget. Cost-management efforts focused on these drugs will generally offer the best return. Cost-management strategies that fall completely under the pharmacy department's control (e.g., purchasing and inventory strategies) will be easiest to implement and should be pursued first. Strategies that require an interdisciplinary effort (e.g., use of protocols or guidelines, therapeutic interchange, IV-to-PO switches) can be led by pharmacists with the proper clinical background. Clinical pharmacy services, such as participation in rounds, pharmacokinetic monitoring, and renal dose adjustment, can also reduce drug expenses.

Cost management efforts should be coordinated. The programs should contain a clearly defined and manageable list of cost containment targets with a goal and specific targets for each initiative. Results should be measured and evaluated, and this information should be shared with the interdisciplinary team involved in the effort as well as with health-system administration.

When selecting and implementing drug-cost-management strategies, pharmacists must keep patient safety and the quality of patient care in mind. Cost-management initiatives must never compromise the pharmacy department's ability to provide the best possible care. Fortunately, there are many drug-cost-management opportunities that have little or no potential for detrimental effects on patient care, and efforts to improve appropriate use of a drug or drug class often also offer opportunities for cost containment.

References

1. Hoffman JM, Shah ND, Vermeulen LC, et al. Projecting future drug expenditures—2006. *Am J Health-Syst Pharm.* 2006; 63:123–38.
2. Vogenberg FR, ed. Understanding pharmacy reimbursement. Bethesda, MD: American Society of Health-System Pharmacists; 2005:17–42.
3. ASHP Practice Resource Center for Pharmaceutical Reimbursement. www.ashp.org/s_ashp/cat1c.asp?CID=490&DID=532 (accessed 2007 Sep 10).
4. Clinical Initiative Center interviews. The Advisory Board Company. Washington, DC 2000:20–1.
5. Hoffman JM, Shah ND, Vermeulen LC, et al. Projecting future drug expenditures—2007. *Am J Health-Syst Pharm.* 2007; 64:298–314.

6. Hoffman JM, Shah ND, Vermeulen LC, et al. Projecting future drug expenditures 2004. *Am J Health-Syst Pharm.* 2004; 61:145–58.
7. Hoffman JM, Shah ND, Vermeulen LC, et al. Projecting future drug expenditures 2005. *Am J Health-Syst Pharm.* 2005; 62:149–67.
8. Heffler S, Smith S, Keehan S, et al. U.S. health spending projections for 2004–2014. *Health Aff (Millwood).* 2005; W5:74-WS-85.
9. Rough S, Saenz R. Benchmarking and productivity monitoring: practical strategies for pharmacy managers. www.ashp.org/s_ashp/docs/files/2004LeadershipSummary.pdf (accessed 2007 Sep 10).
10. May BE, Herrick JD. Evaluation of drug-procurement alternatives. *Am J Hosp Pharm.* 1984; 41:1373–8.
11. Wetrich JG. Group purchasing: an overview. *Am J Hosp Pharm.* 1987; 44:1581–92.
12. Yost RD. New economics of the pharmaceutical supply chain. *Am J Health-Syst Pharm.* 2005; 62:525–6.
13. Schumock GT, Meek PD, Ploetz PA, et al. Economic evaluations of clinical pharmacy services—1988–1995. *Pharmacotherapy.* 1996; 16:1188–208.
14. Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996–2000. *Pharmacotherapy.* 2003; 23:113–32.
15. Bond CA, Raehl CL, Patry RL. Evidence-based core clinical pharmacy services in United States hospitals in 2020: services and staffing. *Pharmacotherapy.* 2004; 24:427–40.
16. Bond CA, Raehl CL. Clinical and economic outcomes of pharmacist-managed aminoglycoside or vancomycin therapy. *Am J Health-Syst Pharm.* 2005; 62:1596–605.
17. Coalition Working Group. Principles of a sound drug formulary system. In: Hawkins BH, ed. Best practices for hospital & health-system pharmacy. Bethesda, MD: American Society of Health-System Pharmacists; 2005:125–8.
18. American Society of Hospital Pharmacists. ASHP guidelines on formulary system management. *Am J Hosp Pharm.* 1992; 49:648–52.
19. Gray T, Bertch K, Galt K, et al. Guidelines for therapeutic interchange - 2004. *Pharmacotherapy.* 2005; 25:1666–80.
20. Schachtner JM, Guharoy R, Medicis JJ, et al. Prevalence and cost savings of therapeutic interchange among U.S. hospitals. *Am J Health-Syst Pharm.* 2002; 59:529–33.
21. Goldwater SH, Milkovich G, Morrison AJ Jr, et al. Comparison of therapeutic interchange with standard educational tools for influencing fluoroquinolone prescribing. *Am J Health-Syst Pharm.* 2001; 58:1740–5.
22. Grace KA, Swiecki J, Hyatt R, et al. Implementation of a therapeutic-interchange clinic for HMG-CoA reductase inhibitors. *Am J Health-Syst Pharm.* 2002; 59:1077–82.
23. Steiner MA, Yorgason RZ, Vermeulen LC, et al. Patient outcomes after therapeutic interchange of dolasetron for granisetron. *Am J Health-Syst Pharm.* 2003; 60: 1023–8.
24. Stull DM, Bilmes R, Kim H, et al. Comparison of sargramostim and filgrastim in the treatment of chemotherapy-induced neutropenia. *Am J Health-Syst Pharm.* 2005; 62:83–7.
25. Bollinger KA, Vermeulen LC, Davis SN, et al. Comparative effectiveness of low-molecular-weight heparins after therapeutic interchange. *Am J Health-Syst Pharm.* 2000; 57:368–72.
26. Nelson WW, Vermeulen LC, Geurkink EA, et al. Clinical and humanistic outcomes in patients with gastroesophageal reflux disease converted from ome-prazole to lansoprazole. *Arch Intern Med.* 2000; 160:2491–6.
27. Sodorff MM, Galt KA, Galt MA, et al. Patient perceptions of a proton pump inhibitor therapeutic interchange program across the continuum of care. *Pharmacotherapy.* 2002; 22:500–12.
28. Carroll NV. Formularies and therapeutic interchange: the health care setting makes a difference. *Am J Health-Syst Pharm.* 1999; 56:467–72.
29. Rodehaver C, Fearing D. Medication reconciliation in acute care: ensuring an accurate drug regimen on admission and discharge. *Jt Comm J Qual Patient Saf.* 2005; 31:406–13.
30. Gleason KM, Groszek JM, Sullivan C, et al. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. *Am J Health-Syst Pharm.* 2004; 61:1689–95.
31. Saunders SM, Tierney JA, Forde JM, et al. Implementing a pharmacist-provided discharge counseling service. *Am J Health-Syst Pharm.* 2003; 60:1101,6,9.
32. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's role in the development, implementation, and assessment of critical pathways. *Am J Health-Syst Pharm.* 2004; 61:939–45.
33. American Society of Health-System Pharmacists therapeutic position statements. www.ashp.org/s_ashp/cat1c.asp?CID=516&DID=558 (accessed 2007 Sep 10).
34. American Society of Health-System Pharmacists therapeutic guidelines. www.ashp.org/s_ashp/cat1c.asp?CID=516&DID=559 (accessed 2007 Sep 10).
35. Pedersen CA, Schneider PJ, Scheckelhoff DJ. ASHP national survey of pharmacy practice in hospital settings: prescribing and transcribing—2004. *Am J Health-Syst Pharm.* 2005; 62:378–90.
36. Safe practices for better healthcare: 2006 Update: A Consensus Report. Washington, DC: National Quality Forum (NQF). 2006:22.
37. Schumock GT, Nutescu EA, Walton SM, et al. Survey of hospital policies regarding low-molecular-weight heparins. *Am J Health-Syst Pharm.* 2002; 59:534–8.
38. Bernard GR, Vincent JL, Laterre PF, et al. Efficacy and safety of recombinant human activated protein C for severe sepsis. *N Engl J Med.* 2001; 344:699–709.
39. Matthay MA. Severe sepsis—a new treatment with both anticoagulant and antiinflammatory properties. *N Engl J Med.* 2001; 344:759–62.
40. Thompson CA. High-cost sepsis drug forces pharmacists to weigh patients' future. *Am J Health-Syst Pharm.* 2002; 59:692,697. News.
41. Dranitsaris G, Spizzirri D, Pitre M, et al. A randomized trial to measure the optimal role of the pharmacist in promoting evidence-based antibiotic use in acute care hospitals. *Int J Technol Assess Health Care.* 2001; 17:171–80.

42. Fugit RV, Resch ND. Conversion of patients from simvastatin to lovastatin in an outpatient pharmacy clinic. *Am J Health-Syst Pharm.* 2000; 57:1703–8.
43. Mazzola JL, Belliveau PP, Cheeseman SH. Guidelines for liposomal amphotericin B. *Am J Health-Syst Pharm.* 2003; 60:1480–1.
44. Bower AN, Tang HM, Guglielmo BJ. Compliance in two medical centers with criteria for use of caspofungin and lipid-based amphotericin B. *Am J Health-Syst Pharm.* 2004; 61:915–20.
45. Vermeulen LC Jr, Ratko TA, Erstad BL, et al. A paradigm for consensus. The University Hospital Consortium guidelines for the use of albumin, nonprotein colloid, and crystalloid solutions. *Arch Intern Med.* 1995; 155:373–9.
46. Lucarelli CD. Formulary management strategies for type 3 serotonin receptor antagonists. *Am J Health-Syst. Pharm.* 2003; 60:(10, suppl)S4–S11.
47. Devlin JW. Proton pump inhibitors for acid suppression in the intensive care unit: formulary considerations. *Am J Health-Syst Pharm.* 2005; 62:(10, suppl 2):24–30.
48. Chernin EL. Pharmacoeconomics of inhaled anesthetic agents: considerations for the pharmacist. *Am J Health-Syst Pharm.* 2004; 61:(suppl 4)S18–S22.
49. Teich JM, Merchia PR, Schmiz JL, et al. Effects of computerized physician order entry on prescribing practices. *Arch Intern Med.* 2000; 160:2741–7.
50. Fischer MA, Lilly CM, Churchill WW, et al. An algorithmic computerised order entry approach to assist in the prescribing of new therapeutic agents: case study of activated protein C at an academic medical centre. *Drug Saf.* 2004; 27:1253–61.

Appendix—Therapeutic Interchanges, Prescribing Guidelines, and Other Interventions

Therapeutic Interchanges

The following are some examples of drugs and drug classes for which health systems have successfully implemented therapeutic interchange protocols:

- Angiotensin-converting-enzyme inhibitors
- Adenosine–dipyridamole for cardiac stress test
- Amphotericin, lipid-based
- Angiotensin-receptor blockers
- Benzodiazepine hypnotics
- Beta-lactamase inhibitor antibiotics
- Cephalosporins: first- (oral), second-, and third-generation
- Cholesterol-lowering agents
- Colony-stimulating factors (filgrastim and sargramostim, darbopoetin and epoetin alfa)
- Fluroquinolones
- Glycoprotein IIb/IIIa inhibitors
- Hepatitis B vaccine, pediatric strength
- Histamine H_2-receptor antagonists
- Inhaled and intranasal corticosteroids
- I.V. immune globulin
- Insulins – various, including insulin aspart and insulin lispro
- Iron products, injectable
- Low-molecular-weight heparins
- Narcotic analgesics (fentanyl group) in anesthesia
- Neuromuscular blocking agents
- Nonbenzodiazepine hypnotics
- Proton-pump inhibitors
- Respiratory agents (tiotropium interchanged with albuterol–ipratropium [Combivent, Boehringer Ingelheim], albuterol–ipratropium [Duoneb, Day] interchanged with individual drugs)
- Respiratory spacers
- Selective serotonin-reuptake inhibitors
- Serotonin-receptor antagonists
- Surfactants for newborns
- Thrombolytics
- Viscoelastic agents

Generic Substitutions

Generic products should be used routinely with few exceptions. The following are particularly important for cost savings:

- Amiodarone
- Fluconazole injection
- Megestrol
- Milrinone
- Pamidronate
- Propofol

Prescribing Guidelines

The following are some examples of drugs, drug classes, and diseases for which health-systems have developed prescribing guidelines, protocols, or pathways in collaboration with the medical staff and nursing staff.

- Albumin
- Anesthesia gas, low flow and guidelines for selection
- Antibiotic surgical prophylaxis
- Antibiogram and antibiotic guidelines
- Antifungal (injectable) agents (voriconazole, itraconazole, caspofungin)
- Aprotinin dosing
- Carbapenems
- Chemotherapy-induced nausea and vomiting
- Colony-stimulating factor guidelines/monitoring
- Drotrecogin alfa
- Fosphenytoin
- Heparin-induced thrombocytopenia
- Intensive care unit sedation protocol
- I.V. immune globulin
- Levalbuterol
- Nesiritide
- Octreotide
- Pneumonia protocol
- Postoperative nausea and vomiting
- Proton-pump inhibitors (i.v.)
- Venous thromboembolism, use of anticoagulants in acute coronary syndrome
- Ziprasidone injection

Interventions—Other

Other initiatives or activities that pharmacists can collaborate with the medical staff to reduce drug costs.

Cost per case in anesthesia
Antibiotic monitoring, laboratory reporting of sensitivities
Antibiotic restrictions
Eptifibatide waste reduction
Epoetin alfa waste reduction, prepare syringes
Pegfilgrastim is used in outpatients only

Approved by the ASHP Board of Directors on January 17, 2008. These guidelines supersede the ASHP Technical Assistance Bulletin on Assessing Cost-Containment Strategies dated September 27, 1991. Developed through the ASHP Council on Pharmacy Management.

ASHP gratefully acknowledges the expert panel that developed these guidelines: Michael Rubino, M.S., FASHP; James M. Hoffman, Pharm.D., M.S., BCPS; Larry J. Koesterer, M.B.A.; and Robert G. Swendrzynski, M.S.

The bibliographic citation for this article is as follows: American Society of Health-System Pharmacists. ASHP guidelines on medication cost management strategies for hospitals and health systems. *Am J Health-Syst Pharm.* 2008; 65:1368–84.