

Structuring an indigent care pharmacy benefit program

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Disproportionate-share hospitals (DSHs) and safety-net providers are integrated health care systems that provide substantial outpatient pharmacy services to indigent patients. These organizations have come under increasing financial pressure, since funding from state and local governments—the primary sources of support for indigent care programs—remains fixed or limited. Safety-net providers are paying more for drugs as new drugs are introduced, the use of prescription drugs increases, and drug costs skyrocket. While increased use of pharmaceuticals can be considered positive from a quality-of-care and pharmacoeconomic perspective, rising drug expenditures have a negative financial impact on health systems that operate on a fixed budget. Drug expenditures now receive board-level attention at most DSHs, because continued growth threatens the viability of pharmaceutical services and perhaps the entire organization.

Pharmaceutical care is a patient-focused philosophy that requires the pharmacist to work with the patient and the patient's other health care providers to promote health, prevent disease, and improve quality of life by achieving positive clinical outcomes.¹ Pharmaceutical care recognizes the integrated role that drug therapy plays in achieving these goals and the need for realistic economic expenditures. To achieve these diffi-

cult goals in a financially restrictive environment, pharmacy directors at DSHs have begun to look to private health insurers for tools to design a pharmacy benefit for indigent patients. In this article, we discuss the elements of pharmacy benefit design and management as exercised by managed care organizations (MCOs) and how they apply to programs for the uninsured.

The prescription drug expense problem

Prescription drug expenditures in America continue to escalate.^{2,3} The amount spent on prescription drugs increased by 17.1% between 2000 and 2001 to \$154.5 billion.³ Drug expenditures are growing much faster than the cost of other health services. For example, physician and clinical service costs and hospital costs increased by only 3.7% and 6%, respectively, in 1999 compared with 1998.² According to the Centers for Medicare and Medicaid Services, spending on prescription drugs will continue to increase at annual rates

of 10–12% through 2010.² Key reasons for this increase in drug expenditures include the expansion of the elderly population, increases in identified and treatable diseases, changes in medical guidelines that have led to more aggressive treatment (including treatment with new drugs, earlier treatment, and longer duration of treatment), the trend toward outpatient delivery of health care services, improved patient compliance with prescription instructions, the use of newer and more expensive drug therapies, and direct-to-consumer marketing of prescription drugs.⁴⁻⁷

The pharmaceutical industry argues fervently that new, often more expensive drugs offer improved patient outcomes and lower costs. This “pharmacoeconomic” benefit can be quantified as a cost-to-benefit ratio, indicating that the money spent on a drug will provide financial benefit in the future beyond the drug's price. However, the economic outcomes associated with many new drugs have not been adequately compared with those of existing therapies, making it difficult to gauge the true benefit provided by these expensive new agents.

The uninsured and the safety-net system

The U.S. Bureau of the Census reports that the number of uninsured

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Americans increased by 10 million between 1990 and 1998 to 44.3 million.⁸ However, in 1999 the number decreased by 1.7 million, representing the first decline since measurements began in 1987.⁹ The decrease can be attributed primarily to an expansion in employment-based insurance as a result of a booming economy with a strong job market and to the enrollment of children in the State Children's Health Insurance Program.⁹ The economic prosperity of the 1990s has faded, and the number of uninsured is predicted to rise to 55 million by the end of the current decade if action is not taken.¹⁰

Despite 1999's decline in the total number of uninsured people, there was no significant increase in the proportion of the insured poor,⁹ perhaps in part because of new immigration laws and the 1996 welfare-reform legislation, which limits eligibility for federal Medicaid programs.¹¹ Nearly 1.25 million low-income people lost their Medicaid coverage as a result of welfare reform; an estimated 675,000 were added to the ranks of the uninsured in 1997 alone.⁶ Federal changes in Medicaid policy are predicted to produce an even greater number of uninsured people in years to come, especially if the economy continues to falter.¹¹

The definition of low-income or indigent financial status used to qualify for the Medicaid program generally requires recipients to be at or below the federal poverty level. Nonetheless, many people in need of health care services are unable to qualify for Medicaid coverage and remain uninsured. These patients may have reached Medicaid coverage limits or may have an income high enough to preclude qualification for Medicaid but low enough to limit financial resources for health services. State and local governments and health care providers often provide coverage to these people; an example of such a program is the Virginia Coordinated Care (VCC) system. Vir-

ginia defines medical indigence as "the lack of adequate health care insurance benefits to the individual or family under a federal, state, local, or private health care program and/or the lack of financial resources available to the individual or family unit to obtain necessary medical services."¹² VCC provides various levels of coverage to patients who are at 100–200% of the federal poverty level. Other state and local programs vary in qualification criteria and coverage options, depending on the general political and economic environment, the local health care market, the number of uninsured people, and the level of Medicaid coverage.¹³

The burden of caring for uninsured, medically indigent patients falls primarily on DSHs, community health centers, and other government-supported health care facilities.¹⁴ These institutions are frequently members of the National Association of Public Hospitals and Health Systems (NAPH) and have an "open-door" policy under which they provide medical services regardless of the patient's ability to pay. One out of every four persons treated at an NAPH facility is uninsured.¹⁵ The level of uncompensated care at NAPH hospitals averages 22% of total costs, compared with 6% for the average U.S. hospital.¹⁴ Hospitals often attempt to defray these losses through cost shifting by increasing charges to one group of patients in order to compensate for losses from others.¹³ Safety-net hospitals generally have a relatively small privately insured patient population, making them unable to shift the cost burden to paying patients. This makes them particularly reliant on government support.

The continued viability of safety-net hospitals is being threatened by changes in the U.S. health care system. An increasingly price-driven health care marketplace has resulted in fee-for-service insurance being replaced with prepayment and risk-based capitation agreements, leading

to mergers and other consolidations of many systems.¹³ As other health systems and MCOs identify Medicaid patients as a potential source of revenue, safety-net hospitals often lose market share, especially in historically profitable areas, such as low-risk obstetric and maternity care.¹⁴ The enrollment of Medicaid recipients in managed care plans with cost-control objectives has also contributed to decreases in revenue. Higher penetration by managed care—bringing lower reimbursement rates for physician services—has had a pronounced effect on the willingness of many providers to supply uncompensated care.^{11,16}

Safety-net facilities receive funding from various sources, including Medicare and Medicaid and state, county, and local governments.¹⁴ As a result of the Balanced Budget Act of 1997, payments to DSHs were subjected to substantial cuts.¹³ The Greater New York Hospital Association has predicted that reduced Medicare payments will force the closing of departments operating at a loss and may precipitate the shutdown of entire hospitals.¹² State and local funds often remain static or are not increasing enough to cover the rising cost of care.¹³ As the number of uninsured people continues to grow, DSH facilities will find themselves unable to provide services to indigent patients without commensurate increases in government funding. This situation places safety-net hospitals in direct conflict with the mission of serving all those in need, regardless of ability to pay.¹⁷

Impact of rising drug costs on safety-net providers

The fiscal problems of safety-net institutions are strongly felt by pharmacy departments.¹⁸ Safety-net pharmacies aspire to provide the most effective drugs to all patients requiring treatment. Yet, as drug expenditures continue to rise, government funding has generally declined or re-

mained the same. This has made it difficult for safety-net pharmacies to use expensive new pharmaceutical agents and the more aggressive treatment approaches of disease management programs. Although new pharmaceuticals represent “cost-effective” alternatives, they cause enormous growth in pharmacy expenditures. Even when long-term cost savings are ultimately realized by an organization or a state program, the immediate effect on the operating costs of an outpatient pharmacy can be disastrous.

Some amelioration of high drug costs is provided by federal statute. DSHs qualify for special pricing of outpatient prescription drugs under section 340B of the Public Health Service Act.¹⁹ The Drug Pricing Program requires pharmaceutical manufacturers who participate in the Medicaid program to offer DSH pharmacies the lowest price charged to any purchaser of their drugs. DSHs receive a minimum discount of 15% for brand-name prescription products and 11% for generic prescription and nonprescription drugs. Entities qualify for this program if the hospital is government owned or government controlled, has a Medicare disproportionate-share-adjustment percentage above 11.75%, and does not use a group purchasing organization to obtain outpatient drugs. This act provides basic relief to DSH pharmacies. Nevertheless, as expensive new products are introduced and adopted, DSH pharmacy costs rise at the same rate as for other providers.¹⁸

Applying managed care principles to a pharmacy benefit program for the indigent

The pharmacy benefit provided to indigent patients by state or federal programs is of utmost importance to maintaining optimal health outcomes and reducing the total financial burden of caring for these people. Uninsured groups may also have

a greater need for prescription drug treatment than the population at large. In a recent survey by the American Society of Health-System Pharmacists (ASHP), respondents from the lowest-income households reported using prescription drug products more often than higher-income families.²⁰ Many uninsured patients come from traditionally poorer minority groups and are often at higher risk for certain chronic diseases, including diabetes and hypertension, which can be effectively treated with pharmaceuticals.

Pharmacy directors in safety-net organizations stand at the forefront of the struggle with rising drug costs, reduced payment rates, and decreased government funding. As financial pressures mount, directors have begun weighing practices used in the private sector for controlling pharmacy costs.^{13,18} Managed care has come up with several effective strategies. Using guidelines published by ASHP, the Academy of Managed Care Pharmacy, the American Association of Health Plans, and several other sources, we have developed a list of the key elements of pharmacy benefit design and management as exercised by MCOs. These features are presented below, along with a discussion of how they apply to programs for the uninsured.

Element 1: A formulary system.

All aspects of the formulary and pharmacy and therapeutics (P&T) committee functions in MCOs are applicable to designing drug coverage for indigent patients. However, several new issues arise because safety-net pharmacies operate under a different business model. Although MCOs have responsibility for the health outcomes of patients, many such plans also function with the aim of maximizing shareholder equity. Private health insurers have the option of adding drugs to the formulary as a marketing initiative or to improve purchaser or member satisfac-

tion in order to maintain or increase enrollment. This strategy may include offering “lifestyle drugs” such as sildenafil for erectile dysfunction and finasteride for hair growth.

Safety-net pharmacies have a different goal. Instead of focusing on making a profit, they seek to do the most good for the most people with the funds available. When dealing with limited government payments to cover the needs of the uninsured, a public health approach to formulary decision-making must be taken. Formulary and drug policy decisions should be made according to population-based medicine, with improvement in health status being the paramount goal. Policies and guidelines for drug use should be developed to ensure that optimal drug use, medication safety, and quality review and improvement activities are supported.

We propose a three-step method for managing safety-net-provider formularies: (1) determine whether a drug treatment is essential in meeting public health needs, (2) perform a pharmacoeconomic analysis to compare this essential drug with other pharmacologic and nonpharmacologic therapies, and (3) ask the P&T committee to determine which drugs offer the highest level of health benefits, given available resources.²¹ This method seeks to maximize population-based outcomes by concentrating financial resources on treatments for chronic conditions that clearly improve outcomes; examples of such conditions are diabetes, hypertension, and cancer. While the modest improvements in quality of life achieved through the use of nonessential drug therapies are important for indigent patients, they cannot command the same level of resources as in the private sector. To use resources wisely, lifestyle drugs either should not be included on the formulary or should require a large degree of cost sharing by the patient.

When P&T committees in safety-net organizations evaluate new drugs

for the formulary, issues that arise in the private sector are underscored. Private health plans may consider adding new drugs with fewer adverse effects to their formularies. However, P&T committees in safety-net organizations must insist on a more stringent criterion for economic benefit. Pharmaceutical companies must demonstrate a pharmacoeconomic benefit characterized by clearly improved patient outcomes before a more expensive new product can supplant an older one, especially an older product with a generic equivalent. The burden should be placed on the industry to supply this information in a useful and transparent manner before a new drug is added.

P&T committees in safety-net organizations should also evaluate the impact of patient assistance programs (PAPs) in formulary deliberations. PAPs are manufacturer-sponsored programs that provide free drugs to qualified patients. It is prudent for P&T committees to consider replacing a drug with one that is marginally less effective but covered by a PAP so that resources can be directed toward other programs.

There are problems with PAPs, however. The enrollment process is time-consuming and stringent and varies among manufacturers. In addition, prescription volumes in many safety-net pharmacies overwhelm the providers' ability to participate in such programs. PAPs can be a great boon to pharmacy directors in controlling costs, but is industry doing enough? It is reasonable to expect the highly profitable pharmaceutical industry to make financial and in-kind contributions to public health, but what level of support should be considered appropriate? Van Diepen²² suggested that these programs are a symptom of unaffordable drug prices and offer no real solution to the problem of providing pharmaceutical care to the indigent. PAPs may be initiated primarily as mechanisms for increasing demand and product

loyalty. Although the medications are initially free, patients who are started on expensive, patented agents may encounter cost constraints when they no longer qualify for the assistance program. State government programs and private insurance companies begin to pick up the tab, potentially leading to an overall rise in the cost of care through increased insurance premiums and higher taxes.

Element 2: Reasonable access to pharmaceutical services. Issues related to access of the uninsured to prescriptions and services generally follow the model for insured patients, with a few notable exceptions. Patients must have ready access, acceptable pharmacy hours and locations, and competent, available pharmacist support.

Mail-order pharmacy services may not be considered a broadly feasible option for the uninsured, since many of these people move frequently or are homeless. Indigent patients may also have difficulties with reading and writing and may have deteriorating health or cognitive status, rendering mail services inadequate.

Many safety-net institutions offer their pharmacy benefit only through an inhouse outpatient pharmacy department. However, uninsured patients often have transportation problems and cannot always travel to the facility. Safety-net health systems should consider joining with community pharmacy groups to provide pharmaceutical services. Access can be greatly improved by working with pharmacies located in areas where the patients reside, although this may be a costly proposition.

Pharmaceutical services, including medication counseling, therapy reviews, and disease management counseling, can help improve the outcomes of drug therapy. However, safety-net pharmacies often cannot shift pharmacists away from dispensing. Understaffing and high prescription volumes make it diffi-

cult to provide a level of pharmaceutical services that meets private-sector definitions of quality.²³ Increased departmental funding and improved compensation packages are desperately needed to improve staffing and expand the pharmacist's indigent care role.

Element 3: Reasonable access to medical services. A pharmacy benefit package must provide reasonable access to medical care. Because it is primarily the responsibility of physicians to diagnose disease and determine appropriate pharmaceutical treatment, a comprehensive pharmacy benefit must consider access to physician services. A physician provider network should be established that is based on one of the many managed care models. The network should allow for low costs to the plan, be acceptable to plan members, and provide access to both primary care providers and medical specialists.

The network used by the uninsured poor includes physicians practicing at safety-net institutions, other local providers under contract, and providers who offer charity services. Because of reduced reimbursement rates from MCOs, many physicians are no longer willing to provide the same level of charity services.¹¹ This makes it increasingly difficult to develop or maintain a physician network. Safety-net providers should devote substantial resources to developing and maintaining appropriately sized and distributed physician networks. This will provide patients with better access to care and timely diagnosis and treatment.

Element 4: Defined financial participation by patients. One of the problems inherent in prescription benefit plans is a reduction in the sensitivity of patients to the cost of pharmaceuticals. Managed care programs generally provide lower-cost access to expensive drugs. In the past, pharmaceuticals were paid for out of pocket. Today, a majority of prescriptions are covered through health

insurance plans. Most plans have historically offered all formulary drugs for a single low copayment. Newer tiered-copayment systems produce acceptable patient financial participation and function as a disincentive to inappropriate or unnecessary prescription drug use.

A potential source of revenue for safety-net pharmacies is the patients themselves. While introducing cost-sharing practices into traditional managed care plans has been controversial, it is even more problematic to apply cost sharing to patients who by definition have insufficient resources to pay for care. Yet, as the number of uninsured people continues to climb, the prices of prescription drugs increase, and funding from state and federal programs remains inadequate, it is appropriate to reconsider this option. The belief that indigent patients must receive all prescription drugs free or with nominal copayments must be reexamined. Even the indigent need to be financially responsible for some portion of their prescription drug costs. Providers need to determine the appropriate level of patients' financial participation and how best to manage it.

It would not benefit the public health or individual patients if the use of necessary pharmaceuticals decreased, saving money in the pharmacy but increasing emergency department visits and hospital admissions. It has been reported that requesting copayments from indigent patients decreases both prescription utilization and prescription service expenditures.²⁴ Research addressing how such increased cost sharing affects patient outcomes in low-income patients is sparse and inconsistent. A recent study conducted in Canada examined the effects of changing a copayment of \$2 per prescription with a \$100 yearly cap to 25% coinsurance with a \$200 yearly maximum for welfare patients and income-indexed ceilings of \$200, \$500, and \$750 for elderly persons.²⁵

This change decreased the use of pharmaceuticals but also significantly increased emergency department visits and serious adverse events. An increase from a \$2 copayment to 25% coinsurance is a tremendous increase in cost sharing. A more rational plan may be a tiered-copayment system, something many safety-net pharmacies have already instituted.¹⁵

Element 5: Health management systems that coordinate the pharmacy benefit with other health programs. All health management principles can be applied to indigent populations. A full range of services, including treatment, prevention, and education, is needed to maximize health status. Since health management has a population-based approach, attempting to channel resources toward those most in need, it fits well with the overall design of a pharmacy benefit package for the indigent. This approach also recognizes the integrated role that pharmacotherapy plays in overall health outcomes.

A disease management approach that seeks to manage and improve the health status of a carefully defined patient population over the course of disease should be employed. This includes not only managing already developed disease but preventing disease manifestations before they occur. Such a goal may be achieved by educating people to take personal responsibility for their health and to become actively involved in their treatment.

Element 6: Basic business support and utilization management systems. Utilization management is central to the success of any health plan, whether it is for insured or uninsured patients. The goal of utilization management is to ensure that resources are used appropriately. Clearly defined criteria should be used to determine that the patient qualifies for treatment under the plan and that the treatment is both reasonable and medically necessary.

To be covered by safety-net institutions, patients must qualify for the federal Medicaid program or for a state or local plan. Safety-net institutions use financial counselors and clerks to identify patients who qualify for state or local programs. Patients who have any form of health insurance, including Medicaid, are generally not eligible for these programs. Accurate assessment is necessary for successful eligibility management.

A prior-authorization system may be initiated for certain drugs. Although prior authorization may limit the use of certain expensive drugs, it also requires restructuring of the pharmacy computer system and may necessitate documentation from the prescriber. Such a strategy is often out of reach for organizations with limited funding.

A tiered-copayment or coinsurance system is another option for controlling utilization. While tiered copayments may be used to set an adequate amount of patient cost sharing, they serve the dual purpose of creating a "hesitation factor." Tiered copayments or coinsurance can be used as an alternative to formulary exclusion for lifestyle drugs. For example, a safety-net pharmacy may have a copayment of \$2 for most prescriptions, a \$10 copayment for more expensive brand-name products, and 25% coinsurance for lifestyle drugs. This approach combines the principles of patient cost sharing and utilization management.

Annual deductibles and certain other financial restrictions may be applied to indigent populations. If set at a reasonable level, deductibles can provide a viable option for increasing revenue. A deductible may serve more as a cost-sharing method than as a deterrent to overuse of the benefit. The effect of a deductible on compliance and therapeutic outcomes is not known.

Payment caps may be attempted to block potential overuse of benefits. While this may be a reasonable

method of cost containment for insured populations, its application to the uninsured is questionable. Many indigent patients are greatly in need of expensive pharmacotherapy, such as cancer chemotherapy. A payment cap could result in poor outcomes and an increase in total health expenditures. For indigent populations, a payment cap may be applied the opposite way, by limiting yearly out-of-pocket expenses. Coverage limitations can also reduce overuse of the benefit, but the same arguments apply.

Physician profiling and prescribing restrictions may be applied to the uninsured the same way they are to the insured.

With limited employee resources, it is important to get the most value out of human capital. While pharmacists always perform basic checking before dispensing each prescription and follow up any discovered problems, it may not be practical to have pharmacists performing extensive manual drug therapy reviews in the indigent care setting. For analysis of drug-use patterns, a new computer system may be needed.

Element 7: An effective purchasing system. Safety-net pharmacies are in a unique situation with respect to the purchase of pharmaceuticals. DSH facilities already receive the “best price,” as stipulated by section 340B of the Public Health Service Act. Therefore, negotiations with manufacturers that are based on the movement of market share may have only a modest impact on the cost of drugs, since reducing prices further will lower the “best price” for other government purchasers. Discounts for bulk purchases should already be optimized at safety-net pharmacies, but efforts to manage costs through contracting at sub-340B prices should be pursued.

Element 8: A benefit contract. Commercial health insurance benefits are legally enforceable contracts under which the MCO agrees to provide explicitly defined prescription

drug benefits for a specific price and the purchaser agrees to accept the coverage and access rules.

No legal contract exists in the provision of care to indigent patients. Federal Medicaid and state or local programs identify the specifics of the benefit. Nonetheless, the terms of the benefit must be presented to enrollees accurately and clearly to ensure appropriate use. Communications should describe the available services, how to access these services, what financial participation is required, and how payments will be collected. The covered population should be considered when developing this statement. Indigent patients may have special limitations, such as inability to read or speak English. Information describing the benefit should be available in all relevant languages or provided in person by a counselor. Patient confidentiality should be maintained at all times for all patients who are enrolled in the plan.

Element 9: Quality control. Quality control and quality improvement measures should be used wherever possible. Because of the financial status of most safety-net organizations, the pharmacy systems used may be aging or ineffective. While there are no specific quality-related guidelines for safety-net providers, internal reviews should be conducted periodically. There should be guidelines for addressing and correcting problems or inefficiencies as they arise. The quality-control system used should be as cost-effective as possible.

Member satisfaction is one of the primary goals of health plans. While safety-net providers should offer as many conveniences as possible to covered patients, their goal is to improve public health rather than maintain a membership base. Nevertheless, participation by beneficiaries in setting expectations for service and quality should be actively encouraged by safety-net providers. In addition, outcomes research should

be conducted if possible to ensure that the care delivered is of the highest quality. Safety-net organizations may be able to establish partnerships with local pharmacy schools in attempting to measure outcomes of the pharmacy benefit.

Discussion

Many special issues must be considered when designing a pharmacy benefit package for the poor. The reasonable and thoughtful application of managed care pharmacy principles may provide an intermediate solution, but a more permanent answer will be needed as costs continue to escalate and financial restrictions tighten. Pharmacists, with their skills and their knowledge of drug therapy, must become actively involved in this process—working closely with physicians, administrators, and policymakers to help the uninsured receive needed pharmaceutical services.

Because the missions of MCOs and safety-net institutions differ, some adjustments are needed to apply these program features to uninsured patients. The adjustments, which should be possible for most safety-net providers with a modest investment in infrastructure, will increase the effectiveness of the pharmacy benefit plan and contribute to its survival.

Conclusion

Many features of pharmacy benefit management in the private sector also apply to programs that support the health care needs of the uninsured.

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