Pharmaceutical Manufacturer Prescription Assistance Programs: Are They Worth It?

Providing medical care for the uninsured population is a growing concern. Approximately 45 million people in this country have no health insurance and the percentage of uninsured continues to grow. Nearly 18% (8 million) of the uninsured are children while 1 in 5 are adults aged 25 to 64 years. In the face of this important social problem, the uninsured may forego health care services due to access issues, and in the end, utilize more costly medical services due to untreated diseases. It has been estimated that every year, as many as 18,000 unnecessary deaths were caused by lack of health insurance. In addition to the effect on quality of life, this issue has a major financial impact on the public health system. The Institute of Medicine estimated that the annual lost economic value of being uninsured in the United States is between $65 billion to $130 billion.

Escalating drug expenditures and reduced insurance coverage in the United States compounds the problem with access to prescription drugs. Pharmaceutical manufacturers offer prescription assistance programs (PAPs) to make certain brand-name prescription drugs available to low-income patients who are not eligible for public assistance programs and are without private insurance. It was hoped that PAPs would have a favorable effect on health outcomes such as hospitalization rates and emergency department visits through improved medication access and adherence. PAPs have evolved to become a safety net for millions of needy Americans who are not eligible for comprehensive assistance programs and unable to afford their medications. Much evidence justifies the benefits of establishing a PAP to assist indigent patients in obtaining their needed medications.

Since 2006, a majority of manufacturers have streamlined their PAPs to require 1 application per year with the exception of Novo Nordisk, Forest, Sanofi-aventis, Sankyo, and Biovolta. The development of a “universal” application process would greatly benefit patients and health care providers by reducing personnel time required to complete individual applications tailored to specific manufacturers. Even if the PAP form is simplified in a more universal format, our experience suggests that most patients will encounter difficulties completing the application on their own since the application requires an accurate interpretation of prescriptions to transcribe specific information such as drug name, strength, direction, quantity, duration, and number of authorized refills. Drug manufacturers frequently change their eligibility criteria and the list of drugs available in PAPs, making it difficult for indigent patients to stay abreast of the program changes. Additionally, many underserved patients may be challenged with limited health literacy and some suffer from deteriorating health or cognitive status that prevents them from completing the application without assistance. Therefore, it is critical for health care providers to help these patients through the enrollment process to ensure that they have access to their required prescription drugs.

The increased need for PAPs makes the question of their operational cost important for administrators of medical clinics considering implementing such a program. In their time and motion study reported in a recent issue of JMCP, Clay et al. attempted to capture the overall cost of a PAP incurred by a free health clinic in Kansas City. The results showed the estimated annual cost of providing PAP service at the clinic was $81,835 at an average expense per patient ranging from $10.42 for a medication with 1 annual application up to $46.30 for manufacturers requiring 4 applications per year. The PAP enrollment process is time- and labor-intensive; therefore, personnel costs accounted for the highest component of the annual PAP expenditure. Clay et al. used the wage of a medical assistant with an hourly rate of $12.21 plus benefits ($4.23) as the basis of the personnel cost. This study establishes a benchmark for administrators who are considering the establishment of an onsite PAP at a medical facility similar in size and nature of the population served at the Kansas City Free Health Clinic. Additionally, this information is valuable for budget development while seeking funding or donations to establish or maintain a PAP.

A comparison with a PAP in another medical clinic provides insight into the considerations made by Clay et al. As the only Federally Qualified Health Center located in the Greater Lafayette, Indiana area, Tippecanoe Community Health Clinic (TCHC) provides coordinated primary health care to more than 9,000 uninsured county residents annually who have limited access to health care due to lack of financial resources or health care expense reimbursement. More than half of the clinic’s patients receive Medicaid assistance, and 40% are uninsured. Furthermore, approximately 67% of a patient’s income falls below the 100% federal poverty level. As the pharmacist at TCHC, one of the authors provides comprehensive clinical pharmacy services through consultations with providers, PAP clerks, patients, and other allied health care professionals.

The PAP at TCHC began in 1999 with 1 part-time nurse working 10 to 15 hours per week and has expanded to its current staffing level of 1.8 full-time clerks with support from doctor of pharmacy candidates. The medical director and nursing supervisor provide managerial oversight of the PAP and pharmacy consultation is accessible onsite. In 2005, TCHC processed 5,671 PAP applications (2,652 new and 3,019 renewals) contributing more than $1.7 million in acquisition costs for the medications received. The PAP office resides within TCHC and offers both scheduled and walk-in services. Clinic patients are referred to PAP by their providers or other patient advocates (e.g., pharmacist, specialists, dietician, and nurses). If an uninsured patient is unable to afford low-cost drug regimens (e.g., discounted generics through the 340B program or $4 local pharmacy generic drugs), individual prescriptions written per specific manufacturer guidelines are given to patients to bring to the PAP office to determine enrollment eligibility and process the application. Some differences exist between the PAPs at the
Kansas City Free Health Clinic and TCHC. Due to the high volume of patient enrollments at TCHC, RxAssist Plus Patient and Medication Tracking Software\textsuperscript{15} was installed to streamline the application process and reduce personnel time. To offset clinic expenses and encourage patient accountability, a $3 processing fee for each application is required. All patients are required to pay, with the exception of homeless patients, for whom the fee is waived. If patients cannot afford the processing fee, the application is placed on hold until they can afford it, or other sources are identified to assist with the fee.

Individual credit checks are not preformed at TCHC because manufacturers do not require this as part of the supporting documents. At TCHC, all new applications are submitted via either fax or mail, with the latter method producing slightly longer processing times but yielding more dependability. The original PAP applications are never destroyed, and only 1 copy of the application is kept on record. Although some manufacturers accept online orders, the majority of refill renewals are communicated through a toll-free telephone number. The personnel time required to renew an application is significantly less than the time needed to process a new application. However, Clay et al.\textsuperscript{14} did not address the costs of renewing applications.

The monetary imputation estimated by Clay et al. may not have adequately captured the entire cost necessary to operate a PAP.\textsuperscript{16} First, the authors only accounted for the direct costs (e.g., personnel, supplies, application submission fees), required to process an application and dispense medications. Indirect costs such as utilities, office space, furnishings and equipment, as well as storage were not included in their final calculation. The overhead expenses may also include salary costs of providers and other patient advocates since they, too, have an active role in ensuring proper functioning of the PAP. In addition, if clinics wish to utilize the computerized application method, the cost of necessary software and associated expenses should be considered in the budget calculation.

Second, the authors’ personnel cost estimate was based solely on the salary of medical assistants, who have relatively low payroll expenses, and excluded costs for any managerial oversight or pharmacy involvement. Providing PAP with the goal of improving patient outcomes requires a team effort from a variety of patient advocates. One also needs to be mindful that the tasks required for PAP submissions and delivery are typical of the functions of a pharmacist, particularly the ability to accurately interpret a prescription, dispense the medication, and deliver appropriate patient education. Without patient education, the full benefit of PAP may not be evident because a lack of patient education may contribute to medication errors and can negatively affect patients’ health outcomes. Inclusion of a clinical pharmacist to support PAP is vital to its effectiveness given the specialized training pharmacists receive. Roles of a clinical pharmacist supporting PAP administration by a medical group or clinic may include but are not limited to: (a) making accessible and effective recommendations for therapeutic interchange; (b) serving as a liaison between the patient, other health care professionals, and the program; (c) dispensing sample medications while patients await PAP coverage; (d) providing coordination of care; (e) providing patient counseling; (f) overseeing other support staff to verify prescriptions; and (g) maintaining an updated formula.

If inclusion of a pharmacist is not a viable option for the medical clinic, the time and resources needed to educate non-pharmacy personnel on methods to ensure medication safety should be accounted for as well as the potential for staff turnover. Alternatively, pharmacy technicians, social workers, or other support staff working under the supervision of a pharmacist may be an effective and less costly choice to administer the program. Pharmacist-coordinated PAP programs in various settings have demonstrated net cost-savings to justify the higher pharmacy personnel costs.\textsuperscript{6-7,11,16}

Third, medication delivery may take 2 to 6 weeks, so other means to bridge with an accessible and affordable therapeutically equivalent alternative may be necessary while waiting. This is a potential area for medication errors since patients are at risk of duplicating drug therapies if they do not receive proper counseling to discontinue the bridge medication. Furthermore, if dose adjustment is needed during this period, a patient may incorrectly administer the medication ordered at the previous dose without appropriate education.

Fourth, Clay et al. apparently did not measure the time required for providers to review patient charts to ensure that appropriate medication doses are dispensed. Additionally, staff to provide coordination of care is needed to avoid potential missteps and overlap that can affect the effectiveness of the PAP. For example, the drug manufacturer only allows one shipping address but medications in a PAP could be ordered independently by a specialist that does not practice in the same location as the primary care provider. If a patient has an established PAP through the primary care provider, all medications from that manufacturer will be delivered to the patient’s primary care clinic. Hence, coordination of care between specialists and the primary care provider becomes essential for proper patient monitoring which makes outsourcing PAP a less attractive option.

Calculating the true cost to deliver PAP services is important to the implementation, maintenance, and improvement of these programs. However, while financial considerations play a significant role, other factors such as patient needs and outcomes are essential for consideration. Despite the necessary expenses involved in administering PAP, the net financial and human benefit generated from PAP for patients and health care providers can be enormous.\textsuperscript{37} Examples of cost-savings from the establishment of PAPs have been demonstrated in a renal transplant clinic (a minimum of $4 was returned to the institution for $1 spent in the pharmacist’s time).\textsuperscript{6} Additionally, a PAP at a medical center clinic resulted in cost savings of $237,985 over 6 months,
yielding a benefit-to-cost ratio of 2.2:1." Nykamp and Ruggles reported that maintaining adherence to needed medications improves care for underserved patients and leads to decreased health care expenditures. This financial information can be useful to help obtain funding or calculate cost-sharing strategies necessary to offset the administrative expenses.

Without PAPs, it will be nearly impossible for a nonprofit clinic serving a large underserved population to financially afford the high cost of medications through the discounted 340B drug-pricing program. Nevertheless, underserved patients will not be able to afford the sliding scale fee associated with the brand medications, and the uncompensated cost from medication expenditures will eventually be absorbed by the clinic, resulting in further debt. The last option would be to deny patients the medications they need that will, in turn, increase the overall health care expenditure through hospitalizations and nursing home admissions, and emergency services. Numerous patients at TCHC have affirmed, “If it were not for PAP, I would not take my medications.” Therefore, medical facilities that serve a large indigent population will benefit from investing in personnel who can assist patients with PAP. The benefits of PAP likely outweigh the overall costs. Future studies evaluating the impact of PAP on patients’ health outcomes (economic as well as humanistic and clinical) for the entire health system are needed to further confirm the benefits of the PAP for uninsured patients.

DISCLOSURES
Judy T. Chen is a pharmacisttherapist responsible for providing pharmacy consultation through referrals from PAP clerks, providers, and other allied-health professionals at the Tippecanoe Community Health Clinic. Kent H. Summers discloses no potential bias or conflict of interest relating to the subject of this article.

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