A Model Oncology Patient Assistance Program

The Problem
Sarasota Memorial Health Care System, a community not-for-profit hospital located in Southwest, Fla., faced a growing challenge of how to effectively case manage its uninsured and underinsured cancer patients.

The Solution
During discussions on how to reduce the negative financial impact on the health system's outpatient infusion department, a suggestion was made to start an oncology patient assistance program.

Uninsured and Underinsured: A Growing Concern

Sarasota Memorial Health Care System is the safety net provider in its region. In recent years, however, its outpatient infusion center has seen a drastic increase of patients who cannot afford their chemotherapy treatment. Before too long, the hospital's outpatient infusion center began to experience fiscal difficulties. After the Pharmacy Department voiced concerns over ever-increasing drug costs, the hospital recognized that it would have to make changes to how it was providing care to its uninsured and underinsured patients.

At the same time, in my former role as oncology case manager, I began to see an increasing trend of repeat admissions and lack of follow-up after cancer diagnosis. A few cancer patients experienced the feeling of getting "lost" in our healthcare system. These patients were often anxious, frightened, and desperately in need of social services.

The Solution: An Oncology Patient Assistance Program

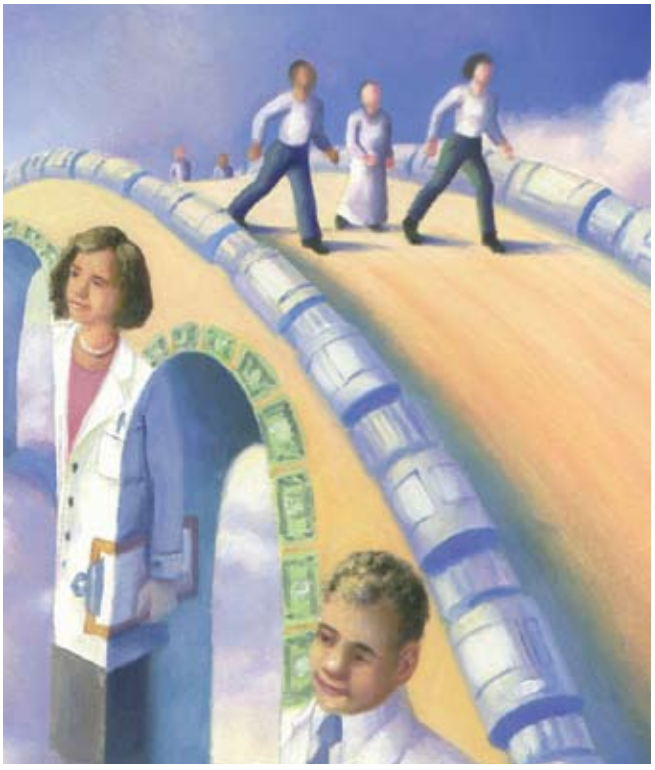
Calling on my years of experience managing an outpatient clinic, I suggested that patient assistance programs might possibly mitigate some of the fiscal challenges the hospital faced. A few hours of research verified that most of the major drug manufacturers have established patient assistance programs. Accessing these programs would benefit the hospital's cancer patients *and* help the outpatient infusion center recoup some of its financial losses. Even more important, these programs would help our uninsured and underinsured patients pay for their chemotherapy and allow the hospital to continue acting as the safety net provider for these underserved patients.

The first step was developing a comprehensive, well-thought-out plan for introducing and managing this new program. Equally important—identifying a champion to encourage and promote the program. In our case, two leaders stepped up to the plate: the director of Oncology Patient Services and the director of Pharmacy. Both individuals recognized the value of an oncology patient assistance program and actively supported and promoted the program.

In the fall of 2003, I started meeting with the hospital's uninsured and underinsured cancer patients, applying on their behalf for drug replacement and assistance from the major pharmaceutical companies. The program started small—in an accordion file that I kept next to my desk. Slowly but steadily, the file and the number of patients I was helping grew. At the start I worked on this program only part-time, but the cancer program quickly realized that its patient volumes required a full-time commitment to truly ensure the program's success.

Once the decision was made to allow me to work full time on the oncology patient assistance program, our cancer program developed a pre-clinic appointment system. All new cancer patients—regardless of payer source—meet with me and our oncology social worker prior to treatment.

At this pre-clinic appointment, we provide an orientation to our unit, perform an admission assessment,



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and obtain any necessary lab tests. We also sit down with patients and family members to review an individualized education packet with information about that patient's diagnosis and plan of care, which was put together prior to their appointment. During this visit, I also evaluate for eligibility and interest in patient assistance programs. Patients and their families spend the last part of their pre-clinic visit with the oncology social worker. Any referrals that need to be made are done at this time to the appropriate agencies.

The addition of this pre-clinic visit has had a measurable positive effect on our cancer patients and their families. Anecdotally, patients have shared that "they feel they are part of their treatment team and better prepared for their experience." From the hospital's perspective, the pre-clinic visit allows staff to be proactive and completely focused on meeting the needs of our patients. Moreover, the pre-clinic visits have improved patient outcomes and reduced hospital admissions—a win-win situation for patients and staff.

Learning as We Grew

As with any new program, we faced our share of challenges. Each pharmaceutical company patient assistance program is different, including the application processes and the eligibility requirements. Even established relationships must be continually monitored, as pharmaceutical companies often make changes to their application process and eligibility requirements.

Once our applications for drugs started being approved, our pharmacy was taking delivery of drugs that had not been ordered through the pharmacy's ordering system. We quickly realized that we needed to develop a proper storage and release method for these drugs. We also needed a full-time pharmacist to oversee the drug replacement program. Eventually, our patient assistance program was bringing in enough volume to justify a part-time pharmacy technician. (For more on the pharmacist's perspective, turn to page 24.)

One of the first tools created by our pharmacist was a spreadsheet that tracks a patient's use of the drug, when the initial patient assistance application is made, and when and how much of the drug was financially recouped for each patient.

At this time, we realized we would need to add another important member to our oncology patient assistance team—a staff member from the finance department. In fact, a financial liaison is necessary to comply with most pharmaceutical company patient assistance programs. At our institution, our financial staff member is responsible for taking the information from the spreadsheet discussed above and placing it in the correct financial accounts so that all patients are credited appropriately.

The Application Process

Enrolling a patient in our oncology patient assistance program is not a simple task.

To assess for eligibility and interest in the program, I must first review each drug application and all of its requirements with the patient. Interested patients must then provide necessary documentation. I make it clear to patients that the process cannot go forward without this paperwork.

Once I have received the proper documentation from the patient and determined that the patient is eligible, I obtain patient consent and forward the application to the appropriate physician for his or her signature.

After the application is submitted to the appropriate pharmaceutical company, I need to monitor it closely and follow up to see if the application has been reviewed and if the application has been accepted or denied. Fortunately, our denial rate is low because of our thorough pre-screening process and because we ensure that all the necessary documentation is submitted with the application.

Once an application is approved by the pharmaceutical company, the drug shipment must be tracked to ensure that the correct amounts are received and credited to the appropriate patient. At our institution, a pharmacy technician or pharmacy inventory control specialist is responsible for identifying the drug shipment as a patient assistance drug program shipment, determining if the drug has been shipped intact, and then dating and initialing the invoice with copies provided to both the pharmacist and the oncology care coordinator. The information is then entered into the patient assistance program drug spreadsheet and held in separate inventory until the pharmacist approves the release of the medication.

Medication is usually shipped in monthly increments and the oncology care coordinator is responsible for applying for continued shipments of the drug or beginning new applications if the patient's drug therapy changes.

We also work with cancer patients to identify other sources of coverage and help them apply to any eligible programs. These programs include federal and state programs, such as Social Security, Medicare, and Medicaid, and nonprofit programs, including the American Cancer Society, the Susan G. Komen Breast Cancer Foundation, the Patient Advocate Foundation, the Leukemia and Lymphoma Society, and the Cancer Fund of America. Once patients become eligible for any other coverage, they are taken off the oncology patient assistance program immediately and their financial class is changed by our financial liaison.

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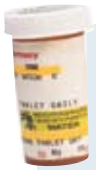

The Pharmacist's Role

by Lisa Hymel, PharmD

Developing and maintaining a successful oncology patient assistance program requires a multidisciplinary approach. Pharmacists bring to the table a unique skill set, including regimen assessment and monitoring; patient and staff education; and expert drug management. Here's a brief look at how our team works within an oncology patient assistance program.

Regimen Assessment and Monitoring

At Sarasota Memorial Health Care System, notification of a pre-clinic appointment for a new chemotherapy patient sets many wheels into motion.

The pharmacy's first responsibility is to review the chemotherapy orders. The process is not simple. In addition to checking for appropriate indications, dose, and rate of infusion, we must also look at the drug regimen in terms of what it will *cost* the patient and the institution. In today's restrictive reimbursement climate, this last question has become increasingly important. At the same time, as a pharmacist, it is becoming more difficult to recommend a lower cost therapy given the more innovative, well-studied chemotherapies that are rapidly becoming the standards of care.

At Sarasota Memorial Health Care System, as in most other comprehensive cancer centers, we believe that *all* cancer patients should have access to the latest treatments, regardless of whether or not they can pay. Our model oncology patient assistance program allows us to treat our patients equally—without incurring heavy financial losses to the healthcare system.

Patient and Staff Education

The chemotherapy education sheets our patients receive at their pre-clinic visits were developed by our pharmacy department.

We also provide face-to-face patient education on the second day or cycle of chemotherapy—sooner if the patient needs immediate education. During these visits, the pharmacist and patient go through a patient care checklist to assess for any chemotherapy-related symptoms. Following this assessment, we provide detailed information about the treatment regimen and/or drugs and make any necessary interventions or changes in therapy.

In addition to patient education, the pharmacy department provides support and education to cancer center staff. The oncology care coordinator, for example, comes to us with any prescription-related concerns, such as a prescription not being filled. Our pharmacy department then works with the oncology care coordinator and our social workers to resolve these issues.

Free Drug Management

As part of a double-check system, the pharmacy department is also responsible for reviewing all applications that come out of the oncology patient assistance program. Once applications are approved, the pharmacist or pharmacy technician faxes the application to the appropriate company. The pharmacist and the pharmacy technician then track the drug until it is received from the drug company. After signing for the drug, the pharmacy technician inputs the drug quantity and the date received into the master drug spreadsheet for the oncology patient assistance program and ensures that the drug is credited to the appropriate patient. When we verify drug receipt from the manufacturer, we can then reverse the drug charges that were made to the patient's account.

One challenge: many of the pharmaceutical programs are prospective replacement programs only. If a patient starts therapy prior to being enrolled in the oncology patient assistance program, for example, some companies do not replace the drug our pharmacy has already dispensed. We have to then charge the patient for the drug that has already been dispensed. If the patient cannot pay, the account may have to be closed with no reversals. In these situations, our pharmacy takes the loss. In the end, however, it is still better than having to take the financial loss for the entire treatment regimen.

Some pharmaceutical patient assistance programs offer retrospective replacement, in which case the pharmacy does not have to incur this bad debt.

The situation can become even more complex for our Medicaid patients. For example, some pharmaceutical companies withhold approval of patient assistance applications if they know that the patient has also applied for Medicaid. (Oftentimes, this information is required on the pharmaceutical company's application.) There have also been times when patients go on Medicaid in the middle of their treatment. In these situations, we reverse the amount of the drug we have already received off of the patient's account, close out all pending patient assistance applications, and bill the remainder of the treatment regimen to Medicaid.

These complex scenarios underscore the importance of having a finance staff member on the oncology patient assistance team.

At least twice a month, the pharmacist reviews the master drug spreadsheet for the oncology patient assistance program.

Another challenge has been to ensure that the drug is actually delivered to the pharmacy department—and not to the office of the physician who signed the application. Given the choice, manufacturers seem to want to deliver to the physician's office versus our hospital-based outpatient infusion center. We rely on our efficient tracking system and the support of the receiving department to successfully manage the drug inventory of the oncology patient assistance program.

As a member of the oncology patient assistance program, I find that nearly every work day offers something new and different to do. Some days, I feel like I am attempting to put together a financial "puzzle" where the pieces don't quite seem to fit. Other times the pieces seem to fall perfectly into place. No matter what the day is like, I know that our program has made a positive difference in the lives of many of our cancer patients.

Lisa Hymel, PharmD, is a clinical pharmacist in the Outpatient Oncology Department at Sarasota Memorial Health Care System in Sarasota, Fla.

10 QUICK TIPS
FOR STARTING AN ONCOLOGY PATIENT ASSISTANCE PROGRAM

Step 1: Gather Your Facts.
Research your patient volume. Know what treatment regimens your cancer center is losing money on and why. Find out if the manufacturers of these drugs have a patient assistance program.

Step 2: Develop a Plan.
If your hospital or practice is going to invest staff time in the program, you need to show exactly how this program will work. Identify staff responsibilities and develop a budget, including a forecast of how much money the program can recoup in drug replacement costs.

Step 3: Identify a Champion.
As with any new program, you need staff and physician buy-in to be truly successful. Oncology will need to work closely with Pharmacy to get this program up and running.

Step 4: Meet with Patients.
Develop a system for meeting with your uninsured and underinsured patients. Establish a process for educating patients about the program.

Step 5: Put Together a Team.
Decide who will oversee the patient assistance program. Know which staff will be a part of the team: case managers, oncology nurses, social workers, pharmacists and/or pharmacy technicians are a good start.

Step 6: Identify a Way for Managing Drug Inventory.
Develop a spreadsheet for all patients receiving drugs through the oncology patient assistance program. This information is necessary to comply with pharmaceutical company guidelines and to credit patients correctly.

Step 7: Familiarize Yourself with the Different Pharmaceutical Patient Assistance Programs.
Build relationships with your industry counterparts. Monitor any changes to their drug replacement applications or eligibility criteria.

Step 8: Streamline the Application Process.
Know what information you need, including any patient documentation. Develop a timeline for submitting, monitoring, and following up on all applications.

Step 9: Measure the Program's Success.
Communicate to management the dollar amount of replacement drugs that the program has recouped. Gather data about patients that your program has helped. Measure how the program is improving patient outcomes and the cancer center's bottom line.

Step 10: Identify Opportunities for Growth.
In addition to pharmaceutical patient assistance programs, consider helping with appeals and denials. As the number of uninsured and underinsured patients increases, invest resources to grow the oncology patient assistance program.

A Wise Investment

Our oncology patient assistance program has been up and running since the fall of 2003, and I have never had a negative experience with a pharmaceutical patient assistance program representative. Instead, it is clear that the goal of these companies is to make sure that eligible patients have access to their life-saving drug.

Pharmaceutical patient assistance programs are either prospective (where product is supplied from the time the application is approved) or retrospective (where the entire treatment is covered). While prospective programs provide drugs for current or upcoming regimens so that the cancer center does not have to supply the drug and wait for it to be replaced, these programs do not replace drugs that have already been provided to the patient. If patient applications are not submitted before the first treatment is given or if an application is held up waiting for signatures or paperwork from the patient, the cancer center can still incur drug costs. To minimize these costs, we review program requirements with patients at their pre-clinic appointment so that applications can be completed as soon as possible.

While the time we spend on our oncology patient assistance program is not reimbursed by any payers, the money recouped from drug replacement more than covers the salaries of a full-time RN (the oncology care coordinator), a full-time pharmacist, and a part-time pharmaceutical technician and financial staffer. Since we started the program, Sarasota Memorial Health Care System has realized approximately $500,000 each year in oncology drug replacement costs—money that our outpatient infusion center and pharmacy used to have to write off as bad debt from non-payer patients. And this dollar number keeps growing. So far this year, our program has already recouped about $400,000 in replacement anticancer drugs. Due to an increasing patient load, we are on target to far exceed our annual projections.

But most importantly, the oncology patient assistance program has stabilized the financial performance of our outpatient infusion center so we continue to offer our patients quality care in their communities.

As far as the future, we see many growth opportunities for our oncology patient assistance program. For example, we have been involved with some cases where Medicare has denied off-label use of a certain anticancer drug. Our patient assistance program stepped in to coordinate an appeal process. In this specific instance, we obtained the drug through the pharmaceutical company's compassionate care program. Off-label and other reimbursement efforts require a coordinated effort from our oncology patient assistance team.

Marie Borsellino, RN, OCN®, is oncology care coordinator at Sarasota Memorial Health Care System in Sarasota, Fla.