

PBM, DSM, DBM, CBM, !

Pharmacy Benefits Manager . . . The New Brown-bagging?

RISÉ MARIE CLELAND

THE GOOD NEWS is that brown-bagging in its original form, where the drug is sent to the patient directly and then transported by the patient to the physician's office for administration, is much less prevalent in oncology today. After years of attempting to get this program into place, most payers have accepted the fact that physicians are not willing to participate in such a potentially hazardous practice. Most of the brown-bagging efforts were focused on two drugs, Neupogen and Procrit. As the use of these costly supportive drugs increased, payers looked for ways to cut costs. Pharmacies and benefits managers saw an opportunity to expand their customer base and increase revenues.

The reaction from the oncology community was nearly unanimous in its refusal to accept the risk of administering a drug whose stability was unknown and the origin of which was, at times, suspect. In Colorado, for instance, one patient whose insurance company contracted with a pharmacy benefits manager (PBM) for mail-order drugs received his Neupogen in an Amgen box that also contained small metal trinkets, including an earring and a dream catcher, along with two boxes of weight-loss pills with Spanish labeling wrapped in masking tape. The Neupogen vials and syringes were still sealed, but the patient and his oncology team were understandably shaken.

Outsourcing

Today, oncology patients and providers are facing new challenges that threaten to undermine their ability to obtain and provide quality cancer care in the community oncology clinic. There are numerous names for the same program—outsourcing, mandatory vendor imposition, and drug management programs. Payers seeking to lower the cost of the chemotherapy treatments necessary for their beneficiaries are turning to third-party entities that promise substantial savings. These third parties claim to offer lower drug costs, identification and substitution of “clinically equivalent” and less expensive drugs, treatment management that would identify and deny treatments deemed medically unnecessary, and data that are purported to compare costs of treatment provided by other payer clients.

PBM, disease state manager (DSM), disease benefits manager (DBM), and chemotherapy benefits manager (CBM) are different names used by the third-party entities positioning themselves for a share of the oncology market. For clarity, this article will

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refer to all these entities by the original title of PBM. PBMs are not new to the health care arena, having emerged in the late 1980s to administer the prescription drug programs for payers and for management of chronic diseases such as asthma, diabetes, congestive heart failure, and coronary artery disease.

The PBM model being promoted in the oncology clinic typically requires the physician to call and order the treatment, which is then reviewed and approved by the PBM (if it meets with the PBM's clinical guidelines). After approval, the PBM ships the patient-specific drug to the oncology clinic for administration. The PBM bills the payer directly for the drugs, and the oncology practice bills for the administration of the drugs.

Risks of Outsourcing

While this system may seem rather innocuous on the surface, it poses numerous risks and liabilities to both the patient and provider. Among the risks is the fact that the source of the drug is unknown to the physician, and the method of shipping and handling that the drug has experienced is also unknown. Other concerns are the timely delivery of drugs from PBMs and PBM-dictated drug substitutions.

The administrator of an oncology clinic in the Midwest said that he recently met with representatives from a national insurance company and their PBM in order to address concerns regarding patient safety and drug integrity. This administrator asked the PBM representative where the PBM obtains the drugs that would be administered to the patients in his clinic and was told that he was not entitled to that information as the contract was between the insurance company and the PBM, not the physician. Turning to the insurance company representative, he repeated his question and was again denied that information. According to the insurer, the purchase and payment for the drugs was an issue between the insurance company and the PBM.

In August 2001, Genentech issued a counterfeit drug warning stating that counterfeit Nutropin AQ was found in several states. Although the company was unable to locate the original source of the drug, it did identify the entity that distributed the drug to four pharmacies, including a PBM. It was found that the entity did not have a purchase or distribution agreement with Genentech and therefore was not an approved distributor.

Specialty Distributors vs. PBMs

Oncology clinics typically purchase their drugs from well-known national specialty distributors who are approved distributors for the pharmaceutical manufacturers and who understand the particular handling requirements for these drugs, many of which must be maintained within a narrow temperature range. In fact, most of the pharmaceutical manufacturers who market oncology drugs prefer to leave the distribution of their drugs to these highly specialized distributors.

Oncology practices generally have a close relationship with their preferred distributor, and they choose their distributor based on service, reliability, pricing, and the value of additional services that may be provided. Oncology distributors do far more than simply deliver drugs to the physician's office. Distributors sponsor state societies that allow practices to form

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coalitions to more effectively and efficiently deliver quality cancer care and provide a more cohesive method of communication with local Medicare carriers (which is greatly appreciated by the Medicare carrier). In addition to other programs and services, distributors also sponsor educational meetings for both clinical and administrative staff, and they provide opportunities to participate in clinical trials that otherwise might not be available to the individual clinic. If there is a significant decrease in sales volume through these distributors, the ability to provide these additional services will be lost. In contrast, the PBMs feel no need to provide any additional services to physicians as their prime customer base is the payers.

Timely Delivery of Drugs

The timely delivery of the drugs from PBMs has posed significant problems for clinics. Practices that have tried to work with the PBM to continue to provide their patients care without interruption report that a major source of concern is the common occurrence of drugs not being delivered in time for the patient's scheduled treatment. These delays in drug delivery occur in spite of the clinics placing orders in a timely manner. In these cases, the physician is left with the decision of ei-

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ther delaying treatment or using a drug from his or her stock and replacing it with the patient's drug when it is finally delivered. The former choice may compromise patient care, and the latter may be a violation of state pharmacy laws.

If a drug is late and the practice has to treat a patient with drugs from its own stock, the practice may not be able to replenish the stock with drugs provided for the patient by an insurance company through a pharmacy. Commenting on this scenario, Jerry Hill, RPh, CPh, chief of pharmacy services for the Florida Department of Health, said, "A dispensed drug for one patient cannot be used on another patient, so it should not be placed into the general office stock under any circumstance. . . . The drug would be considered adulterated under Chapter 499, F.S."

Drug Substitution

Further complications arise when a PBM dictates that the physician substitute one drug for another drug that the PBM has determined to be "clinically equivalent." The decision to substitute the drug is largely based on the acquisition cost and/or other financial arrangements made between the PBM and the pharmaceutical manufacturer. In these cases, the PBM is directly involving itself in patient care and thus becoming a part of the provider team with no direct knowledge of the patient. If the physician does not agree to the change of protocol dictated by the PBM, he or she is left in the position of justifying his or her choice of drug in order to obtain drug coverage for the patient.

For example, the administrator of a large oncology clinic in Arizona was talking with a payer about the PBM's refusal to cover a new supportive drug that the physician felt was both clinically superior and more convenient for the patient. The payer wanted the physician to order an older and less expensive drug that required more injections. As the discussion went on, the payer representative used the analogy that the drug the physician ordered was a Cadillac and the drug the payer was willing to pay for was a Yugo, but in the end they would both get the patient where he needed to go. The administrator asked if the payer wanted him to explain to the patient that everyone else in the clinic was traveling by Cadillac, but he would be in a Yugo as that was all his insurance company would provide. Ultimately, the payer agreed to cover the new drug.

Increasingly, managed care companies and the PBMs they contract with are engaging in drug substitution, which is often referred to as "therapeutic interchange." According to an article in the *ACP-ASIM Observer* (July/August 2000), the practice of PBMs soliciting money from drug manufacturers for increased market share of their drug and/or inclusion of the drug on the PBM's formulary is being investigated for possible fraud and abuse violations.

Costs of PBMs

For a physician clinic, the direct costs incurred as a result of participating in a PBM program make it prohibitive. These costs would include the necessity for additional staff to order, stock, and monitor PBM drugs on a daily basis; separate storage for each patient; increased patient loads due to the need for

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The direct costs listed above, along with the indirect costs of quality control and patient safety, have been significant enough to convince most oncologists that they cannot and will not participate in these programs. At the same time, the increased visibility and rapid proliferation of PBMs has both state and federal investigators looking into the relationship between pharmaceutical manufacturers and PBMs and the lack of sufficient regulation on the PBM industry as a whole. In 2002, Georgia became the first state to authorize its State Board of Pharmacy to regulate and license PBMs. Colorado State Senator Lewis Entz (R-Hooper) has introduced Senate Bill 142 to regulate PBMs. According to a statement made by Entz on Feb. 21, 2003, "Twenty-five states have initiated investigations into PBMs in the last 90 days."

The Payers' Response

The unwillingness of most oncologists to participate in the proposed PBM models has prompted the payers to offer alternative programs. The most recent proposals offer the oncologist the freedom to order from his or her preferred distributor with a reduced reimbursement on the drugs most commonly at 85% of the average wholesale price (AWP), and an increase on the payment of chemotherapy administration of up to 300% of the Medicare allowable. The medical director of one of the large national insurance companies recently sat down with the physicians and administrator of a cancer center and explained that while he could negotiate on the reimbursement rates for the administration and codes for evaluation and management, he could not do so on the drugs.

While this arrangement is certainly preferable to the PBM model, there are fundamental problems with most of the current

proposals. If the payer is suggesting reimbursement on drugs based on a percentage of the AWP and cites that the methodology for arriving at the AWP includes the price that would be available to the payer through the PBM, then the AWP is largely based on a fictitious figure that would not be available to physicians from their approved distributors. In a story dated Feb. 10, 2003, *The Philadelphia Inquirer* quoted a former PBM executive as saying that the majority of the income earned by a PBM comes directly from pharmaceutical companies in the form of rebates and other financial incentives. When this is the case, a PBM profits by "selling" the drug to the payers at or below cost, as many of the fees paid to PBMs are based on market share and the increase in sales would translate into higher profits regardless of the reimbursement from the payers.

One oncology PBM advertises on its website that it provides marketing for biopharmaceuticals and will position the product for success in the health care marketplace. On the same website, the company is selling its services to payers with the promise of lower drug costs through its formulary management, utilization management, and data-reporting services. It is not difficult to see a possible and serious conflict of interest.

The Future

By all accounts, it appears that the PBM model will go the way of the brown-bagging model before it. Recently, the medical director of one of the national insurance companies that was pushing this model stated that oncologists were not accepting of the PBM model. Clearly, this is a model that is not feasible and that would result in a lack of community cancer care providers. In fact, a recent study by the Patient Advocate Foundation, a national non-profit organization, found that the vast majority of respondents were opposed to any form of brown-bagging, including PBMs.

The fact that there are serious doubts as to whether PBMs can or do save money for those managed care companies that contract with them and the outcome of the many lawsuits now pending against these entities will provide an interesting chapter in the history of the American health care system. But the question of how we will continue to provide quality health care in our community oncology clinics is still to be decided regardless of the future of PBMs.

Certainly we can no longer assume that profits from drugs will cover the losses incurred with chemotherapy administration and other services. It is necessary that we begin to look at the services that we provide in our offices and be able to define the costs associated with each service. Then we need to educate the payers on the true cost of quality oncology care and be firm in our resolve to maintain control over our practices so we can continue to provide that care. We are tireless advocates for our patients, fighting to get new therapies covered and to get drugs donated for those who have no insurance; this is no different. In order to be the best advocates for our patients, we must remain financially sound, and ultimately, each practice is responsible for the impact that participation in these programs will have on cancer care in this country. ■