

An Update on Brown Bagging

New strategies for the next part of the fight

by Astara March

Thomas Marsland, M.D., an oncologist who practices in Jacksonville, Fla., is angry. After prescribing a standard post-chemo course of Neupogen[®] for one of his patients, he discovered that the patient's insurance company practiced "brown bagging" and wouldn't let Marsland dispense the medication from his practice pharmacy. Instead, in a classic brown bagging move, the company ordered the drug from its preferred discount pharmaceutical supplier and insisted that the supplier deliver the drug directly to the patient's home instead of to Marsland's office.

Marsland's patient was supposed to take Neupogen from days 14 through 24 of his chemotherapy cycle.

Thanks to the delays caused by brown bagging, the patient didn't receive the drug until day 14, which was too close for comfort as far as Marsland was concerned. In addition, the medication had been thrown into a sack instead of being placed in a temperature-buffering container to protect it from the weather. By the time the drug arrived on the patient's doorstep it was useless, denatured by the Florida heat and no more active than sugar water.

As his patient's white counts dropped, Marsland's temper climbed. "This is all a product of brown bagging," he said in frustration. "Most of the time insurers who are trying to brown bag do things right, but if they don't, it's deadly. When are insurance companies going to realize that they can kill people trying to save money this way!"

The term brown bagging was coined to describe what happens when an insurance company finds an inexpensive wholesale supplier of oncology drugs and has the supplier ship the drugs, not to its physicians' offices, but to pharmacies near subscribers or to subscribers' homes. The subscribers must pick up their medication from the pharmacy, or from off the doorstep, and carry it to their oncologist's office in a "brown bag" for infusion.

Many oncologists say brown bagging creates so many quality control and patient care problems it should be completely abandoned. In response, insurance companies have developed several brown bagging strategies that address physician concerns but allow insurance companies to keep their profits.

Scenario One. The first scenario gave brown bagging its name. An insurance company finds a pharmaceutical supplier with good wholesale prices and asks the supplier to send unmixed chemotherapy drugs to pharmacies near the insurer's oncology patients. Patients must pick up their drugs from the pharmacy, keep the drugs refrigerated at home, and transport them to the oncologist's office when it is time for an infusion. Temperature-buffering containers are usually not supplied.

The problems that result from this chain of events include damaged drugs, delayed treatment, and upset patients.

Since chemotherapy drugs can be denatured by hot weather and precipitate in cold weather, the lack of protection means the drug's potency can be severely damaged during the trip from the pharmacy to the patient's home. Even if the trip goes well, the



ILLUSTRATION BY EYEWIRE

patient may forget to place the drug promptly in the refrigerator. Sometimes patients lie to their doctors about the drug's travel history out of embarrassment, even though taking a useless drug can endanger their lives.

Brown-bag patients also have longer than normal infusion times. Chemotherapy drugs are usually mixed in the oncologist's office on the day an infusion is scheduled and are ready when the patient arrives. Since brown-bag drugs come to the office with the person who will receive them, brown-bag patients must wait until their drugs are mixed to start treatment; a considerable inconvenience that increases patient stress and exhaustion.

Scenario Two. The supplier sends chemotherapy drugs directly to the patient by courier, with no guarantee of how the drugs are handled in the process or when they will be delivered. Sometimes the package is left on the patient's doorstep, regardless of the weather.

Scenario Three. The patient goes to the oncologist's office for a blood count the day before an infusion is scheduled. If the count shows that the patient can tolerate treatment, the physician orders chemotherapy drugs from a pharmacy designated by the insurance company. The drugs are couriered to the office the next day. Patients must make an extra trip, and there is no guarantee that the drugs will arrive at the office in time for the infusion or that they will arrive in good shape since there is no way to tell how they were cared for during transport.

Scenario Four. The patient goes to an oncologist who performs an examination and writes a prescription for chemotherapy. The prescription is filled by the insurance company through its preferred supplier and a nurse hired by the insurance company comes to the patient's home to infuse the drugs.

Scenario Five. The insurance company offers to replace drugs taken from the oncologist's office stock with drugs from the insurer's preferred supplier. The oncologist's drug preferences are not honored, and the payer usually does not ensure adequate expiration dates or compensate the practice for the extra bookkeeping required to maintain a separate drug inventory for one insurance company.

Scenario Six. Insurance companies allow oncologists to purchase chemotherapy drugs themselves, but insist that they use a designated manufacturer. If physicians want to use another manufacturer they may, but their practice will be reimbursed at the discount rate of the designated manufacturer, no matter what the preferred drug costs.

Last year, when *Oncology Issues* published its original article on brown bagging (see *Oncology Issues* July/August 2001, Vol. 16, No. 4), insurance companies were trying to persuade physicians to order chemotherapy drugs from discount suppliers and turn patients into drug

couriers. Physicians, in turn, were focusing on the patient safety issues such practices created.

That was round one.

Physicians who participated in round one learned to deal with brown-bag insurers by terminating their contracts with these companies or inserting "hold harmless" clauses in the contracts that made insurers liable if patients were harmed by damaged drugs. Payers who participated in round one learned that some providers will not capitulate to their demands if patients are endangered.

Now the insurance companies are back for round two. They are focusing solely on finances, and their current tactics could have grave consequences for providers' bottom line.

The New Scenario

While practices that are negotiating at the round one level are fighting to protect their patients, practices that are having a second-round encounter with insurance companies are fighting to protect their finances.

Most insurers now say they will not force a practice to brown bag if the quality control issues cannot be solved. The practice may buy chemotherapy drugs from its own suppliers and mix the drugs in the practice pharmacy if it chooses to do so. The catch is that, if the practice will not accept the insurer's discount drugs, the company will only reimburse drug costs at average wholesale price (AWP) minus 15 to 25 percent in order to secure its

desired level of profit. (Average wholesale price for each drug is determined by the pharmaceutical company that manufactures the drug.)

To put this decision in perspective, Medicare's current reimbursement of chemotherapy drugs is AWP minus 5 percent. Depending on the practice, this amount can produce a small profit or at least allow a practice to break even on pharmaceuticals. Since oncologists are paid only a quarter to a third of what it costs them to perform chemotherapy infusions, the difference between what the oncologist pays the drug manufacturer for the medication and what the insurance company reimburses the practice for the drug (called a margin) compensates for the loss the practice suffers when it administers chemotherapy. Unless Medicare and other third-party payers are willing to reimburse chemotherapy administration costs at an adequate level, lowering the amount insurers pay for chemotherapy and supportive care medications below AWP minus 5 percent means that many practices may not be able to remain viable.

The insurance companies know this and are using the threat of insolvency to force providers to brown bag.

These tactics put practices in a terrible quandary. They can 1) purchase their drugs from the insurance company's supplier to stay financially afloat and run the risk of harm-

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Temperature-buffering containers are usually not supplied.



ing their patients, or 2) buy drugs from the supplier they trust but jeopardize the practice's economic well-being.

Lynn Kay Winters, C.M.M., M.B.A., practice administrator of Eastern Long Island Hematology Oncology in Riverhead, N.Y., tells a typical story. Her practice recently was approached by a large insurer who gave the doctors a choice of buying drugs from the insurance company's supplier or maintaining control of drug ordering and mixing but being reimbursed for drugs at AWP minus 15 percent. Since 60 to 70 percent of the operating expenses of her practice are used for chemotherapy drugs, the practice will probably terminate the relationship with the insurer. The practice's patients who subscribe to that insurance company will have to find a different care provider.

"For the first time, we are really dropping contracts," Winters says. "We will go under if we don't. We have been stripped of the luxury of maintaining a bad contract so we can continue to treat patients on active therapy. There is only one Medicare Plus carrier in our region. If other practices also drop contracts, the number of seniors on eastern Long Island who might be unable to receive cancer treatment near their home could be quite large."

Brenda Davis, administrator for Southeast Gynecologic Oncology Associates in Jacksonville, Fla., says that the insurers in her area insist that her practice purchase the recombinant biologics (G-CSF, GM-CSF, Procrit®, Leukine®, interferon, Neumega®, Neupogen®, and Neulasta®) from drug suppliers chosen by the insurance companies. Not only does the record keeping and maintenance of a multiple-source drug inventory mean a lot more work for the office, the practice must replace its own drugs because no pharmacy can do so in a timely manner. Davis says that if insurers force her practice to brown bag chemotherapy drugs, administering chemotherapy infusions will no longer be affordable and her doctors will send their patients to the hospital for this service.

In some states, if a private oncology practice signs a contract with an insurance company to provide chemotherapy infusions in the practice office, then sends the insurance company's patients to the hospital for chemotherapy when there is no medical reason for them to be treated in that setting, it is grounds for the insurance company to divorce the private practice. Providers should either drop their contract with an offending insurance company or alter the contract to exclude infusion services before patients are sent elsewhere for chemotherapy. Once a practice signs a contract with an insurer agreeing to provide infusion services and agreeing to brown bag, it cannot refuse to administer chemotherapy, no matter how difficult its finances become, until the contract expires.

Which Straw Breaks the Camel's Back?

Other elements of brown bagging contribute to chemotherapy reimbursement problems as well.

"Although insurance companies believe that brown bagging saves their plan money, the additional revenue insurance companies receive comes not from savings on drugs but from transferring some of the costs of chemotherapy from the payer to the oncology practice," says James B. Albertson III, president of Albertson Healthcare Associates, Inc., in Panama City, Fla.

Albertson says that oncologists are expected to maintain drug inventories large enough to allow them to pro-

vide chemotherapy in a timely manner. Insurance companies that practice brown bagging say they will replace drugs that doctors take from their stock, but the replacement process can take several weeks. When the drugs finally arrive, payers insist that they must be used by their patient alone. In other words, the insurance company pays for their patient's next dose, but does not reimburse the doctor for the first dose.

So who pays for the original drug that was administered and who pays for the carrying costs of the physician's drug inventory? The answer is the oncologist. If an oncologist uses the replacement drug to replenish the practice's drug inventory instead of saving the drug for the insurance subscriber's next dose, there can be legal consequences.

The word "nightmare" was used by both Linda Thornrose, the administrator of Gainesville Hematology Oncology Associates in Florida, and Donna Rahal, M.H.A., practice administrator of Valley Medical Oncology Consultants in Pleasanton, Calif., to describe ordering drugs for patients whose insurance companies insist on brown bagging. In addition to all the extra bookkeeping, brown-bag drugs need to be stored separately from the drugs in the practice's regular stock, which creates space problems. Rahal said she strongly suggests negotiating an additional fee from brown-bag insurers to cover the administrative costs, bookkeeping costs, extra time, and extra work that are required to keep brown-bag records accurately.

John Hennessy, executive director of Kansas City Cancer Centers, estimates that 30 to 40 percent of the chemotherapy orders his doctors write for scheduled treatment must be amended when the patient arrives due to low counts or other changes in their health status. "Ordering vials of chemotherapy drugs for specific patients a week in advance is a horribly inefficient way to run a cancer care delivery system, from either a physician's or a health plan's point of view. We work very hard to efficiently manage one inventory. Multiple inventories do nothing but cause problems and lower that efficiency.

"We also have no interest in holding third-party drugs until an insurance company's patient drops in, or working with vendors who want unused drugs returned. Since returning drugs involves unacceptable chain of custody issues, we would have to treat the drugs as waste. None of these scenarios seems to be either efficient or focused on improving patient care."

Every physician we interviewed remarked that if insurance companies thought they were going to save money by brown bagging, they were mistaken.

"The wastage is tremendous," said Marsland. "If the company delivers two months of drugs for patient X and patient X dies, the company, by Florida law, can't ask for the drugs back and they must be thrown away."

Many chemotherapy drugs come in multi-dose vials. For instance, a vial of Herceptin® contains 440 mg of the drug. According to Edward L. Braud, M.D., F.A.C.P., of the Springfield Clinic in Springfield, Ill., and ACCC president, if the patient only needs 200 mg from the 400 mg vial, the remaining 200 mg will go to waste because it can't be given to another patient. Likewise, G-CSF comes in ten-vial packs. If the patient needs only five vials, the remaining five are usually discarded.

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How to Determine Your Practice's "Real" Costs

by James B. Albertson III

Oncologists are on the verge of a reimbursement watershed that could easily overwhelm the unprepared. Rumbblings about the need for reductions in the Medicare drug fee schedule have been going on for years and are growing louder as time goes by. Since other payers are likely to adopt a variation of any change Medicare makes, the potential impact of drug reimbursement reform is enormous.

Medicare's ongoing attempts to reduce drug reimbursement have met stiff resistance. Although CMS continues to believe that Medicare drug payments are too high, the agency has acknowledged that these payments may offset inadequate reimbursement for chemotherapy administration and has allowed the Medicare drug fee schedule to stand at its current rate of 95 percent of average wholesale price.

With drug reimbursement increasingly under fire, it is time to take a proactive approach and learn to analyze practice costs accurately so CMS will pay for oncology services in an equitable manner. Oncology practices must find ways to determine the real cost of 1) the drugs they use, 2) the resources needed to evaluate and manage patients, and 3) the resources needed to administer chemotherapy.

The Hospital "Step-Down" Model

I often see practices using the relative value unit (RVU) method to determine costs per CPT (procedure) code. Unfortunately, the RVU method does not address the true costs of drugs, nor does it properly assign fixed costs to the revenue-generating divisions of the oncology practice from which they originate.

Adopting the "step-down" cost-reporting mechanism CMS has required hospitals to use since 1966 would be a good idea for

private practices as well. Not only will the implementation of this model allow oncology practices to discover their true costs, but CMS's familiarity with the method will ease negotiations with the agency and provide a solid platform for future contracting.

The hospital step-down cost analysis model that I use begins with the practice's chart of accounts and their respective balances. I look at these balances, see how costs are distributed among the practice's revenue centers on a pro rata basis, then assign each account to the most appropriate center, such as E&M visits, the laboratory, radiology, medical supplies, the infusion center, and drugs.

For instance, facility rent is allocated according to how many square feet of space each revenue center uses (including the space needed for management, billing, accounting, scheduling, the drug inventory, examination rooms, reception, storage, and physician offices). When all costs are recorded accurately and assigned to the right accounts and revenue-producing centers, the true costs of any one element (such as drugs) can be realistically determined.

If oncology practices throughout the nation adopted and standardized the step-down method, practices would produce accurate cost information

that would help CMS develop a proper fee structure for services. The step-down method would also demonstrate to CMS that drug profit margins are not significant and E&M codes are seriously undervalued.

Using this cost model may also encourage commercial payers to reimburse oncology services appropriately. Since some commercial payers are considering lowering drug reimbursements and increasing administration fees, oncology practices should have accurate cost analyses available that indicate what levels of reimbursement would adequately cover patient evaluation and management, and which administration codes should be used to offset any proposed reduction in drug payments.

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Hypothetical Example of Drug Costs Using the Step-Down Method

Purchase price of drug	\$10.00
<i>Costs allocated for drugs using the step-down method:</i>	
Facility rent	\$.04
Equipment depreciation	\$.05
Telephones	\$.01
Staff payroll and benefits	\$.31
Malpractice expenses	\$.01
Office and billing	\$.70
Management	\$.14
Physician salaries and benefits	\$.97
Pharmacy costs	\$.06
Other	\$.01
Total Cost of a Drug Priced at \$10.00	\$12.30



Hennessy says his practice has a special interest in being efficient and knowing where its drugs have been. "We've all just survived the Robert Courtney scandal in Kansas City," said Hennessy. "Cancer patients in our area want us to guarantee that the chemotherapy they receive has been prepared appropriately. Sometimes they even ask to watch their drugs being mixed. We will not place the trust our patients have built with us at risk, and this means that we must ensure the integrity of our chemotherapy drug inventory."

The Patients Still Come First

In spite of financial problems, the practices and physicians we spoke to were still primarily concerned about how brown bagging affects patient care and safety.

"The whole concept of brown bagging is ridiculous," said Ralph Levitt, M.D., of the Meritcare Medical Group-Roger Maris Cancer Center in Fargo, N.D., and president of the Dakotas Oncology Society. "Chemotherapy has no standard doses. It's not like Benadryl®, where you prescribe a predetermined amount for an average adult. Each dose must be compounded according to the patient's height, weight, and physical condition. In the best of circumstances there will still be a small number of errors. We can catch those errors, but only if the quality control is done at the point of service.

"Quality control problems can create havoc in how you interpret a patient's response to therapy. Has the patient progressed because the drug doesn't affect the disease or because the drug was frozen in transit, contaminated, mixed incorrectly, or the dose was wrong?"

Thornrose reported that a brown-bag patient in her practice who self-injects a drug received the medication at home in the wrong dose and with the wrong syringes. Several other of her brown-bag patients said their drugs arrived in broken vials. Medication has also been dropped at her patients' houses or delivered to the practice office warm to the touch and denatured because it was not properly refrigerated in transit. When the practice tried to replace these useless drugs, Thornrose said "it nearly took an act of Congress."

The Dangers of Self-Administration

Even when insurance companies allow physicians to choose and mix their own drugs, they often insist that patients inject the medication at home to save the cost of an office visit. Many doctors object to this practice because patients who self-administer drugs, even if they are medical professionals, often misunderstand instructions or interpret them "creatively" and harm themselves.

Phyllis Klein, president of PK Medical Administrative Services in Lakewood, Colo., told *Oncology Issues* about a physician patient who was supposed to take epoetin alfa in between his chemotherapy sessions. The drug made him feel so good he used up the entire month's supply in days instead of weeks. The side effects were significant, and to make matters worse his insurance company would not give him any more epoetin until the month was up.

Another of Klein's patients was sent home with four doses of medication, clearly marked to be taken once a day for four days. The first dose caused nausea and vomiting so the patient skipped the next two doses. On the

fourth day he felt better and took the remaining three doses together to make up for lost time. He was hospitalized within hours.

Art A. Alanis, Jr., R.Ph., director of pharmacy services at South Texas Oncology & Hematology in San Antonio, described having to teach a patient how to inject Faslodex, a salvage treatment for hormone receptor-positive metastatic breast cancer in postmenopausal women. The patient needed to administer the product using the Z-Track technique, which meant pulling the skin back in the gluteal region, injecting into the muscle, then releasing the skin and letting it slide over the injection site to block the drug from leaking out.

"Even a trained nurse would find it hard to self-inject that way," said Alanis. "If a patient tries to put a Z-track shot into her hip she can hit the bone or a nerve like the sciatic nerve. The drug itself is viscous and must be kept refrigerated. If it clumps in the needle, the patient won't know what to do. Of course the insurance company told our patient that if she couldn't master the technique she could bring the drug to us and we would administer it, but didn't mention that they wouldn't pay us for this service."

Two Practices Take Action

Some experts say that when brown-bag insurance companies decided to focus unashamedly on money, they gave their opponents a narrower and easier target to hit. Finances are much more straightforward than the nuances of patient care, and the current emphasis on profits could make it possible for even the smallest practices to successfully oppose a brown-bag insurer. Although group action is still the most effective way to fight, we spoke to two practices that did not have group support and reported success through hard-line, individual effort focused on money.

Both practices agreed that, to create a win-win situation, you must come to the negotiating table prepared to walk away from the contract unless the insurer responds to your requests. Usually insurance companies give in if you hold your position; but if they don't, you will preserve your practice's solvency by jettisoning a financially draining contract.

Pat Cosgrove, M.S.N., OCN®, chief operating officer of Oregon Hematology Oncology Associates, P.C., in Portland, Ore., said that when the members of her practice are approached by payers who want them to brown bag, they consistently say they will not do so because of the safety and liability issues involved. Because the practice uses the same argument with everyone, its doctors have developed a reputation in the area and insurance companies no longer pressure them to brown bag, knowing it will do no good.

But Cosgrove's practice goes a step farther and forces the insurers to perform a reality check. After the practice has established that its stance is immovable, William Mooney, M.D., the president and CEO of Oregon Hematology Oncology Associates, usually asks the insurance company representatives why they chose to go to an outside pharmaceutical company to save money instead of talking with the practice about reducing costs. He usually adds that there are better ways to make a profit than brown bagging, and his practice will be happy to consider revising the way it manages

patients to save money, if the revisions are clinically appropriate.

Mooney and the insurer then examine where the insurer's high costs are actually incurred. Pat Cosgrove, Mooney's COO, reports that, when real financial statements are reviewed, insurers discover that they spend more money on hospitalization and surgery bills for oncology patients than chemotherapy drugs. When Mooney asks insurers how brown bagging will solve these problems, the subject is usually dropped.

Our success is based on getting to the table and negotiating something sensible," said Cosgrove. She added that another tactic is making sure she gets her practice's "big guns" to the conference so the insurance company will be forced to bring people from their organization that can make far-reaching decisions. Cosgrove's group is usually represented by Mooney, an attorney, the business office manager, and Cosgrove, the COO.

Lynn Barnett, the administrator of Southwest Cancer Care in Escondido, Calif., says her situation is unusual and has forced her to accept a modified form of brown bagging that her practice makes work to its advantage. Although Barnett agrees that being willing to drop the contract if insurers won't respond is crucial, she thinks there are many other ways to make the best of a bad situation.

Escondido is near San Diego. The area is a nest of managed care organizations, and most small practices like Barnett's (2.5 full-time oncologists and a nurse practitioner) buy their drugs and negotiate their HMO contracts through independent physician associations (IPAs). IPAs are formed by groups of doctors who band together to cope with the HMOs as a unit. Unfortunately, many of the HMOs and IPAs in the area have gone bankrupt. Barnett says the IPAs need to represent at least 30,000 patients before they are able to effectively deal with insurers, and since most IPAs represent only 5,000 to 20,000 patients, they cannot produce enough savings to stay solvent.

Since the financial climate is unstable, Barnett's practice insists that all drug purchasing be done by the IPAs it works with, and that the IPAs receive reimbursement for the drugs directly from HMOs, not the practice. This way, if a bankruptcy situation develops, the practice is not stuck with a huge drug bill. Barnett and her physicians make sure, however, that the drugs are sent directly from the supplier to their office, and that the supplier is either local or connected with a national oncology drug organization such as the Oncology Therapeutics Network in San Francisco. They also negotiate decent reimbursement rates for the expenses of chemotherapy administration.

New Hope for Group Action

Albertson thinks that state oncology societies should be the ones to negotiate with brown bag-promoting insurers, not individual practices. Although a number of state societies have been unwilling to take action because they are afraid of antitrust issues, Albertson says there is a safe harbor in the antitrust laws that will allow such activity as long as the state societies stick to quality control topics, don't discuss financial issues, and do not threaten to boycott or refuse to deal with payers (see *Oncology Issues*, 2003 January/February, Vol. 18, No. 1, 1st Person).

He also thinks that practices that have to deal with round two insurers individually can do so if they prove that they cannot afford to administer chemotherapy on lower drug reimbursements and will drop the contract if such reductions are instituted.

"This means knowing your costs and your operational expenses down to the penny," says Albertson. "If you can prove your case, the insurer may increase the amount they will pay you for drugs or reimburse administration costs at a higher level."

Jim Albertson suggests that practices that have con-

Usually insurance companies give in if you hold your position...

tracts with brown bag-promoting insurance companies should insist that an indemnity clause be inserted in the contract that holds the insurance company liable if patients are hurt by damaged drugs. To obtain a copy of his sample indemnity clause, send an e-mail request to writer@accc-cancer.org.

Let the Facts Speak for Themselves

Back in Florida, Marsland thinks there is now enough data to formally analyze the savings that insurers really make from brown bagging. He hopes to use such analyses to tip the balance in negotiations.

Thomas R. Barr, M.B.A., general partner, Creative Health Care Network in Fort Worth, Tex., shares Marsland's opinion that scrutinizing brown bag financial information would change insurers' minds about using the tactic. The Creative Health Care Network is a collection of companies that design products and services for community oncology practices that generate revenue from non-traditional sources. Barr thinks financial studies could be incorporated into discussions similar to the ones Cosgrove's practice conducts, and could help create collaborations between insurers and clinicians to find safe but less expensive ways to provide cancer care.

"Everyone's initial reaction to the concept of brown bagging is knee-jerk indignation," Barr said. "If we can get past that and work together with insurers, we will produce much better outcomes for everyone."

Most of the people who deal with brown-bag insurance companies on a daily basis are not as optimistic as Barr. They have coped with the record keeping and scheduling problems brown bagging produces, and have seen both their patients and their practices put in jeopardy by insurers focused on money instead of good medicine. *Oncology Issues* will keep monitoring this controversial topic and will continue to seek out the newest and best game plans for practices that want to oppose brown bagging on either the round-one or the round-two level. 📄

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