

# Is oncology compatible with specialty pharmacy?

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Beneath the Medicare upheaval there is a flood of change emerging at the private payer level. Insurers and employers are seeking greater control over the billions of dollars spent for cancer care. The easiest target: drugs. For years, managed care organizations (MCOs) have used specialty pharmacies to manage high-cost specialized drugs used for diseases other than cancer in the outpatient setting. Both MCOs and specialty pharmacies look at the high amount now spent on oncology drugs and see this as a golden opportunity.<sup>1</sup> However, oncology care is different from the past situations where specialty pharmacy has moved in. Those of us in oncology practices understand these differences and must work as hard now to educate MCOs and specialty pharmacies as we have worked to educate Congress and the Centers for Medicare & Medicaid Services. In this article, we will look at what is specialty pharmacy, why managed care is looking to these programs as an alternative for cost management, what issues may affect the potential compatibility (or lack thereof) between quality community oncology practice and specialty pharmacy programs, and what opportunities lie ahead.

Specialty pharmacies started out by delivering prepackaged hemophilia products to patients' homes. Over time, they added patient education and compliance management and showed that they could effect great savings compared with hospital care. Soon, specialty pharmacy moved into other arenas, such as HIV/AIDS, hepatitis C, multiple sclerosis, infertility, rheumatoid arthritis, and growth hormone deficiency.<sup>2</sup> Specialty pharmacy programs arranged for the distribution, billing, and claims management of specialized drugs, diagnostics, and other products; provided supportive services to patients; and generally brought expertise in a specialized area to managed care organizations (MCOs) and their generalized knowledge bases.<sup>3</sup> Hospital and traditional pharmacies often did not stock specialty drugs, so an alternative specialty distribution option made sense. Pharmacy benefit management companies (PBMs) analyzed utilization and price contracts with traditional pharmacies.

Rising competition and a growing overlap in services made 2004 a record year for mergers, acquisitions, and affiliations between both specialty pharmacies and PBMs. In 2004, a new publication, *Specialty Pharmacy News*, was launched and in an early issue reported the emergence of 13 leaders in the industry (based upon early 2004 projected sales): Priority Healthcare, CVS ProCare, Caremark, Accredo Health, ExpresScripts, Chronimed, Option Care, BioScrip, McKesson, Medmark, Cu-

rative Health Services, AmerisourceBergen, and Anthem Rx Direct Specialty.<sup>4</sup> Now, as we enter 2005, we have already seen new combinations for ExpresScripts and CuraScripts, Advance PCS and Caremark, Prime Rx and McKesson, and Medco and Accredo Health.

## Why would an insurer use a specialty pharmacy provider?

The emergence and pricing of cancer and biotech drugs have made knowing what is being paid for, when, and why of paramount concern. Chemotherapy drugs are delivered in physician offices, billed on the claim with professional services, and paid under the medical benefit by private payers. The drugs are billed under Medicare-issued J codes, which provide no specific information on which brand of drug was used, merely the therapeutic regimen. Employers and MCOs don't like having drug costs buried in the medical benefit, where little information can be tracked to identify what these millions of dollars are being spent for or how they are being used.

As the specialty pharmacy industry consolidates with PBMs, they offer MCOs and oncology what

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## What specialty pharmacies offer MCOs

SPECIALTY PHARMACIES BRING A DEGREE OF EXPERTISE in advising managed care organizations (MCOs) and their members about niche drugs with low volume but high costs or side effects. They offer a variety of “hands-on” services:

- patient education on self-administration
- follow-up to determine whether a drug is being tolerated, working effectively, being taken as prescribed, and needs any adjustment in dosage
- 24/7 answers to questions
- customized guidelines for use of drugs in each specialty class
- communication with physicians if changes in treatment are necessary
- care management
- monitored utilization through prior authorization
- outcomes measurement
- patient reminders to refill prescriptions

Source: America's Health Insurance Plans<sup>5</sup>

they have provided in other disease areas:

- control of drug costs;
- discounts through rebates;
- management of data in a “mysterious and unknown world” (oncology);
- oversight of oncology physicians;
- shifting from the “black box” of medical benefits to more visible pharmacy benefits;
- management of patient compliance, education, and support across the medical condition; and
- management of adverse reactions and inefficient care across a fragmented healthcare system.

### Oncology: the too-quiet success story

Oncology is facing a battle. The sales pitch from specialty pharmacies to MCOs is driven by success in other specialties—but those successes were fueled in less complex environments, with far less toxic treatments and far less global medical management of conditions than already exists in oncology. Oncologists manage the comprehensive care for cancer patients through a carefully evolved infrastructure of facilities and skilled

medical personnel trained to handle toxic agents. Oncologists understand the complex established and newer treatments and balance selection of regimens based upon patient need, lifestyle, outcomes, and complexities of the drugs and treatments themselves. Oncologists manage adverse outcomes, patient compliance, education, and support.

However, as an industry, we have not been as diligent about proving our value. We do not uniformly track utilization, produce data regarding outcomes, or explain the billions of dollars spent for cancer care. For years, several MCOs have proposed various programs to take control of cancer costs, mostly with little success.<sup>6</sup> The year 2005 will be a crossroads for management of cancer. Either those who do the management now—the physicians—will step up into the data-information-and-analysis world and ensure their seat at the table in making decisions for cancer treatment, or those who specialize in data management—that is, outside entities—will move into the medical decision-making arena.

More than 80% of the oncology

care delivered is in community oncology offices. Yet the costs of chemotherapy provided in physicians' offices are usually less than 15% of the full amount spent on cancer by payors. The costs of diagnostics, end-of-life care, hospitalizations, radiation oncology, and imaging far outweigh the costs of chemotherapy. An oncology practice, with its lab, offices, and infusion centers, more closely resembles an acute care center than a physician's office—and yet it also provides the sense of personalized comfort and support that helps patients face each day of treatment. The challenge is that insurers and employers who are paying the bills for cancer care usually have not seen an oncology office and do not understand the uniqueness of this care system. Costs of drugs are an easy target in a world filled with sound bites about drug payment reform. That leaves oncology ripe for specialty pharmacies to make promises to control both costs and how money is being spent.

On the surface, marketing promises made to insurers by specialty pharmacy vendors seem reassuring, and the industry has made some significant growth in disease states other than oncology. However, the implementation of specialty pharmacy programs in oncology and for oncology care-related drugs (for both chemotherapy and supportive care) has been notably sporadic.

### Irreconcilable differences?

There are certain core elements that have worked for specialty pharmacy programs in other specialties and disease settings that don't translate well to the oncology environment.

#### *Distribution cost, reliability, safety*

For a specialty pharmacy moving from another market into oncology, savings that had been achievable in arthritis, for example, or other markets may not translate easily, due to both the small number of competing drugs

and the high risk of making decisions based simply on prices of similarly described products. Even though some generics are entering the oncology market, there are issues of quality and usability among generics that might otherwise appear to be similar. Some have different rates of solubility, some may be in inappropriate formulations, and others may have inactive ingredients that could react with other components of the treatment regimen.

Those differences can have a significant effect on the efficient delivery of care in terms of utilization of resources to prepare parenteral solutions, inventory and safely store supplies, and monitor product quality and drug administration. (For instance, an inadequate response may result if too much precipitate is left in an IV bag rather than reaching the patient.)

Deciding on the use of a drug for chemotherapy or supportive care depends on more than just price. There is an inherent toxicity to cancer treatments. Chemotherapy drugs are designed to kill human cells, and supportive care drugs help individual patients deal with the effects of those drugs. These aspects of cancer care must be weighed as closely as price and are factored on a patient-specific basis into a physician's decisions. Management and choice of such products from afar without knowledge of the patient or the other elements involved in the treatment regimen will result in costly mistakes that either delay therapy or result in additional expense.

With the tracking of the average selling price for drugs by Medicare, there will be significantly fewer opportunities for price concessions of any size by specialty pharmacies or other purchasing groups. Many specialty pharmacies seem to hope for significant discounting, not realizing that either existing terms were already available to the previously established distribution chain or that the market would shift significantly away from direct pricing and rebates in 2005.

Almost all physician practices now purchase from four to five major oncology drug distributors and participate in many of the group purchasing organizations (GPOs) associated with those distributors. Mathematically, there is no logic to dozens of specialty pharmacies claiming to payors that they can bring volume to bear on purchase prices, since it is highly unlikely that any given specialty pharmacy will match the volume already running through any one of the existing distributor GPOs.

For a specialty pharmacy to exert control over the purchasing and pricing of drugs to the insurer, it must take over drug acquisition and distribution. Oncology drug distribution is already specialized. Manufacturers ship to a small number of oncology specialty distributors, and physicians then purchase from those distributors, which they select for service, reliability, and price. Under a specialty pharmacy model, the specialty pharmacy chooses the source of the drug and tells the source to get it to the physician.

The physician, then, has no knowledge of the pedigree of the drug, its handling and provenance, or even its status as an original or restocked product. Mishandling of a drug at any point in the transportation chain could have a devastating, if not fatal, effect on the patient receiving the treatment, either from the cancer drug itself, the cancer if the drug doesn't work exactly as planned, or from side effects if supportive care drugs don't work as planned.

When a specialty pharmacy has contracted an insurer to obtain the lowest possible cost for drugs, there is a built-in incentive to seek out bidding wars and lowest price alternatives. That might work for non-lethal commodities, but oncology and supportive care drugs are not in that category. The effect of cutting corners may not be discernible until the damage is done—a denatured drug looks just the same as a reliable, ready-to-use drug.

In Colorado, one insurer used a specialty pharmacy to ship supportive care drugs to patients at home. Fortunately, one patient was knowledgeable enough to bring the shipment to his physician's office for examination. Although two boxes of Neupogen (filgrastim) had been shipped, the package also contained two boxes of diet pills, a carved onyx frog, a "dream catcher," and a silver earring (all wrapped in brown paper with Spanish writing). This shipment, for a national insurer through a national specialty pharmacy, had come to the patient from Mexico.<sup>6</sup> In Florida, numerous patient shipments of supportive care drugs were left in the heat to denature during transport; the drugs were rendered as useless as water

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against the damaging side effects of toxic chemotherapy.

When specialty pharmacy management of oncology was expanded 5 years ago in Florida, a number of news stories outlined the growth of alternative wholesalers selling at rock-bottom prices to specialty pharmacy contractors (with or without the physicians' ultimate knowledge). There were a number of instances of mishandled, counterfeited, or adulterated drugs reaching patients and physicians. Florida lawmakers spent the past few years developing legislation to control the proliferation of criminal intrusions into the supply chain of specialty drugs, following the aggressive growth of spe-

cialty pharmacy programs implemented by Florida insurers.<sup>7</sup>

*Therapies, not purchasing decisions, drive cost*

Oncology is unique in that the vast numbers of clinical trials and extensive research in the war on cancer mean that standards of care for treatment are constantly changing. New, high-priced, single-source drugs approved for advances in cancer care often are indicated for use in addition to older, established treatments. This trend creates an escalation of cost of care not manageable by the usual specialty pharmacy tradition of buying drugs en masse and driving significant established medical treatments to a few of many alternatives.

One practice calculated that its costs of inventory for drugs rose almost fourfold from 2001 to 2004—driven solely by advances in treatment, since patient mix and practice size remained the same. Practice labor and other operating costs also rose significantly in those years due to the increasing complexity of managing combination regimens, the mix of toxic agents, and the need for expensive supportive care agents to manage toxicity. This is a complex world not previously faced by specialty pharmacy vendors. They have little idea of how oncology care is delivered and assume that their previous successes in managing inventory from afar and shifting relatively simple products from one system to another can be applied with ease in oncology clinics.

*Waste and inefficiency*

Community oncology practices developed an efficient infrastructure with a single, centralized inventory, maintaining enough drugs on hand to handle anticipated and emergent treatments. Oncology drugs have strict handling requirements involving temperature and security. An “on-demand” centralized inventory is critical because

at least one third of treatments do not occur as planned. Patient health status may change, hospitalizations or deaths may occur, and dosages or complete regimen changes may be dictated by current-day circumstances.

If drugs were to be ordered under a patient-specific specialty pharmacy program, the order would predate the care, and insurers would be billed by the specialty pharmacy for the ordered drug, whether or not it was actually used. A drug procured by patient name may not legally be returned and thus is wasted if it is not used. Insurers must also pay for the actual drugs used.

That type of waste does not occur under the current centralized inventory scenario but has rarely been considered by specialty pharmacy companies or insurers in evaluating entry into oncology. The author recently worked with four medium-sized oncology practices to explore what the potential might be for that type of waste under a specialty pharmacy-dominated environment. For 1 week, each practice pretended that all patients had had their drugs ordered individually. Then, when the planned treatments for the day couldn't occur for any of the above-mentioned list of reasons, they jotted down the name of the drug and vial size that would have been “wasted.”

At the end of the week, the cost of each “wasted” drug was summed and annualized based on a 50-week year. For one practice, the annual “waste” was over \$875,000; for another, it was over \$1.1 million; and for the other two, the annual “waste” was over \$1.25 million. Few insurers could bear the burden of that waste in addition to the replacement drug ordered. It might be instructive to have a more organized national review of such potential waste before too much effort is spent in deconstructing the current centralized inventory system.

Oncology practices in New York City, Florida, and California that

have already been forced into accepting specialty pharmacy programs not only have multiple drug inventory systems crowding their aisles to house the drugs but also have boxes and boxes of expensive oncology drugs just sitting around because they can't use them and have not had time to dispose of them.

Beyond the waste issue of pre-ordered drugs, ordering drugs for one patient may certainly be manageable on an isolated basis. However, expecting oncologists to order and stock drugs on an individual patient basis for all insurers and their individual specialty pharmacy programs becomes a crippling burden to the practice. For those who don't understand oncology offices, a grocery store serves as a good analogy: It has a single, centralized inventory system, with perishable inventory that is sensitive to temperature and handling. If grocery stores had to order and stock items on a per-person basis and waste unused product if people didn't pick up their dinner items that day or changed their minds, grocers would quickly go out of business from the increases in labor and facilities.

*Physician liability*

The consequences of errors related to either a chemotherapy drug or a supportive care medication for a cancer patient are significant. The physician who acquires the drug and then administers the treatment accepts the liability for the treatment. Most malpractice carriers have agreed to insure oncologists for the risks inherent in current industry practices. Many have told oncologists that if they accept product from another source not chosen by the physician, the malpractice insurance coverage would not apply to that product or to the treatment with that product. When oncologists have turned to insurers or specialty pharmacies for a complete waiver of liability for product provided under specialty pharmacy programs, they have been met with

refusals. Current Medicare policy does not pay for administration of chemotherapy if the physician has not directly incurred the expense of the drugs.

*Focus on drug prices only:  
it's shortsighted*

Most people don't understand that oncology professional services have been underpaid and that average wholesale price drug payments were made the standard by the Centers for Medicare & Medicaid Services years ago, recognizing that the use of average wholesale price provided a margin that covered costs not otherwise reimbursed. A discussion in the *Federal Register* back in 1988 cautioned about the existence of underpayment on the professional services side (see "A still-timely warning from Congress," at right).

Some programs seek to remove all purchase of—and thereby payment for—drugs from the physician office. But they don't recognize that the professional rates defined under the Resource-Based Relative Value Scale (used as the basis for Federal and private insurer reimbursement programs) fail to cover the professional costs of delivering care. Such programs will leave oncology practices unable to afford to provide services to that insurer's members, no matter how much they may wish to provide that care. Additionally, there are facility and labor costs involved in the order, acquisition, and inventory management of all drugs, even drugs for which a purchase price was not paid. Programs that do not recognize those costs, even if the multiple inventory and drug waste burdens were tolerable, would again render practices in the business of providing oncology services unable to cover their costs of operation.

*Oncologists as care coordinators*

Unlike other scenarios with which the specialty pharmacy may be more familiar, when a patient is diagnosed with cancer, the patient/physician/nurse team becomes the primary caregiver. Oncology patients and their families are guided and supported through the cancer treatment process by a team that is usually available on a 24/7 basis for emergencies. It is the physician's role to monitor patients for side effects and drug interactions with other medications, in addition to treatment response. Insertion of another entity between this physician/patient team only leads to the potential for missed information and devastating or even fatal consequences.

## A still-timely warning from Congress

“CHANGES IN TREATMENT METHODS AND ADVANCES IN TECHNOLOGY now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well....”

“Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety equipment required because of the toxicity of the chemotherapeutic agents and safety procedures issued by the Occupational Safety and Health Administration.”

Source: *Federal Register* October 11, 1988;53:39644

Each day, when a patient presents for treatment, the patient's current health status is carefully evaluated along with his or her ability to continue with the day's planned treatment. No other entity is privy to those discussions; the patient's decisions; the medical, environmental, and psychosocial reasons for determination of one course

*Making medical decisions*

The oncologist evaluates patients, their life situation, their quality of life and work, their family situation, and their medical and mental state. He or she spends hours making decisions about possible courses of therapy and discussing those courses and their pros and cons with patients and their families.

of treatment; or the selection of drugs or dosages. In the few cases where specialty pharmacy programs have tried to institute drug-selection changes or substitutions, seldom have the physician's initial choices been overturned. In the treatment of cancer, medical decision-making without access to the patient, the patient's records, and the multitude of reasons why certain drugs were selected in a certain regimen is an unacceptable risk.

*No visa, no drug*

*No visa, no drug*

Cancer patients have enjoyed decades of access to cancer care. A typical oncology practice often forgives 25% of co-payments for both insured and uninsured patients (after sincere efforts to collect). Last month, one oncologist looked at his patient roster and noted, anecdotally, that he was not likely to collect co-payments from the first five patients on his schedule, but that did not affect their ability to receive care. With oncology treatments running into tens of thousands of dollars per month for the cost of drugs alone, many patients (insured, young, older, employed, unemployed) cannot afford a percentage-based co-payment.

Across the country, where specialty pharmacy programs have been employed for oncology, examples exist of patients who have been denied

drug administration in the middle of their cancer treatment because they could not provide the co-payment before service. Unfortunately, with reform comes change that is not always good. We will be facing a crisis in access to cancer care soon as these financial tiers are tightened. Oncology practices that had been able to absorb the net bad-debt burden of about as much as 5% overall will no longer have funds to provide unreimbursed care as new payment methodologies fail to recognize the impact of bad debt in cancer care.

#### *Redundancy and malpractice*

Oncology practices developed the ability to provide complex, toxic cancer treatments in the community office setting by building an infrastruc-

ture of medical expertise, psychosocial support, and clinical education and outreach. Specialized clinical personnel have been well trained to recognize, treat, and educate patients and families about cancer and how to monitor treatment side effects.

Oncology patients are able to call their offices on a 24/7 basis with any emergency questions. Oncology practices only use answering services after operators are carefully trained to take meticulous notes and to be aware that no bit of information is too trivial; the risks are too great. Oncologists cannot trust that information to an unknown entity. Physicians are too concerned that either conflicting or missed information might significantly affect patients' treatment.

Unless the specialty pharmacy is

willing to accept the liability of inserting its advice and personnel between the physician and the patient, it may wish to reconsider the advisability of providing that service in the oncology setting. We have not yet heard from malpractice insurers regarding the impact of such advice on physician treatment regimens and insurance, but this is a question that must be addressed.

#### **Future opportunities**

There are several significant issues that illustrate why oncology is not compatible with specialty pharmacy (or even PBM) programs as they currently exist. Logic and history would indicate that as the real effects of these types of traditional specialty pharmacy programs are identified, they will

#### *Editor's note*

## Specialty pharmacy and MVI: ill-advised systems, wasteful and harmful

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**D**AWN HOLCOMBE, an experienced and thoughtful administrator of a network of community cancer practices, has eloquently outlined the incompatibility of specialty pharmacy programs and community oncology. Her comprehensive article points out the development of specialty pharmacy in diseases where expensive, but infrequently needed, specialized treatments for rare diseases made sense. That's because individual physician practices were not able to pay for the overhead of highly trained, on-site expertise in nursing, inventory, order processing, and technical delivery that's needed when treatments are given so infrequently. Many still can't.

The opposite, however, is true in community oncology, where clinicians now care for more than 80% of cancer patients. Over the past 20 years, community oncologists have developed expert-level staffing to administer, manage, inventory, process, and monitor the increasingly complex array of pharmacologic, biologic, and immunologic therapies, along with supportive therapies, needed to treat cancer patients.

Unfortunately, cancer is a common disease that requires complex and, increasingly, long-term management. Community oncologists have built teams of highly trained professionals and have partnered with expert specialty delivery groups and oncology group-purchasing organizations to

ensure timely, safe, and well-integrated delivery of highly toxic and expensive therapies. These treatments often require last-minute adjustments to ensure appropriate care for the many types of cancers treated. The community oncology system allows patients to receive these therapies in a compassionate and welcoming environment, where they and their families are known and treated personally throughout the various stages of their illness. In addition, patients and their key family members receive personalized, tailored teaching along with emotional and professional support—all key to achieving the best outcomes.

As Dawn Holcombe points out, our challenge as community oncology

fade like the trial balloon that many seem to be.

However, the billions of dollars spent on oncology care and the diminishing ability of society to fight cancer at any cost will continue to fuel the need for some management and reform. Specialty pharmacy and PBM experience in other disease states and specialties does suggest opportunities for those who provide and pay for oncology care. Oncologists should be at the leading edge of these opportunities, and MCOs should seek out proactive oncologists who are willing to help them better understand and manage oncology care.

To preserve what has been successful in the evolution of cancer care, innovation in oncology management

must include:

- information management,
- utilization and outcomes tracking,
- guideline development and physician control of care quality, and
- a centralized pharmaceutical inventory.

#### *Information management*

Great opportunities exist for physicians and private insurers to collaborate in the analysis and understanding of this complex business of cancer care. Shared information regarding hospitalizations, outpatient treatment outcomes, end-of-life planning, referral to oncology treatment centers immediately upon diagnosis, more timely diagnostics, and imaging will yield tremendous value to those who are able to communicate and work together.

er. Insertion of middlemen and other entities in the process will muddy the discussions and pull more healthcare dollars out of the healthcare stream.

Oncologists spend their lives facing patients and helping them through one of the most difficult periods of their lives; telling someone that he or she has cancer is a thankless job. Pooling information and resources to improve the process for that patient is also the physician's job, but the private insurer has the resources to help the physician bring his or her knowledge to the table. However, it is the actively practicing community oncologist who has his finger on the pulse of state-of-the-art medicine. Oncology is a rapidly changing field with so many variables that only the trained clinical professional seeing patients on a daily

gists is to band together to educate health plans about these comprehensive programs. Only in this way can we prevent disruption of an effective system—a disruption that would lead to an unnecessary rise in costs.

Understandably, health plans have questioned whether they are receiving maximum value from the current delivery system. They have seen the costs of cancer care go up due to an increased number of patients, an increasing number of effective treatments, and the conversion of many cancer episodes from rapidly terminal events into chronic diseases requiring long-term management, followed by complex end-of-life care.

Most health plans assume that if physicians' income were divorced from drug costs, it would remove any incentive to give unnecessary or expensive treatments. As a result, specialty pharmacy and mandatory vendor imposition (MVI) programs now proposed by Medicare to begin in 2006 are being forced on oncologists. But it's clear to those of us who deliver care daily that such pro-

grams are, in fact, more expensive and wasteful. They certainly don't ensure that health plans will get the best value for their members.

#### **A better solution**

Community oncology has a much better solution for health plans. We need to organize around that solution and work with health plans to implement the following:

- *Payments for using quality practice measures.* Such measures include use of evidence-based guidelines and practice procedures that ensure safety and efficiency. Evidence-based guidelines from respected national organizations, such as the National Comprehensive Cancer Network, the National Oncology Alliance, the International Oncology Network, the American Society of Clinical Oncology, and others, are widely available, now covering nearly all aspects of cancer care.

- *Documenting delivery of appropriate guideline-based care.* Using modern technology, such as electronic medical record systems, we can present out-

comes and comprehensive cost data. These data should be the real drivers of health plan contracts.

- *Align incentives for quality care with the providers most able to deliver and document that care.* The way health plans are now contracted with oncologists is fragmented, with large amounts of wasted dollars given over to pre-authorizations, inefficient billing and collection systems, and poor communication between health plans and community oncology specialists. We can maximize patient satisfaction when our patients receive personalized care from the expert team they know and trust.

#### **Despair and outrage**

Those of us who have been forced by some health plans to use specialty pharmacy intermediaries despair at the waste we've seen. We can validate Dawn Holcombe's assertions of the massive waste that would occur with MVI programs.

During two recent on-call weekends, I fielded three separate pleas from desperate patients who had

basis, working with current treatment regimens, and managing the toxicities and side effects and outcomes of chemotherapy truly understands oncologic care. To rely on others for guidance would amount to malpractice.

#### *Utilization and outcomes tracking*

Tracking of drugs is a small part of oncology care. Physicians can track both utilization and outcomes against planned treatments in their offices, but only the insurers have the claims data for all oncology costs. Collaborative efforts should yield valuable insights, but between insurers and oncologists. One advantage offered to MCOs by specialty pharmacies is the delivery of National Drug Code (NDC)-level utilization data. However, now that computer systems

have been modified to universal national standards, physician offices also have the ability to report drug claims by NDC numbers. Once received in the MCO database, even if drugs are paid within the medical claim framework, technology should easily isolate volume by NDC code and diagnosis, thus eliminating the need for a middleman such as a specialty pharmacy to collect and provide that data.

#### *Guidelines and quality of care*

Individually as well as collectively, oncologists can track quality-of-care measures and demonstrate adherence to clinical practice guidelines. However, there is a fine line between physician-driven, medically based guidelines and cost control driven by non-medical personnel. Payers would

be well served to work closely with physician groups in regional markets to create locally developed guidelines. National guidelines are a good beginning, but they fall far short of the details that private physicians can and will generate for reliability and quality determination in their own practices. Cookbook medicine will never apply broadly to oncology care—there are too many variables in individual health status, lifestyles, and support systems.

#### *Centralized inventory*

Due to the variability of individual patient health status, a drug inventory that is not patient specific is critical to the efficient delivery of chemotherapy and supportive-care treatment. For risk and quality reasons, the physi-

been forced to wait for their Neulasta (pegfilgrastim), Aranesp (darbepoetin alfa), or Neupogen (filgrastim) deliveries from a specialty pharmacy vendor required by a health plan. In one case, the dose of Neulasta had not arrived by the third day, which was especially frustrating because by the fourth day, it's no longer efficacious to use the drug. It was the second time this had happened to the same patient, whose desperate daughter cried on the phone as she implored me to help her get proper treatment for her mother to prevent another hospitalization.

The patient waiting for Aranesp did not receive any needles or syringes with his order. The specialty pharmacy promised to mail them out the following week! Most horrifying, however, was the patient who got only one needle and one syringe with his five doses of Neupogen and was told by an employee answering the specialty pharmacy's customer service line to reuse the needle and syringe!

When the health plan's independent practice association was

contacted, it referred the problem back to their specialty pharmacy vendor. It was left to me to calm the patients and find solutions for problems I didn't create. I called in more prescriptions for syringes and needles, our office provided extra syringes and needles, and our nurses spent hours on the phone when supplies didn't arrive or patients had questions.

#### **Our top priority**

We in community oncology can document our cost savings along with the seamless delivery of care provided by our integrated, office-based systems. If treating vulnerable cancer patients is to continue to be our first priority, community oncology professionals must maintain control of the delivery system. Only in that way can we provide seamless care to patients who are overwhelmed just getting through their treatments. To burden patients with the disruption of inefficient specialty pharmacy or MVI drug-delivery programs is wasteful financially and harmful to the delivery of quality oncology care. Obvious-

ly, this does not meet health plans' goals for improved care.

Community oncology practices, legislators, patients, and professional oncology organizations must work with health plans and Medicare to initiate fair oncology contracts for comprehensive care. Specialty pharmacy and MVI programs for cancer therapies are not compatible with high-quality cancer care. It is essential for patients' well being that healthcare dollars be allocated to community oncology programs that can deliver on defined quality measures. In this way, we can best ensure that these vulnerable patients get the most appropriate care in the most appropriate setting.

Cancer has overtaken heart disease as the leading cause of death in the United States. This is not the time to hamper treatment or quality of care.

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cian must be involved in the selection and sourcing of all drugs used in cancer treatment. There may still be creative methods to arrange payment for those drugs, but only if the full costs of ordering and managing that central inventory are also covered and do not involve the management of multiple inventories (even per insurer) in the physician office.

### Who else is concerned about specialty pharmacy and PBMs?

There is a growing unease with some of the techniques employed in the specialty pharmacy and PBM quest for savings for MCOs and a profit for their own shareholders. The essential role of the oncologist as an active participant in the development and implementation of any oncology disease-management program is being recognized as a prerequisite for success—and the lack thereof a predictor of failure.<sup>8</sup>

Recently, 20 states took part in an unfair trade practices claim settlement with PBM giant Medco (until recently owned by Merck & Co).<sup>9</sup> Individual state attorneys general from New York to Washington are embarking on deeper reviews of industry practices and the effect of such practices on employers and patients. Some major companies are realizing that use of a middleman company may not lead to the best opportunities for cost management and are exploring direct contracts with manufacturers and even physician groups for oncology care.<sup>10</sup>

Even MCOs are questioning the ability of specialty pharmacies to deliver on promised savings. Major gaps in information are appearing in the ability of specialty pharmacies to model the financial impact of specialty pharmaceuticals; provide reimbursement support to members; integrate claims data; and deliver quality, targeted clinical programs.<sup>11</sup> In California, the Department of Managed

Health Care is drafting proposed rules to regulate and mandate broad coverage of medically necessary medications, a move that would frustrate specialty pharmacy and PBM programs designed to narrow the availability of medications as part of their cost-savings initiatives.<sup>12</sup>

### So is oncology compatible with specialty pharmacy?

Traditional specialty pharmacy and PBM management programs that are designed for other disease states and specialties will not work in the oncology setting. In fact, such programs will increase the cost of care and put patients and physician practices at great risk. However, there is also a great need for information management, medical guidelines, and outcomes data that remains unfilled.

There is a small window of opportunity for the medical oncology community to simultaneously educate MCOs about the pitfalls of traditional specialty pharmacy and PBM programs while creating new collaborations with MCOs and employers. Doing so would clarify the collective understanding of oncology care and cost. There might be a role for specialty pharmacy programs in a world where professional services are completely and appropriately paid, the full costs of handling and inventorying drugs are covered, and a single central inventory across all payers and distributors exists.

To achieve that end would still require considerable creative thinking across the industry. Until these other issues are resolved, it is imperative that we not jump or be forced into misguided and destructive programs designed to create failure in the cancer-care delivery system. Like the 2005 Medicare changes, we all need to recognize that current specialty pharmacy applications to oncology are not ready for prime time and are still evolving.

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