



Behind Closed Network Doors: Oral Cancer Drugs and the Rise of Specialty Pharm

By Jessica Wapner

Specialty pharmacies provide more than just a pill. As drug companies and oncology offices become more dependent on them, the current model has created friends and enemies. The evolution of the specialty pharmacy reflects the evolution of the industry. We talked to physicians and industry to learn how this industry is changing cancer patient care giving.

While carrying an unprecedented benefit in terms of both outcomes and convenience, oral cancer drugs present a difficult conundrum in terms of administering treatment. For physicians, the problems oral cancer drugs present have become glaringly obvious, such as pills taken with food when they should be taken

on an empty stomach; unreported, and hence, untreated side effects; complicated regimens—2 weeks on, 1 week off—being forgotten or not followed properly; and self-imposed treatment breaks by patients weary from coping with side effects. [cont. on pg 12 >>](#)

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While the reasons behind patient nonadherence—improper following of prescribed medications—are not well understood, the lack of an infrastructure within doctors' offices to monitor the proper taking of these oral agents at home can be considered part of the problem. Also, the benefit structure for many oral agents is creating access issues, requiring considerable time and effort before patients even begin therapy.

Enter the specialty pharmacy—a field that has been growing like wildfire over the past few years. A 2006 Drug Trend Report released by Express Scripts, Inc. put the total specialty pharmacy drug spend for that year at \$54 billion or 20% of the overall spending on drugs. Interestingly, new drugs were responsible for more than 17% of the 2006 increase. It is estimated that by 2010, the total specialty pharmacy drug spend figure will increase to 26% or \$99 billion.

Rebecca Shanahan, President, Shanahan Capital Ventures and former President of OTN Specialty Services, says, "Oncology, today, represents about 50% of overall

specialty pharmacy spend for a health plan," with oral chemotherapy agents comprising a significant portion.

The Challenge of Oral Cancer Drugs

As mentioned, patient nonadherence has been a widespread healthcare issue. For many oncologists, the threat of nonadherence has steered them away from prescribing oral drugs. "Many of us have been reluctant to prescribe these oral agents, and instead we use an IV form or a different treatment because of the lack of control and lack of safety [monitoring]," says Scott Kruger, MD, a hematologist/oncologist with Virginia Oncology Associates.

A study by the Dana-Farber Cancer Institute (Weingart et al. *British Medical Journal*. 2007;334:407-411) found that nearly 25% of 54 cancer centers surveyed (all comprehensive cancer centers as designated by the National Cancer Institute) had no formal system for monitoring nonadherence to oral cancer therapy. Few of the measures taken to care for patients receiving drugs by injection or infusion have been applied to oral therapies.

OBR/MSI MARKET RESEARCH SURVEY

The specialty pharmacy business model is highly dependent on meeting the needs of patients, manufacturers and specialty pharmacies. But there is one more important player that must be incorporated into this model and that is the community oncologist. If community oncologists do not "buy" into this network, i.e., leveraging it for more than just product acquisition, then the model will fail and the potential benefits may never be realized.

Market Strategies International, in conjunction with *Oncology Business Review*, conducted a survey of 50 community-based oncologists in January-February 2008 to find out how physicians perceive specialty pharmacies and whether oncologists view them as benefitting their practice and their patients.



For pharmaceutical companies that have spent millions on developing oral formulations, this reluctance to prescribe them can have dire implications. For instance, patients may order through the mail a 90-day supply of a drug ranging anywhere from \$14,000 to \$20,000, and as Shanahan notes, no one knows whether the patients are even taking them. In addition, poor outcomes that may be due to nonadherence could ultimately reflect badly on a drug.

The consequences to insurers are also abundantly clear. Expenses associated with nonadherence add up. According to Rolando DeCardenas, Vice President and General Manager of Oncology Rx U.S. Oncology, patients who discontinue therapy may have relapses, emergency room visits, and hospitalizations, “all of which add a lot of dollars into the expense of the therapies.”

Solving the Problem of At-Home Treatment Regimens

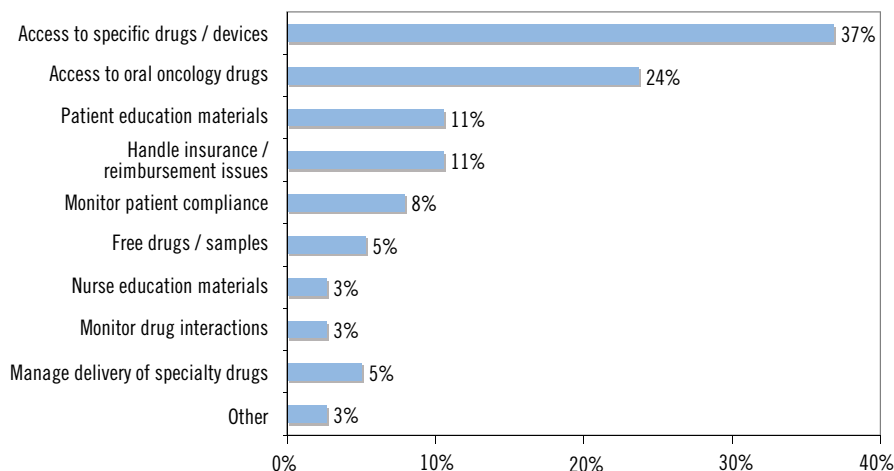
Specialty pharmacies, however, offer a simple solution for following at-home treatment regimens. Specifically, a case manager is assigned to each patient to ensure that

medicines are received and taken according to the prescribed course of therapy. “I always joke that if I had a personal trainer arriving at my house at 6 AM, I’d be in a lot better shape than I am,” says Shanahan, illustrating the strengths of specialty pharmacy.

There is a huge opportunity here for manufacturers to collaborate with insurance plans and specialty pharmacies “to develop consistency and clarity around how all stakeholders in the continuum of care educate and support the patient,” notes Shanahan.

As a first step, once a prescription is ready to be filled, specialty pharmacies help patients navigate through their benefits plan. At Dr. Kruger’s office, Care Oncology Rx Care Advantage, the specialty pharmacy division of U.S. Oncology, guides patients through the process by talking with insurers, or even turning over the patient’s information to another pharmacy if the patient can get a better deal. “It really is one call and one-stop shopping,” says Dr. Kruger. [cont. on pg 14 >>](#)

Services Provided by Specialty Pharmacies



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Clearly, physicians are primarily using specialty pharmacies for drug access, including oral anticancer agents, and less so for the services they provide practices. (Twelve physicians said they do not use specialty pharmacies.)

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In addition, if a patient cannot afford the co-payment or prescription cost, a member of the U.S. Oncology network will help those patients to locate a patient assistance program. Here, U.S. Oncology works with Oncology Reimbursement Solutions, a corporate service focusing on patient reimbursement support programs.

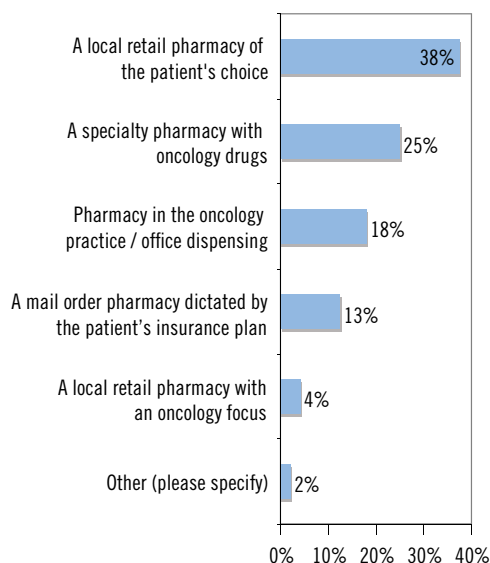
Secondly, once the prescription is ready to be filled, specialty pharmacies offer a medication therapy management (MTM) service that retail pharmacies do not currently provide. When a patient obtains their medication through a local retailer, the physician has no contemporaneous notice of when—or whether, for that matter—the patient has filled the prescription.

With a specialty pharmacy, the case manager knows exactly when the patient receives the pills and educates the patient at the outset about the course of therapy, side effects, and dosing schedule. In addition, the case manager is able to emphasize the importance of following the dosing

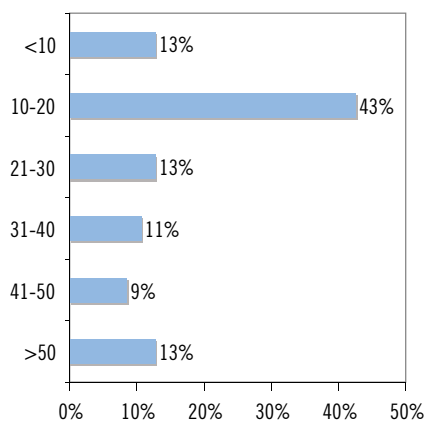
schedule correctly. This last aspect is particularly important for complicated regimens like Xeloda® [capecitabine; Roche]’s 2-week-on, 1-week-off plan. Importantly, the MTM and follow-up programs instituted by many oncology specialty pharmacies are tailored to specific treatment protocols. Therefore, case managers know to be on the lookout for specific toxicities and other issues that clinical trials and other patient experience have made apparent.

Thirdly, when the prescription is ready to be refilled, the specialty pharmacy delivers the new bottle of pills straight to the patient’s home. Some patients may find this level of management intrusive, or may be suspicious of the motives, thinking that such close follow-up is simply the drug company trying to get them to take more of these expensive pills. But that response has to be balanced with patient nonadherence with treatment regimens. “Yes, people don’t like to be intruded upon,” Shanahan concedes, “but I’m not sure people are always their own best advocate.”

How Patients Obtain Oral Oncology Drugs



Percent of Patients Utilizing Specialty Pharmacies for Oral Oncology Agents



How Patients Obtain Oral Oncology Drugs & Percent of Patients Utilizing Specialty Pharmacies for Oral Oncology Agents

Despite the recognition of the potential benefits that a specialty pharmacy can provide, only one-quarter of community oncologists use one for oral drugs and the majority of practices have fewer than one-fifth of their patients obtaining oral drugs from specialty pharmacies. Most patients obtain their oral anticancer drugs from their local retail pharmacy (38%) or from the dispensary or pharmacy in the oncology practice (18%).



In short, specialty pharmacies are providing the infrastructure that is missing in so many cancer centers throughout the country. The approach seems to offer something for everyone. For example, the arrangement benefits the physician, who receives regular emails and phone calls from the case manager regarding their patients taking the oral cancer drugs as prescribed. “We are confident that our service has helped reduce the practice workload associated with oral agents,” notes DeCardenas.

Shanahan praises the patient compliance seen when specialty pharmacy is involved with managing oral cancer drug regimens, and attributes that success to patient interaction with knowledgeable clinicians “who have a great deal of experience and expertise with the disease and the drug and the patient population.” The insurance companies and PBMs benefit by preventing the costs of additional healthcare measures associated with nonadherence and money wasted on unused pills. The pharmaceutical compa-

nies benefit from being assured of optimal outcomes and that their pills are being taken.

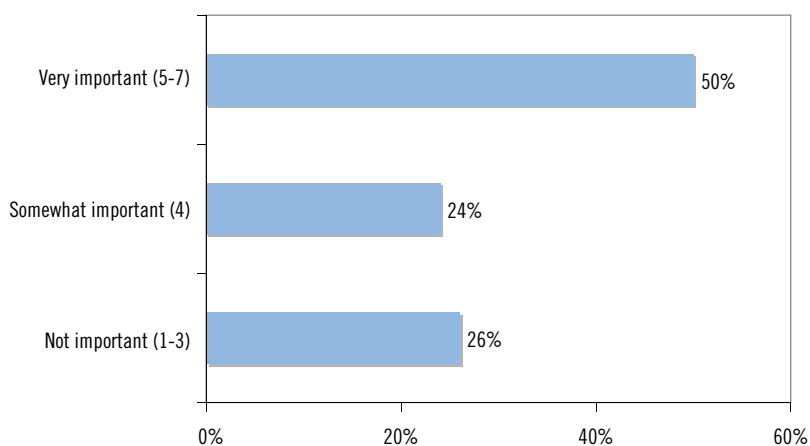
Additional Benefits of a Closed Network

Jay Seemann, of Onyx Pharmaceuticals, notes that in addition to optimal patient care, the use of a closed network helps ensure supply chain integrity. Previously the Director of Managed Markets at Bayer, Seemann helped launch Nexavar® [sorafenib], an oral agent for the treatment of kidney cancer, which was initially distributed along a very limited network.

“If you have a limited route along which the product is being distributed, you have better control over where that product goes from A to Z,” he says. This feature may be particularly important for smaller companies. A limited distribution network is more cost-effective to manage than an open-distribution network. It requires a much smaller staff, and can eliminate or at least reduce product

[cont. on pg 16 >>](#)

Importance of Specialty Pharmacy Services Surrounding Oral Cancer Agents



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Perhaps one reason specialty pharmacies are not utilized more for dispensing oral cancer drugs is that not all oncologists perceive the value they might accrue from these vendors. While half of the community oncologists see support services for oral anticancer drugs as an important benefit offered by specialty pharmacies, the other half perceive them as only somewhat important or not important.

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diversion, as well as the threat of counterfeit drugs entering the supply chain.

A by-product of the closed-network model is that competitors will not be able to obtain sales data that are readily available when a drug is distributed through traditional retail channels. Seemann regards this as a “good side effect.” By comparison with Nexavar, another oral agent for the treatment of kidney cancer, Sutent® [sunitinib; Pfizer], is available through an open-distribution network. It’s too soon to say whether there is any financial advantage to the open or closed approach, but in time these two agents may make for an interesting case study.

While hiding sales data from competitors, closed networks also provide manufacturers with other types of data that may help keep them in tune with the marketplace, the prescriber and the patient. For example, manufacturers can keep tabs on the percentage of patients that don’t start therapy once the co-pay requirement has been determined, discern patterns of care, and track payer policies. Specialty

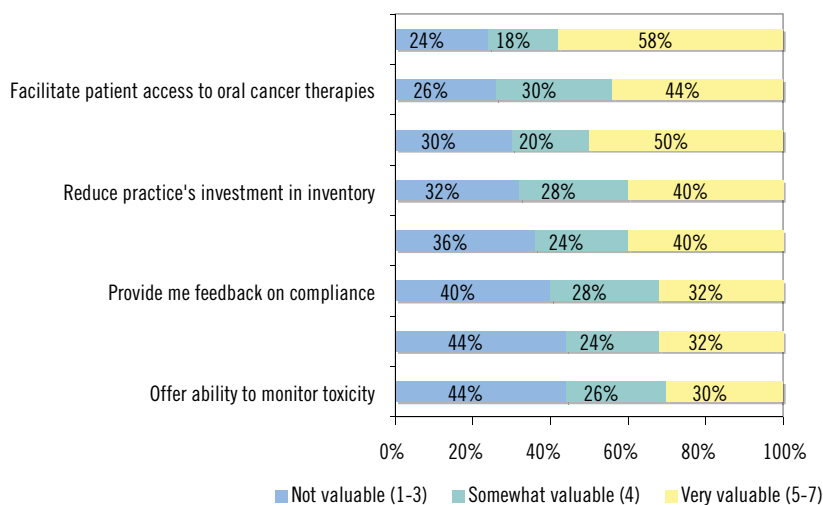
pharmacies can even collect data according to tumor type, stage of disease, and line of therapy, none of which is available through traditional oncology market audits.

A Sign of Broader Industry Changes

The rise of specialty pharmacies is also connected with an overall change in the pharmaceutical industry. Kip Piper was part of the team responsible for implementing the Medicare Modernization Act and worked as a senior adviser on Medicare-related matters at the White House budget office under Presidents Reagan and George H. W. Bush. He currently consults with large private companies and governments about healthcare policies. Piper attributes the rise of specialty pharmacy to the increasingly complex world that the pharmaceutical industry has become over the past several years.

In the tight-knit community of oncology, drug companies have traditionally been able to communicate the benefits of a drug to physicians fairly easily. Now, that access is diminishing, according to Piper, “The health

Value of Specialty Pharmacy Services



Value of Specialty Pharmacy Services

The ancillary services touted as the benefits of specialty pharmacies – those services that differentiate them from other dispensing options – are not perceived to be very valuable today by oncologists. The most valuable service to physicians offered by specialty pharmacies is support for reimbursement claims, followed by ensuring ready access to oral anticancer drugs. Only a third of the oncologists see value in the specialty pharmacy’s role in monitoring patient compliance and toxicity management. For specialty pharmacies to succeed in capturing more patient prescriptions from community oncologists, their marketing focus must be on demonstrating the value of these differentiating services.



plans and government are changing the incentives related to how a physician's office or clinic will make a decision about which drugs to use."

As the demand-side of the supply chain continues to wield more influence on drug choice, manufacturers are under increasing pressure to demonstrate that their products are value added. A partnership with specialty pharmacy is one way to demonstrate that value.

Partnership with specialty pharmacy provides justification of a high price, and of maintaining that price over the life cycle of the product because the cost is not just about the drug, it's about patient follow-up, communication with doctors, education, compliance, and safety.

With so many oral cancer drugs in the pipeline, even the most novel of agents is sure to have a competitor in the near future. Piper says, "Companies need to demonstrate that [using a closed network] is advantageous to the payer, it saves them money, it lowers hospital costs, physician

costs, other drug costs, and there is the clinical and safety argument that it is better than an open network."

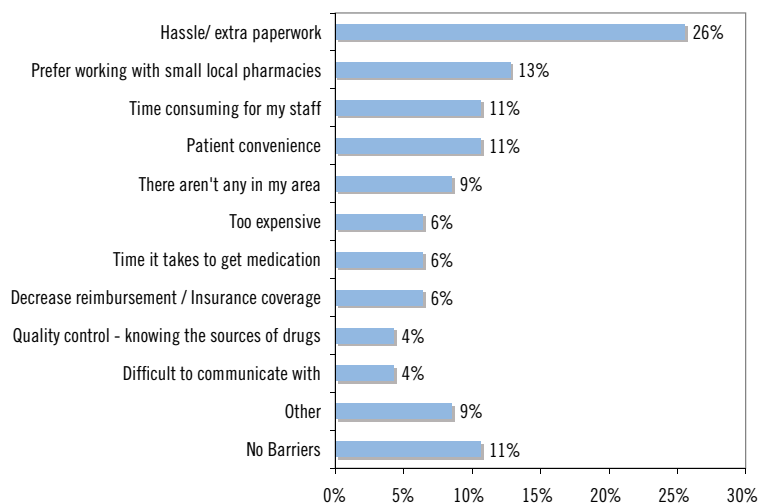
As Shanahan explains, various factors in oncology are creating a perfect storm for the closed-network model: the high amount of money being spent on oral cancer drugs, a pipeline plentiful with more oral drugs ensuring more opportunity for spending, and the Baby Boom population moving into the age range with the highest incidence of cancer.

"If you don't do more than just manage the unit price, it doesn't matter how low the cost of a drug is, the number of people using the drug is going to continue to grow, and therefore cost is going to get higher," says Shanahan.

Recently, payer preferred provider contracts have been issued to oncology specialty pharmacies, in spite of mail order and PBM contracts. This may be a clear sign of the effective job these closed networks are doing at managing the care of patients taking oral cancer drugs.

[cont. on pg 18 >>](#)

Barriers To Use of Specialty Pharmacy



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Given the increased paperwork burden most physicians face today from insurers, it's not surprising that one-fourth of the oncologists indicated the extra "hassle factor" related to using specialty pharmacies and 11% identified staff time as obstacles to use. But it is likely that many of these barriers could be overcome if specialty pharmacies are successful in establishing the value of the differentiating services they offer.

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Objections to Specialty Pharmacies

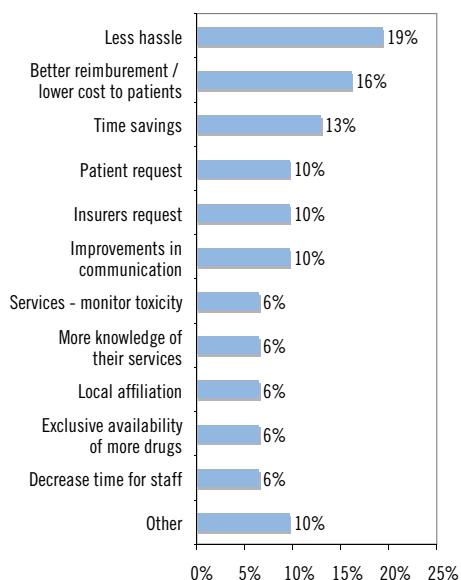
Not all oncologists are enamored with specialty pharmacies, particularly when it comes to very strong cancer drugs. Joseph J. Muscato, MD, FACP, of Missouri Cancer Associates (also part of the U.S. Oncology network), notes several crucial issues. First, refills requests need to be placed four days in advance in order for the shipment to arrive at a patient's house on time. Often, that means doctors are being asked to approve refills before a follow-up appointment.

"There is no way I can do that without seeing the patient," explains Dr. Muscato. If a patient is not tolerating a drug well, a lower dose may be all that is needed; however, if the refill request has already been shipped at the higher dose, that patient will end up with a refill labeled with instructions that are now out of step with the lower-dose orders, leading to incorrect dosing or waste of expensive drugs.

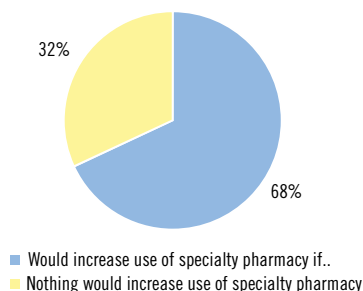
Also, the paperwork required to complete orders with oncology specialty pharmacies can be burdensome for a doctor's office. "I have to pay somebody to do it, and I don't get reimbursed," notes Dr. Muscato.

Sometimes, the confines of a closed network make patient care harder. Dr. Muscato tells the story of a patient hospitalized with breast cancer that had metastasized to the lungs. He wanted to prescribe Tykerb® [lapatinib; GSK] (she had already failed a prior therapy), but the hospital was not in the distribution network for Tykerb and he could not get the drug to the patient. After hours on the phone, the company finally agreed to get the drug. But days later, the patient had still not received it. Further calls revealed the pharmacy had been calling the patient's home to get financial information. When Dr. Muscato pointed out that the patient was in the hospital, the company called there. It took four weeks before the patient received the drug.

Reasons Oncologists Would Increase Use



Willingness to Increase Use of Specialty Pharmacies



Willing to Increase Use of Specialty Pharmacies

The good news for specialty pharmacies, however, is that most physicians are not closed minded about the potential for use of specialty pharmacies. But the primary obstacle community oncologists see today is the "hassle factor" which again implies that community oncologists do not yet see enough added value to make utilization of specialty pharmacies worthwhile.



On another occasion, Dr. Muscato was unable to give blood thinners from the pharmacy 10 feet away from his office to a patient, because the insurers required that the prescription go through a specialty pharmacy. The patient, who had renal cell carcinoma and had been doing fine, suddenly experienced a bout of inexplicable tumor growth. It turned out that the Sutent the patient had been taking had gone bad. Having been delivered when no one was home, the drug sat in 110-degree heat all day on the patient's porch.

"I can't say to you that specialty pharmacies don't try to add some value," says Dr. Muscato. "[But] they are still not the same as my writing a prescription and handing it to the patient."

Other Cautions

Of course, in the pharmaceutical industry, as in life, there are no guarantees. The closed-network model could

backfire on the drug company as a financial strategy. If the approach does not turn out to benefit patients' quality of life, then from a public relations perspective, there could be problems down the road. As Piper notes, companies need to make sure that this model is a positive thing in reality as well as in people's perceptions.

There is also a risk from a political standpoint. Some politicians may consider the use of specialty pharmacies to be inappropriate public policy and may raise issues about restricting access.

Finally, there is the issue of regulatory compliance. Caution must be considered in terms of how the interests of the manufacturers and the pharmacies are aligned. Still, exploring a closed-network model for oral cancer drugs may be worth the risk, particularly if care is taken to ensure that the value-added proposition is actualized.

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SURVEY SUMMARY

While specialty pharmacies are clearly making inroads into the oncology marketplace, they have not yet established their value-added proposition in the minds of community oncologists. Clearly, the ability of specialty pharmacies to be successful within commu-

nity practices is highly dependent on their ability to sell physicians on the value of their services that differentiate them from other dispensing options, such as local retail pharmacies or dispensing services within the practice.



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