

NCCN Task Force Report: Specialty Pharmacy

Rowena N. Schwartz, PharmD, BCOP; Kirby J. Eng, RPh; Deborah A. Frieze, PharmD, BCOP; Tracy K. Gosselin, RN, MSN, AOCN; Niesha Griffith, MS, RPh, FASHP; Amy Hatfield Seung, PharmD, BCOP; Jennifer M. Hinkel, MSc; Philip E. Johnson, MS, RPh, FASHP; Shirley A. Johnson, RN, MS, MBA; Edward C. Li, PharmD, BCOP; Audrea Hotsko Szabatura, PharmD, BCOP; and Michael K. Wong, MD, PhD

Key Words

NCCN, specialty pharmacy, oncology, drug distribution, coordination of care, mail order pharmacy

Abstract

The use of specialty pharmacies is expanding in oncology pharmacy practice. Specialty pharmacies provide a channel for distributing drugs that, from the payor perspective, creates economies of scale and streamlines the delivery of expensive drugs. Proposed goals of specialty pharmacy include optimization of pharmaceutical care outcomes through ensuring appropriate medication use and maximizing adherence, and optimization of economic outcomes through avoiding unwarranted drug expenditure. In oncology practice, specialty pharmacies have become a distribution channel for various agents. The use of a specialty pharmacy, and the addition of the pharmacist from the specialty pharmacy to the health care team, may not only provide benefits for care but also present challenges in oncology practice. The NCCN Specialty Pharmacy Task Force met to identify and examine the impact of specialty pharmacy practice on the care of people with cancer, and to provide recommendations regarding issues discussed. This report provides recommendations within the following categories: education and training of specialty pharmacy practitioners who care for individuals with cancer, coordination of care, and patient safety. Areas for further evaluation are also identified. (*JNCCN* 2010;8[Suppl 4]:S1-S11)

The use of specialty pharmacy is expanding in oncology pharmacy practice.¹ Specialty pharmacies provide one channel for distribution of drugs and biologics that, from the payor perspective, creates economies of scale and streamlines delivery of therapeutics that are expensive or may require special expertise. Historically, payors or pharmaceutical manufacturers have required

the use of specialty pharmacy distribution channels for medications that are costly to purchase, used in specific populations, and associated with complex management issues, including regimen adherence. In oncology, specialty pharmacies have become a distribution channel for various agents, including self-injectable supportive care agents (e.g., erythropoiesis stimulating agents, myeloid growth factors), oral anticancer agents, and, in some instances, parenteral chemotherapy or biologic agents. The proposed goals of specialty pharmacy include the optimization of pharmaceutical care outcomes through ensuring appropriate medication use, maximizing medication adherence, and optimizing economic outcomes through avoiding unwarranted drug expenditure. Patient satisfaction may be an additional goal, as the specialty pharmacy practice provides the opportunity for direct interaction and delivery of information from various health care professionals. However, although the specialty pharmacy mechanisms have found favor with payors because of the potential economic and operational benefits, and have helped optimize patient care, specialty pharmacies also present some challenges to the delivery of optimal patient care. These challenges may include issues related to coordination of care, patient safety, cost/reimbursement, and operational efficiency.

Task Force Objectives and Approach

The objectives of the NCCN Specialty Pharmacy Task Force included:

Schwartz et al.

- Describe the current mechanisms of specialty pharmacies as a distribution channel for oncology therapeutic agents and other medications used in drug therapy for individuals with cancer.
- Examine the potential benefits and risks associated with the use of specialty pharmacy distribution of oncology therapeutic agents.
- Describe financial implications of specialty pharmacy distribution of oncology therapeutic agents for oncology practices, cancer centers, oncologists, and individuals with cancer.
- Identify potential patient safety issues associated with the distribution of oral and parenteral oncology therapeutic agents through specialty pharmacy channels.
- Identify potential risks and liability issues for oncology practices and oncologists associated with the use of specialty pharmacies as distribution channels for oncology therapeutic agents.

To address these objectives, the task force initiated discussions on how specialty pharmacy affects the care of the individual with cancer, formulated recommendations regarding the issues discussed, and identified issues that may require further evaluation within the changing environment of oncology care.

Defining Specialty Pharmacy

Specialty pharmacy is not easy to define, especially in relation to oncology practice, because it encompasses a range of business models that can include disease management or case management features. Medication distribution methods from specialty pharmacies are not standard and may include models such as mail-order distribution (the traditional model for specialty pharmacy) or distribution from a community pharmacy.

One historic feature of specialty pharmacy is the focus on diseases that are chronic and low-incidence medical conditions. The role of specialty pharmacy has been to coordinate the clinical, fulfillment, medication, and disease management functions associated with medication delivery under one organization. Ideally, specialty pharmacy has the potential to reduce expenditures by facilitating appropriate use, and also to optimize patient adherence. Pharmacy service models within the “Specialty Pharmacy” scope have been designed to fill the perceived gaps associated with pharmaceutical care provided

by the traditional health care system. However, no universally accepted definition of specialty pharmacy exists and the terms *specialty pharmacy* and *specialty drug* vary among health plans and pharmacy benefit programs. Defining specialty pharmacy is also challenging because no mandatory certification standards exist for a specialty pharmacy, and specialty pharmacy practice beyond that of standard pharmacy practice is not regulated at a federal level, although state regulations may be in place in some instances. This is an area where change is occurring. The task force did not discuss specialty pharmacy accreditation organizations such as URAC (www.urac.org) or the Accreditation Commission for Health Care (www.achc.org).

Specialty Pharmacy Business Models

Specialty pharmacy has a wide range of pharmacy delivery models; it can be an independent standalone organization, integrated with a pharmacy benefit management (PBM) company. It can include functions of retail pharmacies or home infusion, or be combined with health insurance plans. Some major corporate players in the specialty pharmacy arena include CVS Caremark, Medco, Express Scripts, UnitedHealth (United Health Prescription Solutions), Aetna (Aetna Specialty), Walgreens (Walgreens Specialty), Diplomat Pharmacy, and US Oncology (US Oncology Care Advantage). In addition to oncology therapeutics, other disease areas of focus include but are not limited to asthma, HIV/AIDS, hemophilia, hepatitis, multiple sclerosis, and rheumatoid arthritis.

Operationally, specialty pharmacies may use several different mechanisms to distribute specialty medications. Some medications are distributed through a limited or closed distribution model, in which a manufacturer or payor works with a single specialty pharmacy or selected number of specialty pharmacy providers to control all distribution of a drug or biologic. Infusible medications may be delivered through home infusion services or shipped directly to a provider or provider’s pharmacy for administration to a patient. Oral drugs and injectables for self-administration may be mail-ordered or distributed through community retail pharmacy networks. Some institutions are successful in obtaining specialty pharmacy status from payors for their specific patient population.

Recommendations for Specialty Pharmacy Business Models

Specialty pharmacy distribution models should facilitate methods of increased communication between patients and pharmacists that enhance adherence to medications, identify potential safety issues, and allow for the timely administration in accordance with prescriber directives. Alternatives that allow face-to-face interaction between the pharmacist and patient should be explored.

Traditional Pharmacy Model Versus Specialty Pharmacy Model

In a traditional community pharmacy model (see Figure 1), pharmacies purchase medications from a wholesaler. After a prescription is received from a licensed prescriber, the pharmacist dispenses and provides patient information about the medication. Traditionally, pharmacies receive payment directly from the patient or third-party payors through the patient's insurer. Pharmacists may monitor medication and treatment plan adherence, but this often falls to the original prescriber or health care team. Some pharmacies routinely notify prescribers when patients fail to pick up their prescriptions, and may provide longitudinal follow up of patients during the course of therapy. Importantly, neither the traditional community pharmacy model nor the specialty pharmacy model routinely provides the entire therapy (i.e., all of the patients' medications) when treating individu-

als with cancer, therefore their patient-specific treatment information may not be comprehensive.

In the specialty pharmacy model (see Figure 2), the pharmacy acts as one "hub" of care by interacting directly with the providers, patients, and payors on a routine basis. The specialty pharmacy may also assume a role in monitoring medication adherence and tracking prescription information. One challenge for practitioners working within a specialty pharmacy practice is coordinating information and education with the primary oncology care team; these issues are discussed in more detail later.

Specialty pharmacy services may include patient and caregiver education, such as instruction on self-administration of medications, information regarding adverse drug events, medication handling and administration guidelines, and disease-specific information resources. The specialty pharmacy also may take a role in medication therapy management, assessing medication therapy side effects and management, evaluating medication efficacy, and encouraging medication adherence through prescription refill reminders. Additionally, the specialty pharmacy may coordinate information with providers regarding changes in treatment and medication dose modifications.

Apart from these services, specialty pharmacies may monitor use through prior authorization mechanisms, develop customized guidelines for use of drugs in a specialty class, and undertake measurement of clinical and financial outcomes. Institutional pharmacies also provide this full scope of service.

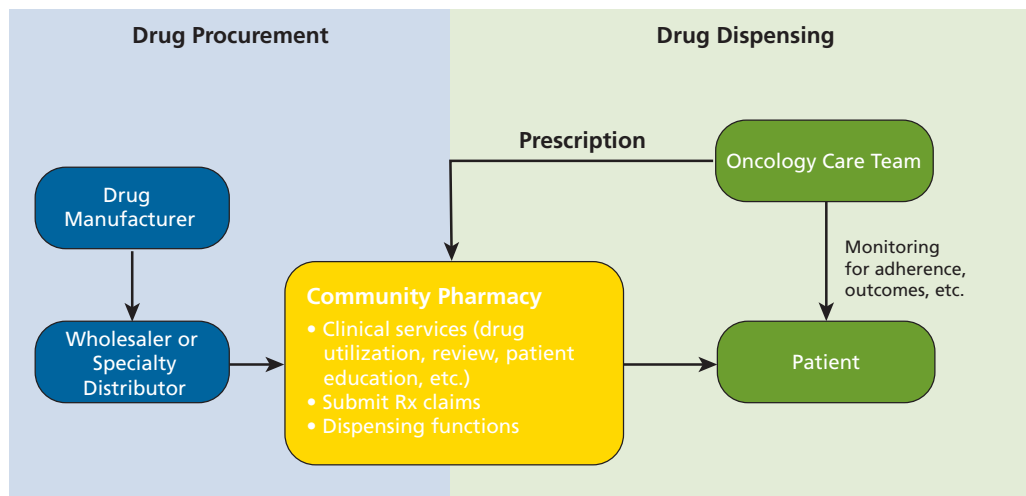


Figure 1 Traditional community pharmacy medication distribution model. Abbreviations: Rx, prescription.

Schwartz et al.

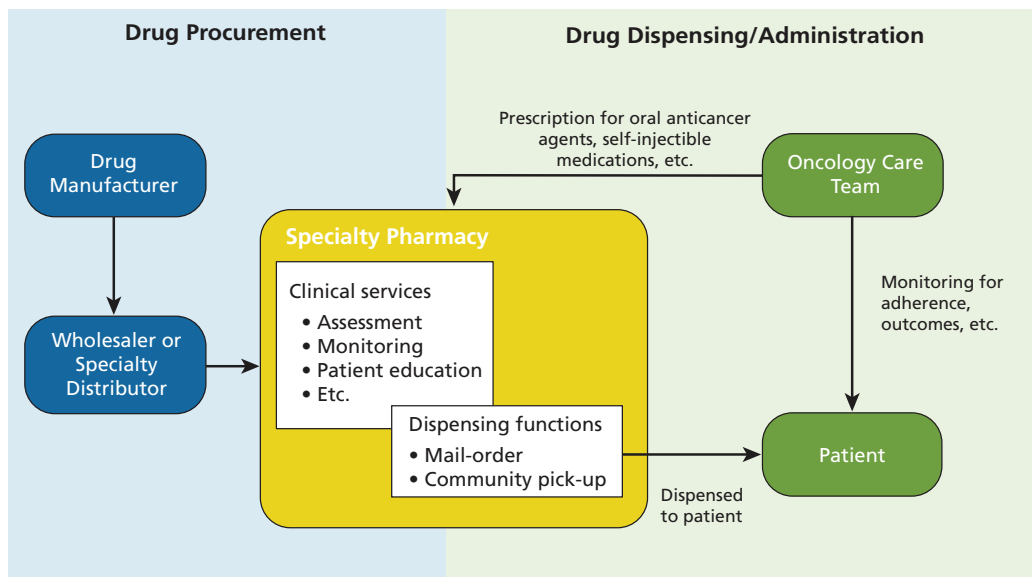


Figure 2 Specialty pharmacy distribution model.

Scope of Specialty Pharmacy for Patients with Cancer

When an individual with cancer obtains medication through a specialty pharmacy, that pharmacy may assume a role in communicating with that patient regarding the anticancer or supportive care therapies. The specialty pharmacy may also communicate with patients regarding treatment-related toxicities or adverse events, and in some cases assumes a larger disease management role, also discussing cancer-related complications, comorbidities, and health maintenance issues. However, this communication may contribute to fragmented care. Although the specialty pharmacy practitioner may communicate with a designated member of the health care team, the team is comprised of an important integral group of health care professionals. As with all communications regarding patient care issues, the information should be available to the entire team. The task force emphasized potential patient care issues that could occur if information regarding adherence to therapy, adverse events, toxicities, or side effects is not efficiently communicated across all relevant providers.

For patients with cancer, the model for drug distribution and management of drug therapy often differs depending on treatment settings and the oncology care team. Coordination of care is essential, with multidisciplinary care teams being optimal. The care

model should encompass not only management of the disease but also treatment-related toxicities, cancer-related complications, comorbidities, and overall health maintenance. In some cases, it is important to also include the clinical research team in the overall coordination. When specialty pharmacies are used, these professionals must coordinate information with this complex health care team.

Better informatics systems are needed to facilitate this information flow among the complex health care team, including, when applicable, specialty pharmacy. In addition, this strategy is important for increasing the real-time reconciliation of the often-evolving patient medication lists. Ideally, electronic health records would be centralized so that the same information can be retrieved by the specialty pharmacy and all members of the oncology care team. Face-to-face interactions between the patient and the pharmacist can also assist in this exchange of information, and should be an available option when specialty medications are dispensed.

Specialty pharmacy has growing significance for the patient with cancer for several reasons. First, oral anticancer agents are becoming more numerous, with an estimated 25% of antineoplastic agents in the research pipeline planned as oral drugs. Additionally, spending on oral agents has more than doubled between 2002 and 2006.² As a result, oral agents are becoming more common, consuming a larger fraction of cancer care spending and attracting

the scrutiny of public policy makers, employers, and contracted health plan administrators.³ For example, in a 2005 survey to 38 Blue Cross and Blue Shield plans, 78% responded that oncology specialty drugs were a concern.⁴ Because many of these therapies may be distributed through specialty pharmacies, systems must be in place for communication between specialty pharmacies and all members of the health care team.

Administrative requirements put in place by payors (e.g., commercial, government, employers) also have implications for the role specialty pharmacies may play in the care of patients with cancer. With increasing needs to coordinate patient information and complete prior authorization processes before a drug can be dispensed, specialty pharmacies may share some of these responsibilities with the oncology care team. The challenge that exists when a specialty pharmacy assumes the primary responsibility for administering the anticancer medication is the potential for fragmentation of care between the specialty pharmacy and the oncology care team, including questions regarding the initial quantity of medication dispensed, communication of dose changes or modifications, and timeframe within which medication is delivered and the avoidance of unnecessary delays.

Education and Training

Pharmacists and other health care professionals involved in the specialty pharmacy setting are often very knowledgeable about specific medications and their place in therapy, but may have a limited patient-specific knowledge base related to underlying disease, comorbidities, and general clinical management of other patient-specific issues. Furthermore, these pharmacies may not provide all drug therapy for the patient, and therefore may not be aware of interactions or impact of care on other medications. Ideally, pharmacists who are handling oncology agents in the specialty pharmacy setting should receive comprehensive oncology pharmacy training or be specialty certified so that they can recognize and make recommendations regarding patient-specific clinical management issues, and effectively communicate this information with the patient's primary care team. This practice model is currently the standard in some specialty pharmacies.

Recommendations for Education and Training

Specialty pharmacies who employ technicians or other support staff (especially staff who have direct patient contact or who may be conducting telephone follow-up) should institute standardized pathways to triage problems to ensure that patient concerns are escalated to the appropriate health care provider. These staff should also receive additional training tailored to the specialty, specialty products, or patient populations with which they most frequently work. The focus for all pharmacy care should be on the patient care issues, and extend beyond product-specific issues.

Challenges in Specialty Pharmacy

Coordination of Care

The NCCN Task Force felt that coordination of care was a major area of concern in its discussions. Specialty pharmacy presents unique challenges in the coordination of care for patients with cancer. Efficient and effective collaboration with a specialty pharmacy may necessitate changes in practice for the oncology care team, because patient information must be coordinated with an additional party. Requirements for prior authorization or other feedback of clinical information from the care team to the specialty pharmacy can also add to the oncology practitioner's workflow. The practitioner within the specialty pharmacy also has a challenge in communicating information back to the patient and clinician in a manner that "closes the loop," to ensure that patients are receiving the correct medications in a timely fashion and to relay critical information regarding adverse events or other patient concerns to the care team.

Recommendations for Coordination of Care

In a system in which information is often fragmented and care can be difficult to coordinate among diverse practice settings, specialty pharmacy can incorporate an additional layer of complexity to the challenge of coordinating care. Solutions to these challenges include better informatics systems to facilitate communication of information and medication reconciliation.

Drug Distribution and Dispensing

With the advent of numerous oral anticancer agents, drug distribution to patients is a growing challenge

Schwartz et al.

in the oncology-specific context for specialty pharmacy. The issues associated with dispensing anticancer drugs often relate to different dosing models than those associated with drugs for other “specialty” diseases, including asthma or rheumatoid arthritis. Although dispensing a large quantity (e.g., 90-day supply) of drugs for chronic illnesses such as asthma may be both efficient and appropriate, doing so with an anticancer agent may actually lead to waste, expense, and safety issues. Many oral anticancer agents are both expensive and require dose adjustments or discontinuation based on patient response in a relatively short time. Additionally, drug therapy is often modified within a relatively short time (e.g., a medication is discontinued) secondary to changes in patient status or toxicities.

Dispensing a smaller medication supply without cost penalties (e.g., 14–30 days) may lower overall expense and decrease drug waste if a patient’s therapy is adjusted or discontinued. However, because of the current reimbursement restrictions, reducing the quantity of dispensed oral medication has implications for patient copayments or coinsurance, perhaps leading to higher patient out-of-pocket costs. For example, if each refill requires a copayment, regardless of the quantity dispensed, it is often more expensive to patients to have small amounts dispensed. The task force recommended that if smaller quantities are to be dispensed, copayments and benefit design should be adjusted to not penalize patients for accepting a smaller quantity, especially because a smaller quantity may lead to improved safety and efficiency in the system (see Case Report).

Communication of dose changes from the care team to the specialty pharmacy can also present a logistic challenge. For example, dispensing large quantities of a drug combined with frequent dose adjustments could lead to scenarios in which patients are combining or splitting tablets to reach the correct dose, which in turn creates a higher risk for error or adverse events and could lead to patient confusion. Furthermore, drug manipulation by the patient presents a safety concern as other family members could be exposed to cytotoxic chemotherapy.

A challenge with the use of mail order distribution models for specialty pharmacy is the impact of the timeframe necessary for medication delivery. Delays in the initiation of therapy may occur if key in-

Case Scenario: Hypothetical Cases of Waste and Safety Concerns by Dispensing Higher Initial Quantities

Example 1: Drug Waste

A patient recently diagnosed with metastatic non-small cell lung cancer is to start treatment with erlotinib, 150 mg, by mouth daily. Ten days after initiation of treatment, the patient develops complications thought to be secondary to cancer progression and the decision is made to discontinue therapy. If the initial amount dispensed was a 30-day supply, 20 tablets will be wasted.

Example 2: Safety

A patient is prescribed capecitabine, 500 mg, tablets, 3 tablets by mouth twice daily on days 1 to 14 (of a 21-day cycle) for the treatment of colon cancer. The initial quantity dispensed was 168 tablets, representing 28 days of medication consumption. Because the quantity dispensed represents 2 active treatment cycles (separated by 1 week off of the medication), the patient could potentially continuously take the capecitabine during the off week. This represents a safety concern because serious toxicities are likely to occur in this scenario.

formation (prior authorization, patient information) is not fully communicated to the specialty pharmacy. Often the clinician’s office, and occasionally the patient, is responsible for communicating information to the specialty pharmacy before initiation of therapy. Additionally, delays may occur secondary to the availability of mail/shipping services. Although patients may expect to begin therapy immediately, this may be unrealistic when the medication must be ordered and shipped from a specialty pharmacy and when extra controls are in place to monitor appropriate use of an agent.

One challenge in dispensing select medications through specialty pharmacy is identifying those that are appropriate for this distribution mechanism. Oral medications seem to present fewer challenges to dispensing than parenteral products that require manipulation before administration, but issues do exist, as discussed previously. Additionally, when injectable medications that do not require manipulation for preparation are provided through a specialty pharmacy, appropriate patient education regarding

administration and handling of medication is important. If a self-injectable medication is sent directly to a patient, the specialty pharmacy or benefit provider should have the responsibility for appropriately educating the patient regarding self-administration techniques.

The task force recommends that medications requiring sterile compounding before infusion, or those that a patient cannot self-administer, not be distributed through specialty pharmacy, whether the product is sent directly to the patient or directly to a hospital, clinic, or physician's office. Sending pharmaceuticals that require infusion directly to a patient ("brown bagging") creates obvious risk to the medication in terms of storage and handling. Pharmacists cannot evaluate the integrity of the product or the chain of custody, nor can they verify storage and handling conditions from manufacturers. Patients may not be equipped or educated to store or handle the drug properly after receiving it from the specialty pharmacy. Brown bagging could therefore lead to administration of a potentially adulterated or misbranded drug product.

Additionally, distribution in this manner may skirt state-specific pedigree laws that mandate verification of the supply chain of pharmaceutical products from manufacturer to administration. Lastly, this scenario creates an uncomfortable situation for providers who are asked to administer a medication, the integrity of which they are unable to verify, and therefore may raise liability concerns for the pharmacist or institution.

Dispensing medications that require infusion already prepared for a specific patient directly to a hospital, clinic, or physician's office ("white bagging") does not necessarily eliminate the concerns of brown bagging and creates additional logistic and efficiency issues. Sending prepared drugs in this manner does not allow for flexibility of dose or schedule changes, including dose modifications or discontinuation of therapy based on patient-specific data (e.g., changing laboratory values). As a result, white bagging may contribute to waste of the prepared drug and financial loss for the provider.

Moreover, the structure of oncology reimbursement does not compensate for preparation of products directly before administration, storage of infusion products, cognitive services involved in the dispensing and checking of high-risk medications, or

similar pharmacy services, whether the medication comes from the pharmacy's inventory or is shipped from a specialty pharmacy. Therefore, white bagging can have a detrimental financial consequence for oncology practices that must still manage, handle, dispense, and administer these agents without the ability to claim reimbursement. Again, white bagging may skirt pedigree laws because the supply chain cannot be verified, and may be considered re-dispensing of already dispensed product and therefore illegal in some circumstances.

Finally, drugs received for a specific patient cannot be re-dispensed to another patient. For example, if patient A has a drug discontinued, it cannot be provided to patient B and must be wasted. However, if the medication were procured through the standard supply chain, this scenario would not exist and the medication would not have to be wasted.

Distribution models for specialty pharmacy should be developed to minimize delay in initiating therapy, and an appropriate estimate of drug delivery should be given to both the provider and patient. Although patients might expect immediate treatment, starting a drug immediately may not be necessary, but these expectations should be consistent among the entire health care team. Both providers and specialty pharmacies should educate patients to have reasonable expectations about when medications will be delivered from a specialty pharmacy.

Only agents that can be safely and appropriately self-administered should be dispensed through the specialty pharmacy model. Therefore, select oral agents and self-injectables (after the patient is sufficiently educated and competent in the self-administration technique) may be appropriate for this channel. Infusion agents and injectables that cannot be self-administered are not appropriate for this channel of distribution, and should not be sent directly to the patient or directly to an infusion center for administration.

Recommendations for Drug Distribution and Dispensing: Specialty pharmacies should dispense a small quantity of drug on the first fill without penalties to the patient. Copayment/benefit design should be adjusted so that patients are not penalized for more frequent refills because of smaller quantities dispensed. Implementation of this recommendation requires engagement with payors and other providers (e.g., physicians and other prescribers, traditional community pharmacy).

Schwartz et al.

Cost of Care

Although a specialty pharmacy model may lower drug costs for the third-party payor (insurer), it may not necessarily lower overall health care costs for patients. Additionally, the extra administrative responsibility of communicating with the specialty pharmacy may add cost to the oncology practice. For patients, because specialty pharmacy most often focuses on oral agents, an increase in cost from co-insurance and copayments may occur. Although individual clinicians or hospital-based pharmacies may have means of mitigating patients' out-of-pocket costs or waiving copayments in some circumstances, specialty pharmacies are unlikely to have these mechanisms. However, specialty pharmacies may be better equipped to direct patients and clinicians to patient assistance programs because of their relationships with manufacturers and external providers of these services.

Overall, although many aspects of specialty pharmacy have the potential to reduce system costs by adding efficiency and creating economies of scale, some aspects have the potential to increase costs or lead to waste, depending on how the model is executed. Moreover, specialty pharmacies may have little to no influence over a patient's out-of-pocket costs if these are determined by policies instituted by third-party payors as part of the patient's medical or pharmacy benefit.

Although the task force discussed cost of care in the context of specialty pharmacy, it also recognized that the overall cost of oncology care is a sufficiently large issue that fell outside the scope of this targeted initial discussion. The task force provided no specific recommendation other than that this topic should be addressed at a future date.

Medication Safety and Specialty Pharmacy

Potential Safety Advantages

The appropriate and effective use of specialty pharmacy has the potential advantage of improving care for people with cancer. A pharmacist or nurse working for a specialty pharmacy or institutional practice may have greater familiarity with oncology products than a generalist community pharmacist. Also, by the nature of their size and number of patients within their catchments, specialty pharmacies have access to data and information that could more quickly

identify safety issues. If specialty pharmacies were to leverage these data for tracking events and for outcomes research, patient safety could be significantly improved. Specialty pharmacies have established strategies to monitor medication adherence, including routine follow-up telephone calls.

However, the distance to a specialty pharmacy can be a disadvantage compared with local hospitals or community pharmacies. Adverse events or side effects that could be quickly recognized by an in-person evaluation of the patient may be missed or downplayed in a telephone conversation with the patient, and the opportunity to report the adverse event to a national incident reporting database may be lost. Under the current paradigm, specialty pharmacy can improve patient safety when the staff has a deep knowledge and understanding of specialty products and the conditions they treat.

Recommendations for Medication Safety

All pharmacies, including specialty pharmacies, should participate in a national incident reporting database to include medication errors and adverse events, and "near miss" errors/events. Because specialty pharmacies participate in a niche market that aggregates several patients with similar diagnoses across large geographic areas, data collected by specialty pharmacies could be a leading indicator of potential safety issues. In other words, specialty pharmacies may be able to identify trends or problems with more robustness compared with the community or institutional practices.

Potential Safety Challenges

The largest challenges to patient safety-related to specialty pharmacy are in communication/coordination of care, access to medical information, product integrity, product manipulation, and disposal of hazardous waste.

Safety Implications: Communication and Coordination of Care

If a specialty pharmacy acts as a silo outside of the care team and information does not flow in both directions, errors may occur if a dose modification is not communicated to the pharmacy or an event that is communicated in a telephone conversation with the pharmacy is not shared with the clinician. Adding another layer to the mix of care coordina-

tion can be challenging for practices and hospitals already burdened with administrative overhead and communication with third parties. Likewise, specialty pharmacies may not have full access to other medical information (e.g., complete medication list, concurrent disease states, comorbidities) needed to perform comprehensive medication reconciliation to assess for interactions and adverse events.

Product Integrity

Product integrity becomes a safety issue for products that require special handling, especially for products that are not for self-administration and need to be delivered directly to a patient. Lack of temperature control during shipping is one example of how a product's integrity may be compromised by a mail-order model.

A larger safety concern, however, occurs in the practice of "brown bagging," which involves a product being shipped to a patient, who then brings the product to a health care provider for administration. The provider may not be able to verify that the product has been handled properly, or even mixed correctly if, for example, it is an infusion drug. Therefore, inability to track a product's pedigree from the manufacturer to the point of administration is a potential safety concern with specialty pharmacy, especially for non-self-administered agents. It is also important to note that pedigree laws are primarily designed to ensure that counterfeit drugs, which are a particular problem with oncology-related products, do not enter the national drug distribution system.

Hazardous Waste Disposal

Prescription drug disposal is rapidly becoming an industry-wide problem, for which recommendations on appropriate disposal methods clearly must be developed. Furthermore, patients require education on proper disposal of pharmaceutical waste, especially when it is labeled hazardous. Recently, the Environmental Protection Agency (EPA) proposed adding "hazardous pharmaceutical waste" to the Universal Waste Rule to allow for a more streamlined system to manage this waste.⁵ The proposal would facilitate pharmaceutical take-back programs from households (by breaking down regulatory barriers) so that health care and other facilities can collect the waste from households and dispose of it properly.

Disposal of hazardous pharmaceutical waste is of major concern to hospitals, physician offices, and any practice that generates this waste when preparing or administering chemotherapy. In its guidelines for handling hazardous drugs, the American Society of Health System Pharmacists provides background information on what constitutes hazardous waste and guidance for proper disposal.⁶ Although these guidelines focus on disposal of hazardous waste within an *institution*, *patient* disposal of these materials is also a concern.

Although the concerns about patient disposal of hazardous waste (e.g., oral agents) are not necessarily different with specialty pharmacy than they would be with a traditional community pharmacy model, the payor mandate for specialty pharmacy to dispense larger amounts of drug covering 60 to 90 days of treatment creates the potential for more waste (see previous discussion regarding dispensing quantities) and therefore more concerns regarding its proper disposal.

Specialty Pharmacy Implications for Clinical Research

Opportunities are available for specialty pharmacy to collaborate with clinical research efforts, but concerns also exist about patients enrolled in clinical studies using a specialty pharmacy. Timely access to drugs, coordination of dose modifications, reporting of adverse events, and coordination of patient information are challenges for patients on research protocols, and these challenges might be potentiated if a specialty pharmacy is involved (especially if the drug must be procured through a restricted distribution channel). Another concern is that drugs mandated to have a restricted distribution system (e.g., through a specialty pharmacy) may not be studied in a clinical trial in which multiple oncology drugs are used in combination, because it would be impossible for a single provider to provide and coordinate the entire therapy.

However, specialty pharmacy can contribute to the clinical research process by facilitating the aggregation of data, especially for patients with rare or low-incidence tumor types, and may be able to assist in better delivery and distribution of drugs when patients are disseminated across a wide geographic area. Through telephone follow-up and disease man-

Schwartz et al.

agement capabilities, specialty pharmacies may also have the opportunity to collect additional data from patients and better facilitate exchange of information as part of clinical research.

Summary of Task Force Recommendations

The NCCN Task Force identified recommendations within the following broad categories:

- Modification of specialty pharmacy processes to better support care of oncology patients
- Training and education of specialty pharmacy practitioners who care for patients with cancer
- Coordination of care
- Coordination of information
- Regulations for specialty pharmacy practice

Recommendations for Modification of Specialty Pharmacy Processes to Better Support Care of Oncology Patients

- Specialty pharmacy should allow patients the option of obtaining their medications at a community pharmacy outlet or receiving them through mail order.

Recommendations for Training and Education of Specialty Pharmacy Practitioners Who Care for Patients With Cancer

- Specialty pharmacy personnel should possess specific expertise in oncology.
- Pharmacists should be knowledgeable about cancer-related disease processes, with oncology board certification encouraged and supported for the long term.
- Pharmacy technicians and other support staff should be trained in appropriate safety and dispensing requirements.
- Pharmacy technicians and other support staff should be trained in appropriate triage and elevation of issues.

Recommendations for Specialty Pharmacy to Ensure Optimal Coordination of Care for Patients and Their Families

- Standardize methods to communicate with the oncology health care team.
- Implement rapid communication strategies to assure ability to dose modify.
- Adopt common language to expedite communication.
- Incorporate a comprehensive approach; include

members of the health care team involved in drug therapy decision-making.

- Develop strategies to assure that the coordination of care for individuals receiving care in multiple treatment settings (e.g., hospital, outpatient clinics, home) is executed seamlessly.

Recommendations for Coordination of Information Between the Health Care Team and Specialty Pharmacies

- Develop and use health information technology systems to foster collaboration of care (i.e., EHRs).
- Integrate case management and insurance coverage.
- Include clinical information and outcomes within EHR databases.
- Develop national standards based on identified shared data needs.

Recommendations for Regulation of Specialty Pharmacy Practice

- Develop and implement regulations for the dispensing and handling of oral chemotherapy.
 - ▶ Individualize education for patients and caregivers.
 - ▶ Develop guidelines for proper disposal of hazardous drugs that are dispensed directly to the community.
- Develop standards and requirements for care coordination and medication safety (and enact into legislation).
 - ▶ Develop strategies to report adverse events.
 - ▶ Develop an incident reporting system for adverse events or safety issues similar to those used in health care systems.
- Eliminate the use of “brown bagging” for injectable chemotherapy, anticancer agents, and supportive care or other medications that are not able to be self-administered.

Conclusions

A vibrant specialty pharmacy industry exists that provides valuable services to patients with cancer, and its impact in oncology practice will expand. An opportunity currently exists for health care providers to engage and collaborate with the specialty pharmacy industry to address the current barriers to care in oncology practice. Training/education of specialty pharmacy practitioners and

Specialty Pharmacy Task Force

improving the communication of clinical information to foster collaboration should be priority topics. The patient must be the collaborative focus of all providers, and patients must fully understand how to navigate and work within a complex multi-provider system. Breaking down these barriers will benefit both specialty pharmacy and individuals with cancer through the improvement of patient care. Next steps include developing and evaluating best practices within specialty pharmacy, and its interaction with the oncology care team. Although the economics of drug costs and specialty pharmacy were too broad for this initial NCCN Task Force to address, this issue should also be addressed in the future.

References

1. Holcombe DG. Is oncology compatible with specialty pharmacy? *Commun Oncol* 2005;2:173–181.
2. Weingart SN, Brown E, Bach, PB. NCCN Task Force Report: oral chemotherapy. *J Natl Compr Canc Netw* 2008;6(Suppl):S1–14
3. Lipsy RJ, Fuller MG, Roski J, et al. Anticipating the future: how the emergence of innovative biologic agents impacts benefit design, utilization, and provider relations. *J Manag Care Pharm* 2004;10(Suppl S-a):S4–9
4. Mullins CD, Lavalley DC, Pradel FG, et al. Health plans' strategies for managing outpatient specialty pharmaceuticals. *Health Affairs* 2006;25:1332–1339
5. Environmental Protection Agency. Amendment to the Universal Waste Rule: Addition of Pharmaceuticals. Washington, DC: Environmental Protection Agency. *Fed Regist* 2008;73:73520–73544.
6. American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health Syst Pharm* 2006;63:1172–1193.

Schwartz et al.

Individual Disclosures for the NCCN Task Force Report: Specialty Pharmacy					
Panel Member	Clinical Research Support	Advisory Boards, Speakers Bureau, Expert Witness, or Consultant	Patent, Equity, or Royalty	Other	Date Completed
Rowena N. Schwarz, PharmD, BCOP	None	None	None	None	6/15/10
Kirby J. Eng, RPh	None	None	None	None	11/23/09
Deborah A. Frieze, PharmD, BCOP	None	None	None	None	11/25/09
Tracy K. Gosselin, RN, MSN, AOCN	None	None	None	None	11/19/09
Niesha Griffith, MS, RPh, FASHP	None	None	None	None	6/30/10
Amy Hatfield Seung, PharmD, BCOP	None	None	None	None	11/29/09
Philip E. Johnson, MS, RPh, FASHP	None	None	None	None	11/20/09
Shirley A. Johnson, RN, MS, MBA	None	None	None	None	11/24/09
Edward C. Li, PharmD, BCOP	None	None	None	None	7/1/09
Audrea Hotsko Szabatura, PharmD, BCOP	None	None	None	None	6/15/10
Michael K. Wong, MD, PhD	None	Argos Therapeutics, Inc.; Bristol-Myers Squibb Company; Bayer HealthCare; Onyx Pharmaceuticals, Inc.; BioVex Inc.; Genentech, Inc.; Merck & Co., Inc.; Novartis Pharmaceuticals Corporation; and Pfizer Inc.	None	None	6/17/10