Director's Forum

Specialty Pharmacy Services: Preparing for a New Era in Health-System Pharmacy

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To deal with the changing health care landscape and the expanding growth of specialty pharmaceuticals, it is imperative that health systems evaluate their current structure of providing hospital-based specialty pharmacy services. Specialty pharmacy services have rapidly expanded over the last decade, and this has affected a wide variety of disease states and in many cases has dramatically enhanced clinical outcomes. However, these medications come at a substantial cost, and a clear plan must be established at each institution to sustain financial viability. By focusing on developing a plan for specialty pharmaceuticals, the pharmacy director can help ensure the institution has prepared a strategy that is conservative, financially viable, and patient-centered.

Specialty pharmacy services are growing, and various health systems are taking the initiative to open specialty pharmacies to help better serve their patients. However, a specialty pharmacy requires a variety of different resources to operate effectively. Many pharmacy directors are faced with the decision of whether to undertake the challenges of opening a specialty pharmacy or to select alternative approaches. This decision is also impacted by whether specialty pharmacies will continue to receive viable reimbursement due to the programs of accountable care organizations and value-based purchasing.

As we look toward possible reduced health care reimbursements, there will be a continual shift to move costs from the inpatient setting by providing more outpatient and ambulatory care services. This is evident by looking at the Outpatient Prospective Payment System (OPPS) proposed rules for 2016, which show a growing number of ambulatory payment classifications (APCs) and payment bundles that include drugs, many which may end up being specialty medications. For this reason, it is critical to understand the need and purpose of implementing a health system specialty pharmacy.

Pharmacy directors are continuously searching for methods to contain costs and generate new revenue, while still ensuring optimal patient care. One example of a rapidly developing pharmacy service that can offer additional revenue along with improved patient care services are hospital-based specialty pharmacy programs. Successful development of specialty pharmacy services can unlock revenue potential provided by the specialty drug marketplace, which is expected to increase by 361% from 2012 to 2020 (\$87 to \$402 billion).¹ This specialty drug market comprises roughly 40% of the national drug spend. Future growth potential is evident by the continued pharmaceutical and biologic research dedicated to the development of specialty pharmaceuticals. About 40% of drugs in development (about 650) are considered specialty drugs, with close to half expected to treat cancer.² At least 60% of the new drugs expected to be approved for marketing in the United States in the near term will be specialty drugs.³

Hospitals and health systems are in prime position to enter into this marketplace due to the increased expansion of specialist medical practices. Integration in the oncology product line is an excellent example, as over 40% of oncologists are now

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in large group practices; this is up from 29% in 2012.⁴ Health systems with a large concentration of specialty providers have the ability to create a substantial marketplace footprint and are ideally positioned to manage the care of complex patients who require specialty drugs.⁵ Further, the average specialty pharmacy prescription generates \$2,100, with many therapies costing in excess of \$100,000 annually, which can make the specialty pharmacy model a revenue-generating proposition.⁶

Participation in this lucrative market appears to be necessary to keep up with the expanding marketplace, but each institution needs to carefully consider all the benefits and risks involved to successfully create and sustain a specialty pharmacy program. This service needs to be evaluated to determine whether it can be a rewarding opportunity for health systems and larger hospitals in terms of patient care and financial benefits.

Hospital-based specialty pharmacy services can provide a great benefit for patients and the pharmacy department. However, each institution must make its own assessment to determine which services will be feasible to provide initially and over the long term. The goal of this article will be to help pharmacy directors understand the intricacies behind developing specialty pharmacy services and identify effective alternative options. The aims of this article are to (a) determine the size and scope of a specialty pharmacy practice, (b) conduct a market assessment for providing specialty pharmacy clinical services, (c) develop a financial model for short- and long-term needs, (d) discuss management of payer contracts and specialty manufacturer contracting for limited distribution drugs, (e) outline operational workflow considerations, and (f) assess common alternative options that exist for providing specialty pharmacy services.

STRATEGIES FOR IMPLEMENTING SPECIALTY PHARMACY SERVICES

Size and Scope

One of the first decisions that needs to be made when considering opening specialty pharmacy services is to define its size and scope. Specialty pharmacies across the nation vary greatly in the extent and types of specialty pharmaceuticals that they provide to patients. Many larger institutions have affiliations with physician clinics that specialize in providing services to a variety of disease states such as rheumatology, HIV/AIDS, hepatology, and hematology that support the need of specialty pharmaceuticals. However,

some smaller institutions may be better served by providing specialty medications to serve a smaller patient population, such as cystic fibrosis and transplant patients. Table 1 provides a look at the size and scope of different specialty pharmacies. Generally, each specialty pharmacy is going to be a tailored to meet the demands and needs of its patients.

To help define the scope of the specialty pharmacy, a decision must be made about whether the site will start off small to serve a few specific patients (ie, transplant) or will enter into multiple marketplaces like oncology, hepatology, and rheumatology. One strategy is to start with an initial pilot program that evaluates the use of a single or few specialty medications; this tests the sustainability and success of the program prior to providing full-scale pharmacy services. Another decision when determining the scope of the practice site is to consider whether the employee pool (including employees, retirees, and their dependents) at the facility is going to be covered by this new service and the volume that this could add to the business model. One of the most important steps is to decide whether the health system is large enough to sustain its own specialty dispensing pharmacy. It may make more sense to partner with other hospitals to accommodate the volume necessary to remain financially viable.

Market Assessment

An evaluation of specialty pharmacy services must also include an initial market assessment to help identify potential marketplace competition and other

Table 1. Institution or health-system providing specialty pharmacy services

Size of institution or health system	Specialty pharmacy services provided
Large	Dispensing specialty pharmacy (ie, oncology, rheumatology, HIV/AIDS, hematology, hepatology), clinical pharmacy services, data reporting, limited-distribution drug access, manufacturer contracts
Medium	Dispensing specialty pharmacy supporting outpatient clinics (ie, rheumatology, hematology), clinical pharmacy services, few contracts for limited-distribution access
Small	Clinical pharmacy services, narrow scope specialty pharmacy medication (ie, cystic fibrosis)

sources that could hinder patient volume and prescription capture rate. Established large national specialty pharmacy distributors may have a significant competitive advantage. There must be careful consideration to determine how the specialty pharmacy is going to be able to outperform these national specialty pharmacies. Many of these distributors were established at the beginning of the specialty pharmacy era and have a large portion of the market share. Additionally, it is likely that patients have been utilizing their services for an extended period of time, which could present a challenge when encouraging patients to start using the health-system specialty pharmacy. When marketing the health-system pharmacy to attract patients, focus on promoting increased access, decreased time to therapy, and enhanced communication. Keeping patients within the health-system network enhances patient care, allows the collection of outcomes data, and closes the loop on transitions of care. Overall, health systems need to perform a market assessment of the specialty pharmacy that is patient-centric, identifies unique features that separate it from the competition, and demonstrates its ability to improve clinical and economic outcomes for patients.

Financial Modeling

After conducting an existing market survey, the next critical step is to develop financial analysis models that fit the proposed specialty pharmacy plan. This financial model must be conservative yet realistic and encompass short- and long-term planning for the prospective specialty pharmacy. The financial plan must be based on payer contracts that are competitive with large, national specialty pharmacies such as CVS Caremark, Accredo, and Diplomat. The level of competitiveness with contracting and the prescription capture rate will determine how many patients can be served within the health-system pharmacy; this will be a key factor in determining the payback period during the initial ramp-up timeline. The process of obtaining specialty medication contracts can take several months to finalize, and third-party consultants may be needed to help expedite the process. This additional time needed for start-up should not discourage health systems from starting a specialty pharmacy, however, it should be factored into the total time needed for payback of the capital investment and other start-up costs.

When building a financial analysis utilizing specialty drug reimbursement as a pharmacy revenue generator, it is important to consider the institution,

the associated clinics, and which patients are eligible for the 340B Drug Pricing Program. Covered entities in the 340B Drug Pricing Program are eligible for outpatient drug discounts that are 25% to 40% off typical drug pricing available to health systems. The 340B discounts that may be available when purchasing specialty drugs can help provide additional revenue to the covered entity to stretch scarce federal resources and provide greater comprehensive services to more eligible patients.⁷ Institutions and clinics that are eligible for the program should use the 340B Drug Pricing Program ethically and maintain strict compliance with regulations, as there will likely be major changes that affect the program in the coming years. Potential changes with the 340B program may lead to decreased covered entity eligibility and should not be the sole purpose for pursuing the implementation of a health-system specialty pharmacy.

When looking at capital start-up costs for a health-system specialty pharmacy, the information technology (IT) resources that are required should be given significant consideration. New specialty pharmacies will require large IT infrastructure costs for items that can include computers, work spaces, call centers, dispensing automation, and pneumatic tube systems. In addition to the physical structures, pharmacies must plan for software costs for the pharmacy dispensing system, case management systems, analytics, and potentially other dispensing software programs to improve ease of communication and access for patients.

The financial analysis model for a health-system specialty pharmacy must include the staffing component necessary for initial start-up as well as a projection for long-term growth and maintenance of clinical services. Specialty pharmacists, technicians, and prior authorization specialists must all be considered in the staffing equation for the ramp-up timeline of the pharmacy. When justifying staffing, one strategy may be to ask for all necessary full-time equivalents (FTEs) prior to opening and proceed with phasing FTEs into the pharmacy; another strategy is to ask for additional staff as growth increases the need. When determining the necessary staffing requirements, it is important to determine whether the specialty pharmacy will be paying for clinical specialists who will be imbedded into the various specialty clinics (hepatology, rheumatology, etc). In some cases, health systems may already have clinical specialists in these clinics or the clinics may be paying for their own clinical specialist through a prior hospital-based

clinic agreement with the pharmacy department. These pharmacists in clinic can be invaluable in providing patient education and in helping to increase prescription volume to the specialty pharmacy.

Contracting

Obtaining and maintaining payer contracts and specialty manufacturer limited distribution agreements is the most important aspect of the start-up, implementation, and continued growth of a health-system specialty pharmacy. When negotiating payer contracts, it is important to recognize all of the resources available to the institution and to the specialty pharmacy. In many cases, pharmacy departments can work with their health-system payer contracting department to help facilitate the negotiation and contract development process of starting a specialty pharmacy. Additionally, academic medical centers can utilize the University Health-System Consortium (UHC) to help provide leverage when negotiating payer contracts and manufacturer contracting for limited distribution drugs. Smaller, non-UHC member hospitals interested in starting specialty pharmacy services can utilize numerous pharmacy consulting companies that can help obtain specialty contracts based on previous payer and distributor relationships and other strategies. These consulting firms may also be able to devise unique specialty pharmacy models for smaller hospitals that can be as beneficial as a full-service health-system specialty pharmacy.

When negotiating payer contracts and manufacturer contracts for limited distribution drugs, data can be leveraged and used to increase reimbursement rates by modifying current contracts and to obtain new contracts that may have been previously unobtainable. Valuable, available data at the health system entity could include patient outcomes from case management programs, patient satisfaction data on current specialty pharmacy services, and data on innovative specialty pharmacy services that increase the level of patient care compared to specialty pharmacy competitors. High-quality data of this caliber can have far-reaching benefits for health-system specialty pharmacies that are looking to expand or increase the value of their current contracts.

Operational Workflow

The processes and operational workflows of a specialty pharmacy are significantly different from a traditional retail pharmacy. Considerable

thought must be given to the long-term services provided by the health-system specialty pharmacy, which may include the use of mail order dispensing, white or brown bagging, interstate dispensing, and dispensing of infusion medications with or without the use of home care services. Compared to typical retail pharmacies, additional consideration and resources must be given to the case management and prior authorization processes, because all specialty medications will require these additional steps to some degree.

As previously mentioned, health-system specialty pharmacies can distinguish themselves by implementing innovative operational services that increase the care provided to patients. Common services include the use of white or brown bagging at outpatient or inpatient visits, bedside specialty medication delivery at discharge, home health visits for adherence monitoring and administration education, and courier services for specialty medication delivery. Efficiently operationalizing these services from a health-system specialty pharmacy can help to decrease drug costs while increasing patient adherence and satisfaction.

When starting a health-system specialty pharmacy, it is important to obtain Utilization Review Accreditation Committee (URAC) accreditation. From an operational and Continuous Quality Improvement (CQI) prospective, the URAC accreditation process is considered the gold standard. URAC provides an external validation of specialty pharmacy management and CQI that validates the operational procedures and compliance of individual specialty pharmacies.⁸ Without URAC accreditation, specialty pharmacies can still function and serve patients, but they may face barriers when they try to obtain additional specialty contracts from payers.

ALTERNATIVE OPTIONS FOR PROVIDING SPECIALTY PHARMACY SERVICES

Program Self-Assessment

According to the 2015-2019 Pharmacy Forecast Survey, 79 forecast panelists (FPs) estimated that it is at least somewhat likely that one-fourth or more of health systems will conduct their own specialty pharmacy programs.⁹ Although these programs help to meet the demand and growth of specialty pharmacy services, perhaps your institution does not meet the criteria necessary for expanding into specialty pharmacy services (ie, large start-up costs, infrastructure developments, reimbursement hubs, and limited patient scope, etc). It

may be more appropriate for your institution to pursue alternative options. There are 3 effective strategies for providing specialty pharmacy services to patients without having a full-service specialty pharmacy.

Partner with specialty contractors or organizational affiliates. Consider using a specialty consulting firm or pairing with organizational affiliate specialty pharmacy programs such as Excelera Corporation and UHC's Specialty Pharmacy Program. These partnership programs help member institutions develop new specialty pharmacies and expand existing ones. Both programs provide members with tools, sophisticated data reporting, and access to limited-distribution drugs and restrictive payer agreements (limited or closed channel access).

Independent specialty pharmacy partnership. The second option involves partnering with a large national specialty pharmacy (eg, Accredo or Diplomat Specialty Pharmacy) as the sole provider for distribution of specialty pharmaceuticals. This relationship helps to ensure quality and access to specialty medications through limited distribution channels. Further, this relationship can allow a health system to take advantage of the strengths of the specialty pharmacy (ie, contracting, retail space, staffing).

Innovative operational services. The third option is for the health system to develop detailed hospital policies and procedures that would allow for patients to safely participate in either the white or brown bagging strategies. Table 2 compares and contrasts the differences between white and brown bagging and describes how each can be utilized. Although issues such as institutional liability and product integrity need to be resolved, this approach provides a patient-centric approach that allows patients to have access to the specialty medications they need.¹⁰ Health systems should consider this opportunity if state legislation and organizational policies support the concept of white or brown bagging specialty pharmaceuticals.

CONCLUSION

Implementing specialty pharmacy services can be an effective way for health systems to generate additional revenue, increase patient access to clinical management services, and develop an enhanced model for coordinating patient care. The opportunities and benefits of implementing specialty pharmacy services can be substantial, but alternative options can bring value to your institution by helping you manage excess costs and enhance the continuity of care for patients.

Table 2. Innovative operational services: White versus brown bagging

Patient situation	Potential problems	Potential solutions
Outpatient clinic visit: Medications administered in clinic	<ul style="list-style-type: none"> ○ Hospital policy ○ Additional contracts or registration may be needed to obtain drug ○ Product integrity concern if medication sent to patient 	White bagging: Patient to receive product from specialty pharmacy or physician office and clinic. Specialty pharmacy delivers actual product to the health care provider.
Admitted as inpatient: Medications needed during stay	<ul style="list-style-type: none"> ○ Waste management for unused patient-specific medications ○ Ability to charge for services provided 	Brown bagging: Patient picks up product from specialty pharmacy and brings to the hospital pharmacy or physician office and clinic.

Adopted from Table 3 in Kirschenbaum BE. Specialty pharmacies and other restricted drug distribution systems: Financial and safety considerations for patients and health-system pharmacists. *Am J Health Syst Pharm*. 2009;66(24 suppl 7):S13-20.

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