

ASHP Specialty Pharmacy

RESOURCE GUIDE



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pharmacists advancing healthcare

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Introduction

The purpose of this resource guide is to provide an overview of the financial and business challenges and opportunities in incorporating specialty pharmacy into hospitals and health systems. This guide can be used by pharmacists, regardless of practice site, looking for guidance on how to design their facility's approach to specialty pharmacy. The document provides a framework for hospitals and health systems to use in deciding which business model of specialty pharmacy best aligns with patient needs and institutional goals. Examples of each business model are provided. Appendices include outlines, glossaries, and tools for identifying and shaping the best business model for the facility and its patients.

HOW TO USE THIS RESOURCE GUIDE

The online version of this guide has actively linked Bookmarks to allow you to skip to the sections most relevant to you.

The introduction of this guide provides a summary of the past and current market placement of specialty pharmaceuticals, future market projections, and the related challenges and opportunities facing all health systems.

Appendix B contains a tool created to help you evaluate which of four general business models best fit your pharmacy's needs and situation. Once you decide which models to explore in more depth, you can navigate directly to those sections.

Following the business model sections are discussions of two topics that apply to all models; legal and regulatory considerations, and business and financial analysis.

In the 2013 ASHP National Survey of Pharmacy Practice in Hospitals, 63% of respondents reported that specialty pharmacy products created burdens they found “challenging” or “extremely challenging.” Thirty-five percent had at least a weekly need to coordinate care with a specialty pharmacy, and 71% indicated that specialty pharmacies interfered with the organization's ability to provide medications in a timely manner.¹ The 2014 ASHP National Survey of Pharmacy Practice in Hospitals found that respondents were using several different strategies to address specialty pharmacy, including functioning as a specialty pharmacy themselves, formally partnering with a specialty pharmacy, and receiving products from specialty pharmacies as determined by payer or manufacturer.²

For the purposes of this document, specialty pharmacy and specialty pharmaceutical are defined in Table 1.

Background

Specialty pharmaceuticals have emerged as the fastest growing segment of the pharmaceutical industry, dominating new drug development for the past decade. It is anticipated that by 2020 specialty pharmaceuticals will represent 50% of all US drug expenditures for only 2% to 4% of the population.³ Many of these drugs are utilized in the ambulatory setting. Many are self-administered injectable and oral therapies.

Similarly, specialty pharmacy practice has evolved rapidly since the turn of the century. Traditional retail pharmacy practice was not structured to handle complex, costly specialty pharmaceuticals. The high cost of specialty drugs makes them financially unwise to stock in the pharmacy, requiring drop-shipment from a distributor or manufacturer. Retail pharmacies were also not equipped to contend with the complex reimbursement issues, nor were they clinically organized to deal with the patient support required for these complex therapies. Large, fully equipped specialty pharmacies from CVS, Walgreens, Medco, and ESI emerged between 2002 and 2006 to capture most of the market, although there were and continue to be independent specialty pharmacies like Avella, Diplomat, and Amber that compete for patients.

Diverting prescriptions for specialty pharmaceuticals to outside entities potentially fragments the care of vulnerable, complex patients, compromising clinical outcomes

TABLE 1**Definitions for Specialty Pharmacy and Specialty Pharmaceutical**

Specialty pharmacy practice encompasses the provision of specialty pharmaceuticals, which typically require unique fulfillment and patient care support services.

Unique fulfillment elements may include:

- Coordination of care and facilitating drug access to limited distribution specialty pharmaceuticals
- Facilitating mail-order delivery logistics
- Negotiating payer contracts
- Maintaining cold-chain distribution
- Dispensing and tracking a significant number of products requiring REMS
- Accounts receivable support/management
- Program accreditation management and development of program marketing materials

Technical and clinical patient care support services will include:

- Benefits investigation, prior authorization, and patient assistance program (PAP) management
- Call-center development, staffing, and monitoring
- Case management, which may include development of protocols and disease state management at a minimum

- Product device training
- Data management of technical and clinical patient care services

Specialty pharmaceuticals have at least some of the following characteristics:⁴

- High cost
- Involve complex treatment regimens that require ongoing clinical monitoring and patient education
- Have special handling, storage, or delivery requirements
- Are generally biologically derived and available in injectable, infusion, or oral form; biologics may also have companion genetic biomarker tests
- Increased potential for limited or exclusive product availability and distribution
- Are dispensed to treat individuals with rare diseases
- Treat diseases or conditions marked by long-term or severe symptoms, side effects, or increased fatality
- May be defined by payers as a specialty pharmaceutical

REMS = Risk Evaluation and Mitigation Strategies

and increasing the total cost of care. Because of this, it is not uncommon for patients to experience interruptions in therapy or delayed start of therapy. The current system exhibits both a high therapy abandonment rate and suboptimal medication coordination resulting in poor adherence and/or unnecessary adverse drug events.⁵ For example, three out of every four hospital admissions in oncology are due to noncompliance with the patient's drug therapy.⁶ Integrated health network (IHN) specialty pharmacies have emerged in the marketplace as the answer to a fragmented system of specialty care caused by utilization of big box and independent specialty pharmacies, which are not operationally integrated with the specialty clinic. Another reason for the emergence of IHN specialty pharmacies is the revenue opportunity. A 2012 UHC study of seven academic medical centers

(AMC) showed that the average AMC wrote over \$200M in specialty prescriptions annually, although most captured less than 15% of the specialty business (unpublished data).

With the growth of accountable care organizations (ACOs) and other payer systems in which hospitals assume the risk, IHNs are developing specialty pharmacies that operate within an integrated model of care. IHN specialty pharmacies can improve patient outcomes and lower the overall episode cost of care by using pharmacists within specialty clinics to manage the drug therapy; operating a central call center that includes benefits investigation, prior authorization, and reimbursement support; and documenting on the same electronic medical record (EMR) as the physician to enhance coordination of care.

Business and Market Environment

When setting payer targets for specialty pharmaceuticals, it is important to remember that all Medicare patients are open access (i.e., all providers have the ability to provide services to Medicare beneficiaries assuming they meet Medicare's provider requirements). However, for the Part D pharmaceutical benefit, payers are allowed to establish preferred networks of specialty pharmacy providers. This can put IHN specialty pharmacy programs at a disadvantage; although they have access to Medicare patients, it is difficult for them to compete with larger chains to be in the preferred network. Nonetheless, some specialty medications, such as Humira, are also provided as a Part B benefit. IHNs can fill these prescriptions as long as they have a Part B registration for their specialty pharmacy.⁷

As of 2015, thirty-two states have “any-willing-provider” legislation.⁸ In those states, as long as the pharmacy can meet the terms and conditions of a pharmacy benefit manager (PBM) or other payer contract, they can participate. This often involves program accreditation, reporting call metrics, and sometimes providing limited clinical data.

IHNs that contract directly for health services with self-insured employers can add specialty pharmacy services to their offering. In the 2015 Pharmacy Benefit Management Institute Specialty Drug Benefit Report, about half of the 336 employers surveyed rated specialty drug cost trend among their top two management goals for the coming year.⁹ This is an opportunity for IHNs willing to manage utilization and improve patient outcomes for those receiving specialty pharmaceuticals.

Infused therapies make up approximately one-third of specialty medications and are often provided in a hospital outpatient department or a physician clinic. These drugs may provide a substantial source of revenue for the health system. Yet insurers and PBMs are moving many of these specialty and nonspecialty infusion therapies to alternative treatment sites where it is less costly, such as in the home or at an infusion pharmacy. Health plans indicate that they can benefit from savings of 20% to 60% in average cost per infusion. United HealthCare was an early adopter of this strategy, but now other insurers are following, which is negatively impacting IHNs. In the 2014 EMD Serono report of health

insurers, 63% of payers currently use or expect to create limited or preferred infusion networks, and this percentage is expected to increase in the future.¹⁰

Specialty pharmaceutical manufacturers may also have an interest in directing the market to a lower-cost site of care. Payers prefer lower-cost self-administration over higher-cost hospital outpatient administration, and they may privilege self-administered products over outpatient-administered ones on the payer's formulary. Payers can use prior authorization and step-therapy techniques to position other, less costly therapies ahead of them and negatively impact their market share.

Emerging changes to medication benefit design are also intended to influence the site of care. Both the 2014 EMD Serono report of health insurers and the Magellen 5th Edition Medical Pharmacy Trend report show a trend of moving specialty pharmaceuticals from the medical benefit to the pharmacy benefit.^{10,11} In a number of those plans, specialty pharmaceuticals are restricted to preferred network pharmacies. If the health system does not have a specialty pharmacy within the payer network, the patient is forced to use the plan's specialty pharmacy. This creates a white-bagging scenario when the patient wants to have the medication administered in their physician's office or the hospital outpatient infusion center. White-bagging refers to a specialty pharmaceutical being shipped or delivered by an off-site specialty pharmacy directly to the location where it will be administered. However, most hospitals do not allow white-bagging because they cannot assure the pedigree of the drug or proper prior storage, which is required for compliance with accreditation standards. Unfortunately in this scenario, the patient can experience extreme difficulty in obtaining access to care.

There is a good business case for IHNs to develop a specialty pharmacy program and be proactive in negotiating contracts for specialty medications and infusion therapies with major insurers. Most health systems have not transitioned from legacy percentage of charges contracting to average sale price (ASP) plus or average wholesale price minus contracting. This leaves them at a disadvantage in the market. Table 2 provides examples of the potential difference in reimbursement rates depending on calculation method.

TABLE 2

Reimbursement Rates by Method^{10,11}

SITE OF CARE	METHOD			MEAN REIMBURSEMENT RATE			
	ASP+	% of AWP-	Charges	ASP+	% of AWP-	Charges	New Unclassified (AWP-)
Office	53–78%	17–20%		Range: 4–20% Mean: 9–15%	Range: 10–26% Mean: 10–16%		20%
Home Infusion	31%	46%		18%	14%		20%
Hospital Outpatient	13%	15%	38%	?	?	66%	17%

Adapted from *Magellan 2014, 5th Edition Medical Pharmacy Trend Report* and *EMD Serono Specialty Digest, 11th Edition*.

Care Processes for Managing Patients Receiving Specialty Pharmaceuticals

As science continues to evolve and more complex specialty therapies are developed, so must the patient care process advance to assure the safe and effective use of specialty pharmaceuticals. In our current delivery system, there are three broad approaches to patient care that have evolved for specialty pharmaceuticals namely; (1) traditional patient care; (2) coordinated patient care; and (3) integrated patient care. These processes successively progress from less comprehensive to more comprehensive patient care.

In both the integrated and coordinated care processes, metrics are often required by insurers contracting with specialty pharmacies. A list of sample metrics can be found in Appendix A of this resource paper.

Traditional Care

The traditional care process is typically seen in the care of patients who have their specialty medications filled at a retail pharmacy. The pharmacist can check for allergies and drug interactions using the profile of medications filled by the patient at a particular pharmacy or retail chain. The pharmacist can also educate the patient on the use of the medication and instruct the patient on how to administer it.

The traditional care process does not include the use of a standardized case management protocol nor regularly scheduled follow-up communication to assess adher-

ence to the prescribed therapy. It also does not include a standardized education program for the patient. Often the abandonment rate can be high due to problems with affordability and the absence of specialized reimbursement assistance. In addition, there is not a direct link with the physician to notify him when the patient has prematurely stopped taking his medication. Adherence to therapy is also typically less than would be found with other care processes unless the pharmacist has a unique relationship with the patient and their physician. Many of the specialty pharmaceuticals released over the past five years have not been distributed through channels using the traditional care process.

Coordinated Care

Pharmacies that have the majority of their business devoted to specialty pharmaceuticals usually provide coordinated care. These pharmacies typically offer reimbursement assistance, patient care coordination, pharmacist involvement in the initiation of therapy, and ongoing monitoring of the patient. The care provided in this process of care is more comprehensive than the standard process of care.

Once a referral is received to initiate therapy, a reimbursement specialist is assigned to perform benefits investigation and verification. One of the greatest challenges faced by the reimbursement specialist is obtaining necessary and accurate paperwork from the physician's office. This can sometimes result in delays in therapy or therapy never being initiated.

In larger specialty pharmacy operations, reimbursement specialists are assigned by therapeutic area and geographic region. They also assist the physician's office with prior authorization when required. However, when authorization is denied, it is the physician's responsibility to respond with a written letter of medical necessity. In this model, the pharmacist does not have access to the medical history and the justification for therapy contained within the patient's medical record; therefore, the pharmacist cannot assist the physician in preparing the letter of medical necessity.

Many specialty pharmacies will assist patients in need of a patient-assistance program; however, it depends on the specialty pharmacy's business model and the time commitment that is required. For example, if a manufacturer's patient assistance program (PAP) requires that the patient be transferred to another pharmacy, then the originating pharmacy may offer only minimal assistance to the patient.

Specialty pharmacies are usually organized by therapeutic area. Some assign each pharmacist a defined case load of physicians and their patients. Others utilize a queue system where patient calls and referrals are taken in the order received. It is easier to achieve consistent and thorough coordinated care in a system in which the pharmacist manages a defined case load of patients and physicians versus a queue system with a large variety of providers and patients. This is because the pharmacist can more easily build a professional relationship with the prescriber and the patient that promotes patient-centered care.

Coordination between the pharmacist and the reimbursement specialist is also essential in the coordinated care process. Sometimes patient shipments can occur before prior authorization is received when the pharmacist and the reimbursement specialist are not teamed together within the same physical location.

Pharmacists working in specialty pharmacies often provide standardized case management and patient education programs. Patient care technicians are utilized to follow up with patients about their therapy and to process refill reminders. When required, the patient care coordinator will refer patients to the pharmacist to address medication management issues or questions they have about their therapy.

In the coordinated care process, pharmacists do not have access to a common patient EMR. Therefore, the pharmacist has to rely on patient-reported information. In this care process, physicians are typically not made aware when the patient abandons therapy and usually receive no measurement of patient adherence from the pharmacy. However, patient adherence is usually better than the standard care process due to the scheduled follow-up calls from the patient care coordinator. Nonetheless, problems with initiation of therapy, inability to adequately monitor therapy, and abandonment are the foremost issues experienced with this process.

Integrated Care

The integrated care process for specialty pharmacy looks similar to integrated processes for other aspects of healthcare. Integration occurs when services are well coordinated with good communication among providers. For specialty pharmacy, this includes pharmacist and pharmacy staff involvement in comprehensive medication management and team-based care. Pharmacists practicing in this care process are often residency trained and board certified. Often the pharmacist has a collaborative drug therapy management agreement with the physician.

In an integrated, specialty pharmacy process, pharmacists are embedded in the specialty process. This ideally includes the physical presence of the pharmacist but may also mean ready access to a remote pharmacist. The pharmacy team is involved with transitions of care between settings, patient training and education, and ongoing patient monitoring. Pharmacists in the integrated process have ready access to information and can review full medication lists, diagnoses, lab results, clinic or discharge notes, and past treatments. Using this information and information gathered directly from the patient, the pharmacist is able to review patients' needs and make treatment recommendations. These interventions are documented in the EMR.

Key success factors of the integrated process include:

- Complete and timely information about the patient and the services they are receiving
- Access to the EMR
- Adequate resources for patient education and self-management support

- The ability to measure and report on the quality of care
- A culture of teamwork among staff and physicians

In addition to clinical intervention, the integrated care process generally includes the pharmacy team in coordinating nonclinical functions. This often comprises services described in the coordinated care process including reimbursement tasks such as obtaining prior authorization or obtaining alternate funding for medications. As an integrated part of the team, these functions can often be performed more quickly.

The integrated care process is most closely aligned with the Recommendations of the ASHP Foundation Ambulatory Care Summit. The recommendations call for interprofessional patient care teams and for pharmacists practicing on those teams to have the proper credentials.¹³ The integrated care process encourages collaborative drug therapy management with physicians in which pharmacists are allowed to write prescriptions, order laboratory tests, and coordinate care. It promotes standard care processes and seamless transitions across the continuum of care.

Lastly, in a truly integrated approach, medication dispensing occurs as part of the process. In addition to education, patients are able to receive their medication from the care team.

Strategic Planning

Having a solid understanding of the health-system's preferred care process provides a background for strategic planning and determining the best business model to fit the needs of patients, prescribers, and payers. Appendix B outlines factors to consider and provides a decision tree to further assist in strategic planning of specialty pharmacy services.

Ideally the specialty pharmacy program is part of the overarching health-system plan; however, this can be managed as part of the pharmacy enterprise. It will be important to identify services that are already in place within the health system or that can be built using existing resources. It is also beneficial to know and incorporate accreditation requirements into the plan from the beginning to minimize surprises and revisions.

Due to the swift evolution of the specialty pharmacy market, time to specialty pharmacy launch is an important consideration. Not only does the competition increase substantially, but for every 6- to 12-month delay the difficulty of program implementation also increases due to emerging payer and manufacturer restrictions. Consider the pros and cons of internal support for implementation versus external consultation to determine the most expeditious means of program roll-out.

Prior to implementation of specialty services, it is critical to identify areas of opportunity and resource needs to support patients and providers. An internal analysis can be completed by evaluating prescribing trends of specialty medications within ambulatory clinics and quantifying the patient and prescription volume by disease state and therapeutic class. This allows for effective clinic targeting approaches and will assist in return-on-investment (ROI) calculations for new staff requests and program financial performance metrics. Drugs included in the analysis may be identified by reviewing existing specialty pharmacy contracts, identifying disease states of organizational importance, or focusing on centers of excellence within the organization. It may be beneficial to approach specialty pharmacy services by therapeutic area and determine predominate payers by therapeutic area. Because many specialty pharmaceuticals have a high number of drug interactions, some health systems have taken the approach of wanting to fill all of the patient's prescriptions, specialty or not.

Current standards of service for program initiation include prior authorization support, PAP support, and patient financial support. Implementation of these services synchronously with dispensing operations is necessary to offset the support clinics are already receiving from external specialty pharmacy vendors. These services must be marketed aggressively to clinic staff and patients to drive patient recruitment and internal pharmacy capture. However, the difficulty of integrating services with specialty clinics will be contingent on existing clinic relationships with external specialty pharmacy vendors who are already integrated and offer support services. The key in changing behavior is identifying how internal services are different, better, and will make staff workflows more efficient through a single point of referral and via the organization's access and use of the medical record.

Data analysis and financial tracking will lend long-term support for programmatic expansion and resourcing needs. Patient outcomes tracking and pharmacist interventions will provide necessary marketing information to clinic providers and physician leadership. It also provides critical information to support third-party payer negotiations and to share during discussions with pharmaceutical manufacturers. Without the development of data analytics to support overall operations, long-term programmatic viability is jeopardized as the payer marketplace shifts to outcomes-based measures to become more restrictive.

If the organization is planning to partner, outsource or even forgo a formal specialty pharmacy program, it is critical to determine if working with other entities will involve a short- or long-term agreement. Strategic planning in a nonformalized specialty pharmacy model should involve a timeline for implementation of an alternative model recognizing that doing nothing is not in the best interest of the organization or the patients. Long-term allowance of white-bagging, brown-bagging, or redirecting patients to other sites for specialty pharmaceutical administration introduces risk, results in loss of revenue for the organization, and adds to fragmentation of care.

Most organizations are not likely to fill 100% of specialty pharmaceutical prescriptions due to payer contracting and distribution networks. Health systems should develop an approach that includes at least appropriate initiation of therapy for patients with specialty prescriptions the hospital specialty pharmacy cannot fill.

Specialty Pharmacy Business Models

Organizations evaluating the best option for addressing specialty pharmaceuticals will need to consider which business model meets the needs of providers and patients. This resource guide provides guidance on four prospective business models: (1) build; (2) partner; (3) outsource; or (4) manage individual patient risk (no formal specialty pharmacy program). Pros and cons of each model will be discussed in the section that addresses key domains relevant for all business models and how they relate to each specific model.

Specialty Pharmacy Build Model

The “build” model of specialty pharmacy development refers to the organization developing and providing specialty pharmacy services to its patients. There may be situations or distribution/contractual requirements that necessitate patients to seek pharmaceutical care external to the organization, but the intent of this model is to provide comprehensive services to all specialty patients internally. Organizations have a unique opportunity to provide patient-centered specialty pharmacy services, which improve outcomes for their patient population, through access to the complete medication record, opportunities for face-to-face pharmacist-patient encounters, and the opportunity to provide specialty medications to the patient throughout the continuum of care.

Special Considerations

The “build” model requires careful consideration of resources needed to maintain service level expectations of patients, pharmaceutical manufacturers, and payers. Prospective monitoring of capacity and patient volume is critical to maintain scalability of service and avoid patient care interruptions. In short, this model will incorporate all aspects of specialty pharmacy listed in the specialty pharmacy definition, Table 1.

To be market competitive, this model requires capital investment for financial management (including both budgeting and accounts receivable [A/R] management), systems personnel (for diversification of roles including patient management and drug dispensing), and facility space (including refrigerated product and shipping supply storage). Incremental patient volume expansion and new contract inclusion will require careful evaluation of capacity and facility requirements. Constant monitoring and projections of specialty pharmacy growth is required to ensure service levels are meeting expectations.

Examples of successful models

Although constant monitoring and projections of specialty pharmacy volume is required, multiple strategies to meet service levels exist. Some organizations may choose to introduce a specialty model that has the capacity to service a large proportion of their organization from inception. In other instances, organizations may choose to utilize an “incremental” approach to specialty pharmacy services expansion in which existing resources (e.g., facilities, personnel) are leveraged until a critical mass of patients are obtained to warrant a significant capital investment.

Care coordination

The strength of the build model is the internal management of care coordination and care transitions for complex patients, and placing medication in-hand for these complex patients prior to discharge. Internal visibility of the full EMR allows pharmacy staff to prospectively view upcoming appointments and coordinate medication delivery to align with appointments (e.g., lab, therapy education, follow-up), and most importantly, provides pharmacists with the information needed to make meaningful interventions. The presence of internal specialty pharmacy services can decrease the likelihood of transitional issues, thereby reducing the organizational risk related to readmission rates and patient satisfaction (HCAHPS).

Organizational infrastructure/systems

Rapid implementation of the build model is possible by leveraging existing ambulatory pharmacy services. However, dedicated space to support ancillary services required for comprehensive services will be needed long-term. The timeframe for this build-out is dependent on current capacity for service expansion, ability of current pharmacy services to accommodate increased volumes, and existing capital for investment in resources needed to initiate the program. Product fulfillment requires, at minimum, access to product and to patient lives, and the ability to care for patients longitudinally. Those requirements are further described below:

Access to product: The ability to provide specialty pharmacy services is contingent on being able to provide product fulfillment services for specialty patients, but it should not be delayed due to perceived lack of access to individual therapeutic agents. Comprehensive pharmacy services can be initiated with access to standard distribution medications, and access to limited distribution pharmaceuticals should be considered only when service level expectations (from the patient, pharmaceutical manufacturer, and prescriber perspectives) for the specific product can consistently be met by the organization.

Access to patient lives: Increasingly, third-party payer contracts are restricting pharmacy inclusion to narrowed specialty pharmacy networks. However, as is the case with access to product noted above, access to all third-party payer contracts should not delay implementation of specialty pharmacy services. Contracts may be targeted individually on a payer-by-payer basis or can be targeted through the use of a Pharmacy Services

Administrative Organization, which serves as a contracting solution for pharmacy members. Following implementation, coordinating medical and pharmacy benefit payer contract negotiations synchronously provides additional leverage for pharmacy benefit contract inclusion.

Ability to care for patients longitudinally: Prior to the implementation of specialty pharmacy services, establishment of home delivery services (with product delivery and tracking capability) is critical for long-term patient management. Specialty medications are typically taken chronically, often require cold-chain distributional requirements and may require distribution to patients across broad geographical areas. Careful consideration and capacity to support these requirements is critical to providing comprehensive service. Shipping services must ensure that product integrity is unaffected by pharmacy operations and that refrigerated medications can be delivered in a timely and temperature-controlled manner.

Patient care services

The key differentiator between specialty and traditional ambulatory pharmacy services is the patient care services provided after initial product fulfillment. Specialty pharmacy operations require longitudinal patient management and monitoring—the majority of which is done via telephone. This requires the implementation of a dedicated role or focus on patient outreach and management, refill intake, and patient care services. As services grow, a centralized call center should be considered for these services. Increasingly, specialty pharmacy contracts require patient access to a pharmacist 24 hours/day, 7 days/week. This requirement can be accommodated by a variety of means and should not be a significant decision point when deciding to proceed with implementation.

Integration of pharmacist-based patient management with call center operations is critical for longitudinal patient management. Pharmacist involvement at the point of new patient intake should include confirmation of patient condition (i.e., appropriateness of the medication prescribed for the patient), a comprehensive medication review for the patient (i.e., inclusive of medications being ordered by providers internal and external to the organization), disease state education as necessary to support patient engagement, and patient goal/expectation setting.

Data collection and management is a core component of performance improvement planning to assess the cost of care, identify additional opportunities for growth (with third-party payers and pharmaceutical manufacturers), and identify opportunities for service improvement. Data management surrounding compliance rates, patient outcomes, and patient and provider satisfaction should be hallmarks of any program and feed directly into performance improvement initiatives. A long-term focus on data reporting and quality will be mandatory for future payer contract inclusion and support for service expansion within the organization.

Personnel

The implementation of specialty pharmacy services requires the integration of several layers of staff providing complementary patient and provider support roles. All staff, including pharmacy department management, will require training in specialty disease states covered by the program. Specific training regarding relationships between patient management and drug distribution processes may need to take place. Few specialty-specific training programs exist, necessitating the development of an internal training and credentialing program for employees.

The optimal ratio of technicians to pharmacists is best determined on a case-by-case basis and may be influenced by the organizational decision to integrate pharmacists within ambulatory clinic settings. Technician roles are typically broken into area of positional support: Prior Authorization, Call Center, Operations, and Patient Support. Pharmacist division of responsibility is similar to those previously described and may include Clinic, Operations, and Call Center.

Due to the breadth and visibility of specialty medication provision within organizations, it is often necessary to have dedicated management staff who can manage the complexity of operations. Again, the ratio of management to staff cannot be quantified and should be reviewed on a case-by-case basis. Irrespective, the resourcing of management personnel is equally as important as resourcing technician and pharmacist staffing pools appropriately to maintain a high level of patient support.

Specialty Pharmacy Partner Model

Sometimes a health system may decide to operate a specialty pharmacy but finds strategic value in partnering or contracting with another entity to offer the full range of services required for an accredited specialty pharmacy. This section discusses that model.

Institutional-specific needs will determine which services are needed from a partner. Services that could be offered by a partner include call center management (during operating hours or after-hours), prior authorization and PAP program support, contracting, case management, clinical support, staff training and education, fulfillment (complete or therapy-specific due to limited distribution), etc. The degree to which an organization decides to partner often varies based on the organization's desired time to market, existing infrastructure, health-system priorities, and in-house specialty pharmacy expertise.

Special Considerations

It is critical to find a partner that is aligned with the mission and goals of your organization. The service level agreement needs to contain service level requirements, a process for regular feedback that demonstrates acceptable service levels are being achieved and possible penalties for nonperformance.

Care Coordination/Transitions

It is important to note that this model could make some aspects of continuity of care for patients receiving specialty pharmaceuticals more challenging depending on the specialty pharmacy services, hand-offs, and service levels that are provided by the partner. The health-system pharmacy should consider what processes need to be put in place to ensure the best possible care coordination because it is likely future acute care and other outpatient services will be provided by the health system. The information in Appendix C will aid in identifying critical areas to address in selecting a partnering option.

Organizational Infrastructure/Systems

Similar to the build model, all fulfillment and patient care services will need to be met by the licensed health-system pharmacy. Determining who provides these services and the manner in which they will be provided will need to be addressed. There needs to be a clear understanding of which entity is responsible for each service of the specialty pharmacy enterprise. The overall responsibility, oversight, and accountability will fall under the control of

PARTNER MODEL

Health System Specialty Pharmacy Example

A specialty pharmacy vendor provided a proposal to health-system administration to establish on-site pharmacy services in the health system's cancer center for one-third of the gross profit. The cancer center was a 340B child site of the Disproportionate Share Hospital (DSH). The health system's Director of Pharmacy proposed establishing a health-system-owned specialty pharmacy. Due to the revenue potential in the vendor's proposal, the health-system administration gave the Director only 90 days to establish the service. The health system had an outpatient pharmacy but none of the specialty infrastructure to support a specialty pharmacy program. The Director contracted with a channel partner (to provide business intelligence/business value (BI/BV), prior authorization and PAP support, as well as a 24-hour call center and case management). The health system's retail pharmacy filled the specialty prescriptions. A partner pharmacy, as a contract pharmacy for the DSH, filled many of the prescriptions for the specialty products to which they had no access. These prescriptions were private labeled with both the health-system name and the specialty pharmacy name. Until the pharmacy could establish their own infrastructure, they utilized the contract specialty pharmacy as their channel partner.

pharmacy services. This is imperative so that the specialty service is aligned and integrated with the overall goals and strategy for the pharmacy enterprise.

An ideal structure would have the specialty pharmacy staff, including all partner services, reporting to the specialty pharmacy director (manager or lead) and the specialty pharmacy director reporting to the overarching health-system pharmacy leadership team. Key stakeholders for this model include the department of pharmacy (system pharmacy leaders, ambulatory pharmacy, clinical pharmacy, supply chain pharmacy, and 340B leadership), finance, payer contracts, legal, compliance, communications, IT, quality/medication safety, and

physician and nursing leaders from specialty clinics. A health-system innovation, strategy, or new business development group could also be an important ally. They may be helpful in aligning this program with the overall goals of the organization, assisting with organization awareness, and marketing and helping to kick start or fund the program.

Personnel

One of the advantages to the partner model is reduced personnel needs. Many health-system pharmacies lack the staff resources and expertise necessary to appropriately plan and implement specific services. For instance, a new health-system specialty pharmacy may work to utilize existing staff by having a prior authorization technician who also provides fulfillment services during peak hours. That model might be practical in the short term, but it may inhibit long-term growth. An in-house specialty pharmacy would likely have to bring on more staff with specialized areas of expertise.

The partner model allows the health-system pharmacy to focus on leveraging its core competencies while leaving the management of services outside the system's expertise or ability to experienced partners contractually obligated to provide them. Because of this balancing of strengths across two entities, in the partner model it is crucial to ensure that necessary internal and external competencies are clearly identified, understood, and met. Internally, staff needs to understand the specialty pharmacy market, service expectations, accreditation standards, supply chain and inventory management unique to specialty pharmaceuticals, as well as the often complex clinical management of each specialty agent.

In addition, the health-system specialty pharmacy leadership needs to ensure that partners are aware of local brand and service expectations and maintain competency in all contracted specialty pharmaceuticals and services. Although many health systems have programs in place to keep staff updated on the clinical and operational aspects of new therapies, partners likewise need to ensure such competencies. A call center partner that is unfamiliar with the newest oral oncology agent will lack credibility to patients and providers. On the other hand, many partners may have disease state or even drug-specific competencies available for the health system's consumption should the health system lack the manpower or expertise to provide those on its own. Partnership

contracts should include requirements for contracted staff to meet the competency standards of the health system.

Specialty Pharmacy Outsource Model

The common definition of outsourcing is purchasing (goods) or subcontracting (services) from an outside supplier or source. In relation to specialty pharmacy, this would involve contracting with a vendor to provide all (or most) specialty pharmaceuticals and specialty pharmacy patient care services to the patients of the outsourcing health system.

Special Considerations

Typically, organizations considering outsourcing the specialty pharmacy process have made the determination that they do not have the ability to provide specialty pharmacy services in-house. This may be due to limited access to capital, lack of significant specialty physician groups, no owned retail pharmacies, or some other organization-specific reason. In contrast to the true partnership model, outsourcing assumes you are not likely to internalize fulfillment or patient care services associated with specialty pharmaceuticals. Elements of outsourcing may be very similar to partnering with a specialty pharmacy, depending on the ultimate goals.

OUTSOURCING MODEL

Health System Specialty Pharmacy Example

A community hospital has six oncologists, four gastroenterologists, two rheumatologists, two infectious diseases specialists, and no retail pharmacy services. Realistic options for these practices are either a specialty pharmacy provider—it could be a contract pharmacy if the hospital owns the practices and they are 340B child sites—or it could be a hub service that will provide the BI/BV, prior authorization, PAPs, and other support the patient needs. These hub services are paid by the specialty pharmacies for transferring the prescription to them, which is how they make their money.

Building a Successful Model

Perhaps in the outsourcing model more so than other models, the goals must be clearly understood by all stakeholders before the appropriate factors can be considered for implementing this model. Three questions to ask regarding the organization's goals:

1. Is the organization interested primarily in reducing drug spending associated with employees because the organization is self-insured?
2. Does the organization want to take advantage of 340B eligibility?
3. Does the organization desire more standardization of care coordination across the organization's physician practices?

Once the organization's goals are clearly defined, the priorities in seeking out vendors can be set.

Contact potential vendors and ask specific and detailed questions about the services they provide and their ability to meet your hospital's unique needs. It is important to determine if a vendor is Utilization Review Accreditation Commission (URAC) or Accreditation Commission for Healthcare (ACHC) accredited. Many group purchasing organizations are currently offering specialty pharmacy services to their members. Wholesalers may also offer specialty pharmacy services through a subsidiary. Take care to find a company that can cover all patient populations that are important to your health system, either within their own company, or through collaborative relationships with other companies. Many also offer cobranding, allowing a hospital or health system to have its name and logo placed on promotional literature and prescription labels along with the name of the specialty pharmacy. Key questions to cover within a request for proposal (RFP) for outsourcing vendors are included in Appendix C.

Care Coordination/Transitions

It is important to note that this model could make some aspects of continuity of care for patients receiving specialty pharmaceuticals more challenging depending on the specialty pharmacy services, hand-offs, and service levels that are provided by the partner. Simply put, this model makes provision of integrated care more difficult. The health-system pharmacy should consider what efforts and processes need to be put in place to ensure the best possible care coordination

because it is likely future acute care and other outpatient services will be provided by the health system. The information in Appendix C will aid in identifying critical areas to address in selecting an outsourcing option.

Organizational Infrastructure/Systems

Infrastructure needs will depend on whether or not the health system or hospital will be filling any specialty pharmaceuticals onsite. The organization must determine which specialty pharmaceuticals will be outsourced and how many different specialty pharmacies will need to be under contract to meet the needs of the patient population. Each specialty pharmacy will likely have different policies and procedures for fulfillment of specialty pharmaceuticals, so the internal organization may need to adapt to work with multiple outsourcing vendors.

Delivery of specialty pharmaceuticals to the organization needs to be evaluated to determine if state laws allow products to be shipped in from out of state, and if so, what the licensing and regulatory requirements are for mail-order pharmacies and pharmacists working at those facilities. If products are outsourced to in-state vendors, transportation of these items must still be evaluated, and turnaround time added to workflow considerations. Outsourcing of patient care services requires careful consideration of ease of use for intake, call centers, and/or hubs for both patients and providers. Vendors may provide mobile applications and/or web portals for managing their products. A careful assessment of these services is needed to determine how they will integrate into existing workflow and to validate data safety and Health Insurance Portability and Accountability Act compliance. Stakeholders that will utilize various patient care services being outsourced should be represented during the decision-making process. Provision of data management and reporting of metrics should be evaluated by the end users of each, both healthcare professionals and patients.

Manage Individual Patient Risk Model (No Formal Specialty Pharmacy Program)

This model represents facilities that have no formal arrangement to oversee specialty pharmaceuticals or specialty pharmacy services. Specialty pharmaceuticals brought onto the campus of a hospital or health system under this model would be dealt with in a white-bagging format, previously defined as a specialty pharmaceutical

being delivered by an off-site specialty pharmacy directly to the location where it will be administered, or through brown-bagging; delivery of a specialty pharmaceutical by a specialty pharmacy directly to the patient, who then brings the drug into the health system themselves as a “patient own medication.” Both white- and brown-bagging bring medications into a hospital or health system without the institution’s direct oversight. Although this practice is similar to a patient bringing a “home medication” into the hospital, it differs in that many specialty pharmaceuticals have strict storage and preparation guidelines, which cannot be traced or guaranteed if brought into the system by a patient or delivered to the infusion center after being prepared outside the system. Further, the preparation of many specialty pharmaceuticals requires manipulation of the product within a clean-room setting, which represents a risk for contamination that is not routinely a risk associated with existing “home medication” policies within the health-system setting.

It is possible that an organization may find itself in this situation when the first patient arrives with a specialty pharmaceutical. In this era of exploding growth in the specialty pharmaceutical marketplace, organizations should be ready for this reality and know what the policies and procedures are for handling such situations, even if the policy is not to accept them and to refer the patient elsewhere.

Special Considerations

If an organization makes the decision to not allow specialty pharmaceuticals on-site, this model requires the facility to establish a “hard and fast” rule of not allowing white- or brown-bagging, which can lead to situations where the patient is referred to a different facility/care setting. Without this policy decision in place, the pharmacy leader will be placed in a position of working in a reactionary mode as product arrives from outside sources. It is possible this may also generate legal/compliance concerns (e.g., regulations regarding “redispensing,” pedigree).

A no-white-bagging policy is difficult to administer consistently across a medical center campus because of the number of potential points of entry. A product might be shipped and routed to a number of different mailing addresses or mailboxes and not even be recognized as a medication. In the event of brown bagging, the patient brings the medication to the clinic to be administered.

Any healthcare facility with complex patients or highly specialized providers can expect to encounter a patient who is a candidate for a specialty medication. Making arrangements for this care to be provided at a specialty clinic or home infusion practice is one option. A properly planned “do-nothing” approach would require the healthcare facility to complete this type of “refer-out” planning in advance of encountering a patient. Alternatively, the health system could consider formalizing a service agreement, the outsourcing model, with an external specialty pharmacy service provider capable of procuring and preparing specialty pharmaceuticals on behalf of the patients of your facility.

Care coordination/transitions

The organization needs to determine how the patient will be referred out to another provider to receive specialty pharmaceutical administration and follow-up. Similarly, if a patient arrives at a point of entry with the medication in hand, all personnel need to know the policy and procedures for addressing the situation. Care coordination can be very challenging because the health system is in a more reactive position based on situations such as the patient’s payer requirements and other provider’s patient management processes. These policies and procedures for health-system staff should include prior authorization management, product storage, documentation in medical record, and product disposal in the event a product is not used for a patient.

Organizational Infrastructure/Systems

Fulfillment: Specialty pharmaceuticals may arrive in a variety of dosage forms if the organization has not made arrangements with one specific specialty pharmacy service provider. Dosage forms may require additional manipulation prior to administration. Dosage forms may present with barcoding that is not readable by your organization’s compounding and/or administration systems (BCMP and BCMA technology). The physical delivery of these products could come through a variety of courier services that would require coordination with other departments within your health system (e.g., loading dock, facilities, etc.) Many of these products require refrigeration, which places urgency on how quickly they are identified and moved into a refrigerated storage location. It is critical for organizations without specific arrangements with specialty pharmacy providers and/or payers to anticipate these challenges and develop procedures to reduce

risks and safely manage patients and medications (i.e., educate materials management and loading dock staff on critical nature of deliveries and/or have pharmacy staff routinely check with these areas daily).

Personnel

Personnel are likely to be impacted even if the organization determines fulfillment and utilization of specialty pharmaceuticals will not occur on-site. Personnel at most likely points of entry (i.e., infusion centers) must be notified of the health-system’s policies and procedures for white- or brown-bagging specialty pharmaceuticals.

Legal and Regulatory Considerations

In analyzing an institution’s current and future approach to specialty pharmacy, it is critical to first understand both the big picture and the details of applicable legal and regulatory considerations. The legal and regulatory framework will help guide and structure the institution’s eventual approach, regardless of what model the institution chooses to implement.

A gap analysis of state and federal regulations as related to the provision of specialty pharmacy services should be a first step in planning or improving the institution’s approach to specialty pharmacy; and policies and procedures consistent with that gap analysis should be developed to support the identified scope of operations. Providers must also consider Risk Evaluation and Mitigation Strategies (REMS) requirements for specific products, and the organization must create policies and procedures to ensure and monitor adherence to established internal policy and procedure documents as well as FDA-mandated REMS and regulatory requirements.

Within the specialty pharmacy marketplace, there are three primary accreditors focused on specialty pharmacy operations. Although all accreditors are focused on standardization of service and elevation of patient care services, third-party payers and manufacturers may note specific accreditations within contract language. The decision of which accreditation is most appropriate and when to accredit does not have clear answers. Generally, accreditation is not required for implementation of specialty services unless contractually required by the primary regional payer within an organization’s care area. In the absence of a specific requirement, accreditation should be pursued at an appropriate timeline following the implementation of specialty pharmacy services.

Specialty Pharmacy Accreditation Agencies

- ACHC www.achc.org
- Center for Pharmacy Practice Accreditation (CPPA) <http://pharmacypracticeaccredit.org>
- URAC www.urac.org

In the case that it is pursued at program initiation, it is critical to understand any accreditation restrictions based on limited scope of services or disease states covered by specialty pharmacy programs.

Specialty pharmacy accreditation is an important consideration for the partner model. Accreditation standards are a valuable resource to health system pharmacy leaders to ensure that all regulatory elements are in place; those controlled internally and those provided by a partner. If one of the goals of an institution implementing the partnership approach is to become an accredited specialty pharmacy, it is important to remember that the onus of ensuring all accreditation standards are met is on the accredited health system. The health system must be able to confirm that each partner is, at a minimum, providing services at the level contractually agreed upon. Detailed Business Associated Agreements and Policy and Procedures documents outlining the legal and practical relationship between the health system and the partner services will be critical to accreditation. These documents must also take into account any services provided across state lines that require the third party to carry licenses from multiple states.

The accrediting body will expect the health-system specialty pharmacy or any entity providing services on behalf of the health-system specialty pharmacy to meet the regulatory statutes laid out in the accreditation standards. Therefore, careful selection of partner services and validation that such services meet the accreditation standard initially and in an ongoing manner is essential.

It will be vital to work closely with internal legal and compliance departments when establishing relationships with partners. These departments will provide guidance as relationships are established to ensure that all necessary contracts are completed and patient health information (PHI) is protected. The extent of the partnership will determine the degree to which legal

considerations need to be investigated. For instance, there will be unique requirements for partners that need access to PHI or health system dispensing system or EMRs, those that provide proprietary electronic systems for case management and those that are doing business as the health system in their capacity as a partner (Table 3). Experience has shown that comprehensive education for health-system leadership will be critical, particularly when entering into a contractual relationship in which PHI is exchanged.

TABLE 3

Patient Health Information Considerations

- Considerations with channel partners about the extent of use of PHI and ownership of data
- Considerations with PhRMA about the extent of use of PHI (for example, marketing and risk management)
- State regulations (for example, some states prohibit sharing prescriber information)
- Considerations with data aggregators and the de-identification of data before it is transmitted to a pharmaceutical manufacturer
- Use of business associate agreements to limit the use of PHI

PHI = patient health information; PhRMA = Pharmaceutical Research and Manufacturers of America.

Health systems may determine that the submission of specialty pharmaceutical utilization data to payers or manufacturers warrants a strategic partnership rather than a less formal relationship. This data is valuable to payers to ensure appropriate use and to manufacturers to monitor and evaluate institution and market-specific trends. Payers may require this information for the specialty pharmacy to remain in network. Manufacturers may require this information to allow the health-system specialty pharmacy to purchase a limited distribution pharmaceutical or may offer special financial incentive for providing it. Many health systems will be cautious about sharing de-identified data and may lack the necessary expertise to mine and format the data correctly.

Therefore, direct contracts with manufacturers should be carefully vetted internally to ensure all parties in the health system have a high level of tolerance for the terms of the contract and that appropriate infrastructure is in place, internally or through partners, to meet all the data reporting elements required by contract. Third-party case management software may be used to query large patient populations and can be easily formatted for submission on request. It is critical that any partner relationship maintain data elements that may be needed for future reporting.

Health-system specialty pharmacies need to be prepared for managing third party audits, including those conducted by governmental payers. Although audits can be managed internally, partners can provide necessary expertise and manpower to complete audits successfully. Such audits often seek to ensure appropriate utilization. Given the high cost of care, payers are keenly interested in ensuring that specialty pharmaceuticals provide value and are used efficiently and appropriately. Audits often seek remuneration for inappropriate use. Thus, working closely with the institution's legal department and internal auditors or external firms who are familiar with local third-party and government payers is an important strategy health systems may employ to protect revenue streams and remain compliant with all oversight and governing agencies. Just a few incorrect claims can have a significant negative impact on a specialty pharmacy program. Therefore, establishing the appropriate expertise and resources to manage the complexity and volume of audits is essential.

Organizations choosing not to have a formal specialty pharmacy model must involve legal and risk management departments in the decision-making process because the implications in these areas have the potential to be significant. A hospital or health system allowing white- or brown-bagging needs to consider the risk to the organization and the patient of allowing this practice with no direct oversight of the medication preparation or storage. Conversely, the organization needs to evaluate the risk of not providing care to patients requiring specialty pharmaceutical administration and the introduction of fragmented care into the system.

Specialty pharmacy regulations continue to evolve, and organizations involved in the delivery of specialty pharmaceuticals and specialty pharmacy services must keep abreast of current legislation.

Preparing a Business Plan and Financial Analysis

No matter what model an institution chooses, specialty pharmacy represents a substantial budget consideration. No organization should decide on a specific approach to specialty pharmacy without carefully considering the business case for or against each model. There are key decision points that should not be overlooked during the creation of a business plan. This section contains practical information and details to aid in the preparation of a business plan and an assessment of financial impact to the organization based on various scenarios. A business plan should examine the options of building, partnering, or outsourcing with the advantages or disadvantages of each, the proposed solution, the rationale for this solution, and the risk involved in implementing and in not implementing the solution. In the event the health-system plans to redirect patients to receive infusions in a different facility or care setting, the organization should evaluate and document the financial impact of reduced volume.

A business case supporting one or more specialty pharmacy model options should address these core areas; market conditions, capabilities, and resources within the organization; philosophy of care processes most aligned with the organization's goals; and alignment with the organization's desires and risk tolerance. The domains discussed in this guide under each business model should be considered in the business plan. Additionally, cost/benefit assessment and decisions will need to be made as elements of the business plan are formulated and assigned revenue and expense values. An understanding of the payers and the difference between medical and pharmacy benefits will be helpful in conducting a financial analysis.

An effective business plan will create a framework that describes the feasibility and profitability of pursuing a specific approach to specialty pharmacy. Answering the key questions required to complete a business plan will provide the structure and discipline to thoroughly think through the most accurate projections and strategies.

The framework included here as Appendix D can provide a guide in analyzing the areas mentioned above, doing organization and region-specific research, collating data and assumptions, projecting start-up costs and ongoing

cost of operations, and incorporating strategic relevance for organization. Each organization will have a different analysis, given that such analysis relies heavily on organization-specific measures such as prescription fill rates, cost to obtain and manage prescriptions and patients, and bottom-line margins.

Creating a specialty pharmacy business planning committee can be invaluable in engaging in the business plan/financial analysis process. This committee should include at least one sponsor from the administrative team and members from the medical staff, finance department, clinic practice management staff, and the contracting department.¹⁴ It is also important to identify an internal coach and supporter from finance and payer contracting, as well as facilities management. The finance team can be a vital resource for planning inventory, managing cost and revenue, and managing relationships with third parties. That said, a health-system finance team may be unaccustomed to the significant gap between purchasing, processing third-party claims and collections.

Applying basic financial management principles along with a keen understanding of the specialty pharmaceutical market, an organization can be clinically and financially successful in providing specialty pharmacy services. Typically, payers require prior authorizations for specialty drugs to manage inappropriate utilization of medication. One core tactic for remaining financially sound is for a specialty pharmacy to directly provide, or partner to provide, benefits investigation and management of prior authorizations. Doing so in-house or with a partner reduces risk to the institution. Given the high cost of specialty pharmaceuticals, some institutions are cautious about purchasing and dispensing new products. Having a strong degree of confidence in an internal or partner benefits investigation/prior authorization program will alleviate the concern and mitigate much of the risk associated with the significant expense of specialty pharmaceuticals, because reimbursement is authorized prior to dispensing.

For patients who are uninsured, underinsured, or who have been denied coverage of a specialty pharmaceutical by their third-party payer, medication access services should be offered to decrease out-of-pocket expenses for the patient. Medication access services typically

consist of facilitation of PAP applications, assistance with identification of foundation funding sources, and consideration for organizations' charity care programs. Those services can be provided in-house or through partners. Health-system specialty pharmacies should be cautious about using hub services provided by manufacturers to provide benefits investigation or prior authorization support. These services are often designed to move business to a preferred specialty pharmacy or to a preferred network of specialty pharmacies. Instead, using internal or partner services to work directly with assistance programs and charitable foundations is advisable.

Due to the inventory valuation, revenues, and claim management implications of specialty operations, implementation of a dedicated A/R system and staff should be evaluated. Critical management of A/R includes: total A/R outstanding; percent of A/R aged over a specific period of days (i.e., A/R that is not likely to be collected); and bad debt (e.g., payer take-backs) as a percent of total revenues. Although dedicated A/R staff may not be needed at program implementation, consideration of current A/R services must be part of the pre-implementation gap analysis to identify areas of staffing support and organizational need. Many health systems will have the necessary functions to manage payer contracting and A/R internally. However, health systems may lack the manpower to manage high volume, high impact A/R.

Using partner-provided services to help manage A/R can be an important way to match revenue and expense and to ensure the minimization of risk associated with specialty pharmacy. Additionally, third-party services are available to help contracting departments navigate the complex PBM contracting space. Although health-system contracting departments often have significant expertise, the knowledge necessary to ensure the best reimbursement terms possible within the specialty pharmaceutical market and to advocate for inclusion in limited networks may not be an area of strength. Contracting consultants can help health-system specialty pharmacies ensure the best positioning possible in their local and regional marketplace. In a scenario where patients are allowed to bring in medications from an outside vendor, the health system would need to block the charge for the medication if it is provided by an external pharmacy that has already billed the patient's insurance plan. This often leads to a denial from the

patient's insurance company when the organization attempts to bill for the administration of the medication (e.g., claims are routinely denied when billing for dose administration but not for the drug itself).

Any financial analysis should include both a short- and long-term financial model with the demonstrated ROI. If the organization's short-term plan involves outsourcing or partnering, the analysis should include a discussion of the growth in size/scale necessary for reevaluation of the decision and reconsideration of building internally versus outsourcing. The health system should evaluate the balance between sharing the revenue opportunity with a third party versus investing in the resources and infrastructure to create an internal specialty pharmacy service. If a 340B program is part of the ROI, it is advisable to include financial models with and without 340B to demonstrate that there is benefit to be gained in both models.

The financial analysis for a partner model will depend on which specialty pharmacy services the partner will be providing. The overall analysis should ultimately be the same as for a build model. For example, there might be an annual fee to the partner or shared earnings that will need to be negotiated and included. There might be shared revenue if you are an investor in the partnership. The cost for each service provided by a partner and any revenue received from a partnership will need to be clearly defined in the financial analysis. It will be important to include partnership cost and revenue in the financial management of the program. The degree to which core business functions are provided through partnerships will determine the degree to which financial oversight will need to be managed. Similarly, in an outsourcing model, terms such as fee-for-service and gain-share need to be negotiated with the vendor prior to implementation.

Financial monitoring of the specialty pharmacy's performance should occur on a regularly scheduled basis and include income statement review (as compared to budget), 15/30/60 day balance statements, and ongoing modeling of the present (and future) impact of industry trends.

In summary, a full financial assessment to determine the opportunity and viability of pursuing a specialty pharmacy business requires researching and gathering the necessary data to ultimately develop a projected balance sheet. Utilizing the information of this resource guide to determine what level of engagement your organization is positioned for or has resources to achieve is a critical first step. Once this initial decision is made, understanding the overall marketplace and speaking with key stakeholders will provide the projected prescription volumes and market access assumptions necessary to complete a financial analysis that supports a comprehensive business plan.

Conclusion

This resource guide provides an introduction to the market scope, trends, key questions, and opportunities for hospitals and health systems in the growing field of specialty pharmacy. Engaging with specialty pharmacy, and the associated care needed by patients whose diseases are being managed with specialty pharmaceuticals, is not a decision of if but a decision of how in the US healthcare market. Coupling the information from this resource guide with concrete analyses of patient needs and program feasibility in your organization should provide a solid indication of which specialty pharmacy business model will provide the greatest benefit to an institution and its patients.

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APPENDIX A

Care Process Metrics

In both the integrated and coordinated care processes, metrics are often required by insurers contracting with specialty pharmacies. Sample metrics can include the following:

- **Referral Intake:** Percent intake of clean referrals processed within one (1) business day of receipt.
- **Benefits Investigation:** Percent of clean cases having benefits investigation completed within two (2) business days.
- **First Dispense (Primary Adherence):** Percent of referrals resulting in a first dispense provided prior authorization is in place, prescription is clinically appropriate, the member is eligible, and the member has accepted receipt of the drug.
- **Dispensing Accuracy:** Percent of prescriptions filled with the correct drug, correct strength, correct dosage form, and correct labeling.
- **Dispense Time:** Mean number of days between receipt of a clean prescription and scheduling shipment.
- **Inventory Outs:** Out-of-stock rate per quarter, excluding manufacturer(s) short supply, allocation, and backorder of specialty medications beyond the pharmacy's control.
- **On-time Delivery:** Percent of prescriptions received by the member or physician on the scheduled delivery date. Such metric shall exclude prescriptions that are subsequently cancelled or requested to be held for future processing, as well as situations beyond the pharmacy's control including but not limited to, act of God, natural disasters, strikes, and war.
- **Reships:** Percent of reshipped prescriptions in comparison to the total number of prescriptions shipped. This metric shall exclude situations beyond the pharmacy's control including but not limited to, prescriptions reshipped as a result of member or physician negligence, acts of God, natural disasters, strikes, and war.
- **Average Speed of Answer:** Percent of calls to the pharmacy's toll-free specialty customer service lines that are answered within thirty (30) seconds or less. This measurement excludes calls routed to an interactive voice response.
- **Abandonment Rate:** Percent of calls to the pharmacy's toll-free specialty customer service lines that are abandoned. Measurement excludes calls abandoned by participants within the first thirty (30) seconds.
- **Response to Escalated Complaints:** Percent of escalated complaints calls to the pharmacy's toll-free specialty customer service lines that are abandoned. Measurement excludes calls abandoned by participants within the first thirty (30) seconds.
- **Response to Written Complaints:** Percent of written inquiries responded to within five (5) business days.
- **Participant Satisfaction:** Percent of responses categorized as satisfied or completely satisfied.
- **Providers Satisfaction:** Percent of responses categorized as satisfied or completely satisfied.
- **Adherence to Therapy, Clinical Medication Possession Ratio:** Total days of supply for all claims during a defined period of time divided by the number of days elapsed during the period.
- **Persistency:** Percent of chronic patients achieving 180 days persistency on a given therapy.

APPENDIX B

Considerations for Developing a Specialty Pharmacy Program

Score your facility, then use the category descriptions on this page to plan your Specialty Pharmacy model.

When considering the development of a specialty pharmacy program, one should evaluate the following factors:

1. Does the IHN (Integrated Health Network)/hospital have its own group health plan? (2 points)
2. Does the IHN/hospital have a large staff of employed specialty physician practices (>50 specialists initiating 200 patients on specialty therapy annually)? (2 points)
3. Is there access to 340B pricing? (2 points)
4. Is the IHN/hospital accepting risk, such as participation in an ACO (accountable care organization)? (1 point)
5. Does the IHN/hospital have a large employee and beneficiary base (>15,000 employees)? (1 point)
6. Is the IHN's/hospital's market presence large enough to gain access to regional payer contracts? (1 point)
7. Does the IHN/hospital have an ambulatory pharmacy service with a pharmacy benefit manager (PBM) and other payer contracts? (1 point)

Hospitals typically fall into one of three general categories that are described below:

Independent Small to Moderate Size Hospital (≤3 points)

This first category is the smaller organization that does not have a large enough breadth of specialty business and ambulatory pharmacy services to establish a specialty pharmacy program. This category usually represents small- to moderate-size hospitals. In this situation, the pharmacy department should assist the specialist physicians with finding one or more specialty pharmacy partners or hub services. This will provide a service solution for the physician practices that are prescribing specialty pharmaceuticals.

Large Size Hospital (4–5 points)

The second category represents the 350–500 bed hospital with an established ambulatory pharmacy service. In this case, the pharmacy should fill the prescriptions that are open access for which they have payer contracts.

They will need to establish reimbursement support for their patients. They should also provide clinical support services where needed. They will likely not gain access to most limited distribution drugs or limited payer networks because they do not have enough patients to become involved in a narrowed specialty pharmacy channel. If the hospital wants a complete offering, they can contract with one or more national or regional specialty pharmacies that will private-label any prescriptions the specialty/ambulatory health-system pharmacy cannot fill.

Integrated Health System or Academic Medical Center (6 or more points)

This category can be broken down into two subcategories, each with special considerations:

With 340B Needing an Interim Solution

The third category is the health system that has a large enough breadth of specialty business and is 340B eligible, but it does not have the capacity to build the infrastructure to support a specialty pharmacy program. In this case, the organization could sign agreements with one or more contract specialty pharmacies and relay the prescriptions to them. The organization recoups some of the revenue while passing on much of the revenue to the specialty pharmacy. However, it does not solve the fragmentation of care problem where abandonment of therapy is not discovered until the patient is admitted to the hospital, nor can adverse events be avoided by having the pharmacist and physician use a common medical record. This should be an interim solution until the organization can build a specialty pharmacy program with clinical pharmacists coordinating care in the specialty clinic and/or infusion center.

Able to Initiate Specialty Program Within 6 months

This represents a health system that has both a large enough breadth of specialty business and the capacity to build a program. If the expertise does not exist internally, consultants can be hired to develop the service, hire and train the staff, initiate contracting, and prepare the organization for accreditation. These organizations are typical of academic medical centers and large IHNs. If the organization has many of the characteristics in the seven questions outlined above, they should be implementing their own specialty pharmacy program.

APPENDIX C

Potential RFP Questions for Vendors

1. How does the specialty pharmacy call center work?
2. What type of support do they offer both patients and physicians?
3. What is their patient adherence rate?
4. How many different products does the specialty pharmacy have access to?
5. Does your institution have certain drugs that you want filled in your own pharmacies? If so, what does the triage algorithm look like?
6. How quickly can the outsourcing pharmacy deliver products via mail order to your geographic area?
7. If required by your state, are the mail-order pharmacies licensed in your state to supply medications?
8. If required by your state, are the pharmacists at the outsourcing organization licensed in your state?
9. What kind of documentation can the specialty pharmacy provide for verification?
10. How easily are intake, call centers, and/or hubs accessed by patients and providers?
11. Does the outsourcing pharmacy have mobile applications and web portals?
12. How will patients be identified for case management and who is responsible for referring them?
13. What type of data management and reporting is available to physicians?
14. Is the data de-identified to comply with HIPAA?
15. How many insurers can the specialty pharmacy fill prescriptions for?
16. If the specialty pharmacy is not qualified for a particular insurer, is there an arrangement with another pharmacy to fill the prescription?
17. How will cobranding be implemented? Are both marketing materials and labeling services options for cobranding?
18. Who is responsible for informing physicians about the service?
19. What kind of materials will be provided by the outsourcing group?
20. Regarding time to market (to set up system), how quickly can the specialty pharmacy implement their services?
21. How will the health system's name and logo be utilized in the vendor's marketing materials?
22. What bona fide service fee agreements does the vendor have with manufacturers and payers? How will those service fees be split with the health system?
23. What call center metrics does the vendor collect?
24. What reports will the vendor provide the health system?

APPENDIX D

Specialty Pharmacy Business Plan Framework^{15–17}

SCOPE/PROGRAM DEFINITION

Proposed Service/Program

- Define scope of specialty pharmacy, short term and long term (i.e., over five years).
- Describe aspects of service levels to be provided (i.e., prior authorizations, care coordination, billing and collections).

Population to Be Served

- Include number of physicians, projected number of prescriptions covered by specialty pharmacy medication benefits, region targeted for services and management of employee health needs.
- Determine if there will be a focus on specific disease states (i.e., rheumatology, hepatitis C, oncology).

Strategic Relevance

- Provide statement of why you are pursuing particular business model and plan.
- Delineate the opportunities unique to your organization.
- Consider if the plan is a means to prevent loss of patients.
- Address market risks if organization does not pursue business plan.
- Question whether there is an even larger value to organization beyond the margin of specialty pharmacy proposal (i.e., improved transitions of care, physician satisfaction, and reduced waste in the system).

MARKET ANALYSIS/NEEDS ASSESSMENT

Ambulatory Pharmacy Current State

- Consider whether the organization has an existing infrastructure it can leverage or expand on.

Market Size, Growth, and Trends

- Provide scope and potential for your organization as specialty pharmacy is a rapidly growing proportion of medication market.
- Execute estimates of prescriptions generated by target populations for status quo, and extrapolate based on future projections.

- Use resource paper to determine impact of lack of adherence and other patient attrition influencers.
- Question who currently serves as the target population (i.e., competition).
- Question if the contracts are accessible (are you in an “any willing provider” state?).
- Question if there is external competition from entrenched specialty pharmacies.
- Question if there are restrictive payer arrangements limiting access to patients.
- Question whether restrictive manufacturer programs/distribution networks are limiting access to drugs.

Opportunity Assessment

- Define the unique opportunity business plan is taking advantage of.
- Define reasonable impact of competition and goals of market share capture and potential of raw growth of market (defined in resource guide)

Strategic

- Find rationale for seeking to take advantage of opportunity.
- Consider whether nondirect revenue for specialty pharmacy is important to overall strategy for the organization.

MARKETING PLAN

- Define goals and strategies for marketing specialty pharmacy services to providers and payers.
- Explain expected costs and any intrinsic economies of scale for organization.

OPERATIONS

Organization and Management

- Define planned organization chart with specifics on new positions.
- Provide special note on management of billing, prior authorization resources, and revenue capture.
- Include expense of accreditation.

Staffing

- Develop plan with detailed staffing model by position type for expected personnel/full-time equivalents including any outsourced services such as deliveries and mail services.
- Include projections of staffing for each phase of business plan.

PHYSICAL PLANT/SPACE PLANNING

Location and Facilities/Space Utilization

- Define the location required, if rent will be required or purchase of space, or if existing space in organization will be utilized.
- Describe how space is being utilized (e.g., equipment requirements).
- Calculate capital equipment, leases, and technology needs.

FINANCIAL FEASIBILITY

Financial Assumptions and Analysis

- Include financial markers such as break-even point (BEP), net present value, and projected revenues (may be able to describe additional associated revenues such as office visits or other prescription drug needs).

- Provide projected balance sheet for year 1, 2, 3 up to projected BEP.
- Include inventory carrying costs, utilities, insurance, and payroll taxes.

IMPLEMENTATION PLAN

- Define roll out and when revenue, expenses, capital purchases would need to hit the books.

RISK ASSESSMENT

- Define risk points such as patient acceptance, physician utilization of specialty pharmacy, contract access, and manufacturer access.
- Include key metrics to determine success and decision to collapse business.

RECOMMENDATION AND NEXT STEPS

- Provide summarized recommendations based on financial assessment and factors laid out in business plan.



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