DEVELOPING A COMPETITIVE SPECIALTY PHARMACY

By

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Masters Research Project

Title: DEVELOPING A COMPETITIVE SPECIALTY PHARMACY

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List of Acronyms:

bDMARD: Biologic disease modifying anti rheumatic drug

RA: rheumatoid arthritis

I. Abstract

Developing a competitive specialty pharmacy

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Background: Specialty pharmacies provide quality services to a limited population of high cost, complex patients. Developing a specialty pharmacy can provide health systems with an opportunity to integrate healthcare information for their high-risk patients and provide high quality outpatient pharmacy services. Two challenging aspects of developing a specialty pharmacy are obtaining access to medications that may be part of limited distribution channels, as determined by drug manufacturers, and securing contracts with health plans. As more health systems invest in these services, identifying services essential to remaining competitive in the increasingly populated market would be valuable to both new and existing specialty pharmacies.

Objective: Within an identified therapeutic category, develop guidelines for implementing a competitive specialty pharmacy with regards to requirements of health plans and drug manufacturers.

Methods: Preliminary research from case studies, market experts and presentations was conducted to identify potential methods for developing a specialty pharmacy. The need for clinical management, access to medications and contracts with health plans were identified

as crucial areas for success. A targeted disease state was selected to serve as an example for establishing a successful specialty pharmacy practice. A literature review of this disease state was used to develop clinical management guidelines, and to identify drug companies for specialty medications with an FDA indication for this disease. Health plans with a presence in the Memorial Hermann market were selected and interviewed to determine their needs for providing specialty pharmacy services. The information gathered from health plans and drug companies was organized into essential domains and metrics to provide a guide for developing a specialty pharmacy.

Results: The clinical information gathered in the literature review was developed into clinical management guidelines, and the information from health plans and drug companies was organized into essential domains and metrics to provide a guide for developing a specialty pharmacy.

Conclusion: Measuring the quality of services provided with targeted metrics demonstrates the value of a specialty pharmacy to health plans. Developing services in the identified domain service areas and correlating metrics to measure the quality of each service provided will present the specialty pharmacy

II. Background

Despite the selective patient populations serviced by specialty pharmacies, they are quickly becoming a prominent hallmark of healthcare networks. Specialty pharmacies are unique outpatient pharmacies that offer patients an enhanced level of service not provided by a traditional retail pharmacy. Specialty pharmacies dedicate resources to coordinate care for select complex and high cost patient populations, such as patients with rheumatoid arthritis or malignancies. By removing barriers to access and ensuring compliance, specialty pharmacies reduce costs associated with mismanagement and optimize patient outcomes. As Colgan reported, health systems have a unique opportunity to combine high concentrations of specialty physician groups and integrate healthcare for these patient populations. Developing a specialty pharmacy presents clinical and financial opportunities, if the complex operational and administrative aspects of these pharmacies can be understood and managed.

Medications distributed by specialty pharmacies are not defined by a distinct regulatory status but are generally high cost; prescription costs often total several thousand dollars, have complicated administration techniques, complex therapeutic regimens, and may be part of limited distribution channels.

Health plans have a key role in the specialty pharmacy environment. Health insurance companies are motivated to reduce the overall cost of care for their patients, which can be reduced through the support of specialty pharmacy programs. Pharmacies and health plans must enter contract agreements in order to adjudicate claims and provide services for members of said health plan. Through this mechanism, commercial health plans can limit a

specialty pharmacy's access to patients and can potentially lock specialty pharmacies out of networks.

Demonstrating the value of managing patients through a specialty pharmacy encourages health plans to select a particular specialty pharmacy to include in their network, and subsequently provides specialty pharmacies access to their patients. Currently, guidance to evaluate the essential elements of providing specialty pharmacy services for a specific therapeutic drug class does not exist. A systematic approach to identify these elements would be beneficial to those interested in developing value added specialty pharmacy services to ensure their operations were effective and competitive.

III. Objectives

The objectives of this research study are to:

1. To identify specialty pharmacy services requirements from the perspective of health plans and drug manufacturers for a specific identified disease state.
2. To develop guidance to support the implementation of a specialty pharmacy service line to manage patients within a specific clinical category.

IV. Methods

Achieving clinical outcomes and meeting the requirements of health plans, to gain access to patients, and drug companies, to gain access to medications, are essential to developing a specialty pharmacy. The methods of this project will focus on evaluating the needs of these subject areas for a particular disease state.

Identifying Disease State The Houston metropolitan area was identified as a potential geographic opportunity for developing a specialty pharmacy. This geographic area encompasses over 6 million people and is home to the nation's largest medical center, The Texas Medical Center. The Houston metropolitan area does not currently have a health system specialty pharmacy, and would be an ideal candidate considering the high concentration of physician specialists, patients, and market opportunity. Memorial Hermann Health System is an integrated health system in Houston, Texas with over 45% of the Houston healthcare market share. Memorial Hermann was identified as a potential opportunity for developing specialty pharmacy, and was used as a pilot for this research study.

Specialty utilization was sampled using prescription data from Memorial Hermann's health insurance plan. Evaluation of prescription claims of over 25,000 insured patients revealed the highest spend specialty therapeutic category was inflammatory conditions. Further evaluation revealed high utilization of medications inidicated for rheumatoid arthritis.

Identifying Inclusion Medications Research of high cost medications with an FDA indication for rheumatoid arthritis revealed that the biologic Disease Modifying Anti Rheumatic Agents (bDMARDS) are often managed by specialty pharmacies due to their complexity, high cost and improved outcomes with medication adherence. A literature review of the bDMARDS was performed to identify study inclusion medications, which are outlined in Table 1. The package inserts for each of these medications was reviewed to identify each respective drug manufacturer so they could be contacted at a future date to assess their stance on distribution and requirements for obtaining access. This information was recorded in a data collection tool and is displayed in Table 1.

Industry Experts Industry experts were identified through professional contacts and interviews were conducted to gather preliminary information regarding the process of developing a specialty pharmacy. These interviews focused on the operational needs to developing a successful specialty pharmacy and obstacles present in the current market. This information helped direct research, and identified access to medications and patients as two potentially rate limiting step for an up and coming specialty pharmacy practice.

Drug Manufacturers The package insert for each included medication was reviewed to identify the manufacturer of each drug. Then each company's webpage was reviewed to find contact information and establish communication with the manufacturer. Initial outreach was made by phone or email request, and then a follow up telephone interview was scheduled with a

representative from each company. Each drug manufacturer representative was interviewed to determine if access to their medication was limited, and what expectations, if any, they had of specialty pharmacies in order to gain access to their medications.

Clinical Management Interviews with experts in the field revealed that the clinical management of patients taking specialty medications is essential to achieving positive outcomes. Specialty pharmacies must develop clinical guidance to educate their staff and patients about the proper management of complex specialty medications and ensure the complex management requirements are met for every patient. To demonstrate the feasability of self developing this information, clinical management standards were developed. Initially, package inserts were reviewed to identify dosage, warnings, precautions, required laboratory monitoring, storage, administration and other clinically relevant information for each included medication. This information was recorded in a data collection tool. Then, a literature review of the included medications was performed to identify any other pertinent clinical management information or disease state risks. Throughout this process outcome measures specific for rheumatoid arthritis were assessed and recorded to be included in the assessment tool to provide a variety of established outcome measures for a specialty pharmacy to measure. This information was developed into a clinical outline that clearly delineate clinical concerns that need to be addressed prior to initiating therapy, during therapy, and other relevant information that may affect the outcome of therapy.

Health Plans Memorial Hermann payor mix was evaluated to identify commercial health plans with the largest patient populations within the Memorial Hermann network. Initial research and interviews with experts in the specialty field revealed that entering contracts with commercial health plans can be very challenging. By focusing research on this group of health plans, the data collected provides insight into a highly sought after but not easily accessible network. Health plans with 80% of Memorial Hermann's payor mix were identified, and contact was attempted via professional connections, telephone and email. One plan was excluded because they had their own internal specialty pharmacy and were unwilling to consider working with another specialty provider. The other three were contacted and two were excluded due to an unwillingness to be interviewed or offer information. The health plan was interviewed to assess their motivations, requirements and needs for contttracting with a specialty pharmacy. The recorded information was evalauted to identify services a specialty pharmacy must provide to satisfy the needs of said health plan. Metrics and measurments that reflect the value and/or performance of each domain were recorded during the interview with the health plan and were assessed through market research and a literature review. Domains and their corresponding metrics were organized in a chart to easily identify essential services and their measurements. Operationalizing the metrics so they can reliably and accurately captured to reflect the capabilities of a specialty pharmacy's services will be a challenge for a developing specialty pharmacy, but identifying this information and its value to health plans provides direction for a specialty pharmacy vying for a competitive edge.

V. Results

Guidance to Develop Specialty Pharmacy Information gathered through research and interviews with industry experts was developed into a stepwise guidance document that outlines esential steps in the process of developing a specialty pharmacy. Aspects of this guidance were piloted through the empiric market assessment in the Houston area and creation of clinical management guidelines for RA. Table 2 outlines the steps identified through this process. Identifying a potential market opportunity is essential but not necessarily the largest barrier to developing a specialty pharmacy. Gaining access to medications and securing contracts with health plans to gain access to their patients were identified as potential impedements to success, and were therefore further investigated to provide guidance to navigate their potentially limiting environment.

Clinical Management Clinically managing patients is essential to achieveing positive patient outcomes, and is particularly valuable to a specialty pharmacy that is marketing their value based on optimizing patient outcomes. Good clinical practice should be standardized within a specialty pharmacy to ensure patients receive consistent quality care, and a specialty pharmacy must either develop this internally or borrow it from another resource. To demonstrate the feasability of developing structured guidelines for managing patient, relevant clinical inforamtion for all inclusion medications were reviewed. Preliminary information was gathered from package inserts and recorded in a data collection tool. Through this process several key clinical patterns were identified and medications were grouped based on commonalities and then unique factors of each medication were highlighted to differentiate the management of

separate medications. This information was organized into a clinical checklist, which provides pharmacists with a baseline for clinical support and ensures patients receive pertinent information and care. An example is included in Table 3, which outlines the clinical management document for Actemra, a IL-6 antagonist. These methods can be applied to additional medications in this therapeutic category.

Clinical literature was also reviewed to identify outcome measures that could be used by a specialty pharmacy to monitor disease response. These items were included in the metrics portion of the 'Clinical Outcome Measures' domain.

Services and Metrics Information gathered from interviews with health plans and content experts was reviewed and developed into the content for the assessment tool. Measuring performance and collecting data in a transmittable report that can be easily interpreted and/or integrated by the requestor (i.e. health plans) was identified as an essential requirement for entering into contracts with health plans, and therefore is required to develop a successful specialty pharmacy. The services that must be provided to patients and their corresponding measurments and metrics vary between health plans, but are required to some degree by all plans. Several consistent domains of service were identified through interviews with health plans, industry experts and a literature review. These domains were identified as required services, and corresponding potential measures were included in the guidance document. A specialty pharmacy should expect to provide the services outlined in the domain areas, and can consider using the suggested metrics as a measurment to demonstrate value to health plans.

This information is outlined in Table 4. The information provided in this assessment tool is intended to be a guide, and to provide insight into the level of detail necessary to advertise successful specialty operations and to secure contracts for services. Anyone interested in developing a specialty pharmacy will need to consider the complexities in operationalizing the outlined services and data reporting elements when developing a business plan.

VI. Discussion

The premise of a specialty pharmacy is to ensure highly complex and costly patients receive attentive care to ensure appropriate, adherent and complete medication therapy which lowers overall healthcare costs, prevents complications and improves patients' quality of life. The quality of care provided in a specialty pharmacy ensures their clinical relevance and competitive edge.

There are many challenges to developing specialty pharmacy services, however access to medications and patients are two potentially rate limiting steps. Without patients or medications a specialty pharmacy has no opportunity to provide services. It is imperative specialty pharmacies understand these networks and influences to remain relevant in this field. New specialty pharmacies entering the market will be competing against existing specialty pharmacies for contract agreements with health plans to gain access to their patients. Health plans want their patients to receive the highest quality care, and they want data to prove high quality care is being provided and outcomes to demonstrate the clinical value of the specialty pharmacy. Understanding this environment, and the motives of the health plan, will give a

specialty pharmacy the competitive edge to effectively advertise their services to health plans, and potentially win contract agreements for patients. The sustainability of a specialty pharmacy will rely on their ability to identify and measure metrics that reflect the quality of care provided.

Within the rheumatoid arthritis treatment class, no medications were identified as being part of limited distrubition channels. This is not the case with all medications distributed by specialty pharmacies, and in some scenarios drug companies require specialty pharmacies to collect and report data on the patients receiving their medications. One drug company within the scope of this project did identify that they preferred to receive data from specialty pharmacies to better understand their patient populations and outcomes achieved, but did not recognize this as a prerequisite to obtaining access to their medication. This availability of rheumatoid arthritis medications may change in the future, but currently are accessible and a potential service line for developing specialty pharmacies.

Developing a specialty pharmacy is not feasible without an initial investment in time, resources and available capital. Some health systems have developed specialty pharmacies with internal resources, learning from industry experts and securing the capital to support the business model necessary to make this a successful investment. An alternative to this option is contracting with an existing specialty pharmacy and bringing them on site as a consultant. This arrangement can provide the health system with access to medications already established by the parent specialty pharmacy, experts at managing the health plan contract environment and operational best practices that can quickly be implemented at the child site. The trade off to

this arrangement is a reduction in potential revenues, which deserves a thorough evaluation before committing to either development model. Investing in a specialty pharmacy can cost anywhere from $1-5 million, depending on the services and FTEs that must be developed. The average cost per prescription varies drastically by treatment class, but an average of Express Scripts data and industry benchmarks show a range from $1,000 – $10,000 per prescription. Net revenue per prescription has been reported in the range of 4-6% (Colgan) and in some cases up to 10% for specific treatment classes. Revenues will be drastically affected by wholesaler or drug manufacturer contract terms, but are generally in the range of less than 10%. Assuming an initial investment of 3 million dollars to establish a specialty pharmacy, an average prescription cost of $2,500 and a net revenue of 5% per prescription, approximately 65 prescriptions per day will breakeven at 12 months. Given the market opportunity in Houston, specialty pharmacy presents an incredible financial opportunity.

VII. Limitations

This study was conducted in Houston, Texas and all market analysis was completed only in this geographic area. Utilization trends were evaluated for a commercially insured, working population, and excludes Medicare and Medicaid patients. Data from Express Scripts demonstrates differences in utilization of specialty medications among commercially insured and those insured by Medicare plans. Incorporating market analysis of both Medicare and commericial populations would provide a more accurate assessment of specialty product utilization and disease prevalence statistics.

The health plans evaluated were specific to one health system and may not be present in other geographic regions. The identity of these health plans is proprietary and not publishable. As discussed in the results section, data collected during interviews indicated that health plans may request different metrics from their specialty pharmacies, and the metrics identified in this study may not be applicable to some health plans.

VIII. Conclusion

Specialty pharmacies can provide a valuable service to the most complex patients. Medications in the rheumatoid arthritis therapeutic class are not currently part of limited distribution channels, and may present a secure opportunity for young developing specialty pharmacies. Understanding the limitations to access of other therapeutic drug classes will be essential to expanding services to cover other therapeutic categories. Health plans determine which pharmacies have access to their patients, and through this mechanism they influence the success or failure of a developing specialty pharmacy.

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Table 1

Inclusion Medications

Drug Name	Manufacturer	Limited Distribution
Actemra® (tocilizumab)	Genentech	No
Cimiza® (certolizumab pegol)	UCB	No
Enbrel® (etanercept)	Amgen	No
Humira® (adalimumab)	AbbVie	No
Kineret® (anakinra)	AmGen	No
Orencia® (abatacept)	Bristol-Myers Squibb	No
Remicaid® (infliximab)	Janssen	No
Rituxan® (rituximab)	Genentech	No
Simponi® (golimumab)	Janssen	No
Xeljanz® (tofacitanib citrate)	Pfizer	No

Table 2

Developing a Specialty Pharmacy
Identify a market with limited specialty presence.
Evaluate disease state and prescription utilization data for the targeted area.
Select a limited number of therapeutic areas to start providing services for to ensure quality is maintained during the initial phases of development.
Identify potential referral sources. Locate specialty physicians and establish relationships if feasible.
Determine the medications that will be provided within the selected disease states.
Determine if the medications are part of limited distribution networks or accessible to your new specialty pharmacy.
Identify health plans established in the target area.
Determine health plans' likelihood of contracting with additional specialty pharmacies.

Table 3

Clinical Management

Actemra (Tocilizumab) Clinical Management		Completed
Prior Therapy:	Patient has failed previous therapy with TNF blocker	
Combination therapy:	Monitor closely for infection when used with corticosteroids and methotrexate	
	Patient is not actively taking any other biologic DMARD	
Baseline Labs:	ANC lab complete and documented	
	Lipid panel complete and documented	
	LFTs complete and documented	
	CMP complete and documented	
Dosage:	Dose does not exceed 800mg	
	If ANC <1,000 or platelets <100,000 -> hold until ANC >1,000	
	If ANC <500 or platelets <500,000 -> discontinue therapy	
Lab Monitoring:	Monitor LFTs and ANC every 4-8 weeks at treatment initiation then every three months	
	Monitor lipids every 4-8 weeks after treatment initiation then every six months	
Screening:	TB test is negative	
	If TB test is positive, active treatment is in place	
	Patient does not have a history of hepatitis or HIV or is followed by a clinical specialist	
	Signs and symptoms of active infection are not present	
	Signs and symptoms of malignancy are not present	
Immunizations:	Verify live vaccines are up to date prior to initiating therapy	
	Wait 4 weeks after administering live vaccines to begin therapy	
	Do not administer live vaccines while on active treatment Live vaccines: Influenza, pneumovax, hep B, HPV and Zoster	
Warnings:	Increased risk of bowel perforation in patients with a history of diverticulitis, especially if used with glucocorticoids	
	Use caution in patients with a history of malignancy	
Pregnancy:	Category C. Evaluate the risk/benefit of continuing therapy	
	May be excreted in breast milk	
Storage:	Patient is instructed to keep medication refrigerated	
Administration:	Patient is counseled on injection technique	
Side Effects:	Patient is counseled to monitor for the following:	
	Bowel perforation (new abdominal pain)	
	Malignancies (night sweats, fevers)	
	Infections (fever, chills)	
	Injection site reactions, headaches	

Table 4 Specialty Pharmacy Service Domains and Metrics

Domain	Potential Metric
Demographics	Patient's age
	Patient's sex
	Patient's address / geographic region
	Patient's diagnosis
	Patient's medication, and FDA approval per indicated diagnosis
	Prescribing physician
	Prescribing physician's specialty
	Prescribing physician's credentials
	Prescribing physician's address / geographic region
Patient Satisfaction	Follow up calls performed after patient inquiry calls to assess satisfaction with pharmacy's response
	Response rate of patient satisfaction survey
	Scores of patient satisfaction survey
	Documented explanation for patients' discontinuation with specialty pharmacy
	Documented explanation for patients' discontinuation of medications
Adherence Optimization Programs	Percent of patients contacted for follow up after initiating new therapy
	Medication possession ratio reported per medication and therapeutic category
	Number of doses dispensed reported per medication and therapeutic category
	Intermittent medication counts recorded at specified intervals (e.g. 2 weeks)
	Documentation of side effects and medication count prior to sending repeat prescriptions
	Number of days' supply reported per medication and therapeutic category
	Documentation of completed patient counseling
Clinical Review	Documentation of complete medication history for new patients
	Medication reconciliation completed quarterly
	Assessment of previously failed therapies
	Documentation of interventions to optimize generic medications where appropriate
	Turnaround time to resolving interventions is reported, and is less than 48 hours
Call Center Operations	Time to answered phone calls is recorded and reported
	Number of unanswered or blocked phone calls is recorded and reported
	Total number of phone calls answered in a given period is recorded and reported
Shipping Operations	Delivery confirmation is provided for all shipped medications
	Tracking is available for all shipped medications
	Patient/recipient is contacted prior to shipping a temperature sensitive medication
	Shipping rate is calculated and reported for a given time period.
	Percent of accurate deliveries is tracked and reported

Utilization Reports	Utilization by drug, therapeutic category, plan or member is recorded and reported for a given time period
	Top prescribers are reported for a given time period
	Top prescribed drugs per cost and volume are reported for a given time period
	Per member per month drug costs
Clinical Outcomes Assessments	ACR 20/50/70
	Number of swollen joints
	Radiographs of joint spaces
	Erythrocyte sedimentation rate level
	C-reactive protein levels
	Patients assessment of global functioning