

Critical Insights for Health Systems Leaders

SPECIALTY PHARMACY

Primary Motivation

Hospitals and health systems have an increasing desire to enter into the specialty pharmacy (SP) space for a variety of reasons. These may include: new revenue capture, self-insured health plan prescription savings, improved access into patient data, better management of at-risk patient populations, and more control over total cost of care.

However, as many hospitals and health systems soon discover, SP is not simply a modified retail pharmacy program with a few resources bolted onto it. On the contrary, SP is a highly-technical, resource intensive, and low margin business with a high degree of risk. Proceed with caution!

Background

While there is no standard industry definition, specialty drugs are generally characterized as high-cost, biological, injectable, infused, inhaled, or oral therapies. The majority of new drugs currently being evaluated by the FDA are SP drugs, with more than 800 in the FDA's pipeline. Their costs can range from thousands to tens of thousands per

States generate more than 25% of this business through their owned hospitals, outpatient medical facilities and specialty practice clinics. Specialty pharmaceutical spend is the fastest growing driver of healthcare costs today and will exceed 60% of total drug spend by 2018. With challenges come opportunities and for many financially struggling hospitals, the potential revenue associated with specialty pharmacy is simply too big to ignore. Couple this trend along with the fact that hospital pharmacists are being asked to offer more and more services across the continuum of care, therein lies a seemingly burning platform for the health system pharmacy leader to jump into the SP space in a big way.

Service Expectations

SP operations require a different care delivery model as opposed to what is traditionally found in the acute care and community pharmacy settings. Services are built around intake and insurance benefit investigation, prior authorizations, patient assistance programming, disease-specific clinically trained support staff, ongoing patient monitoring programs that includes 24/7/365 access to

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month. A shift towards more patient self-administered SP drugs will continue to pull patient volume away from outpatient infusion therapy, which can negatively impact health systems financially. Drug manufacturers and payers have severely limited access to procuring and dispensing these SP drugs in an effort to mitigate expense, while ensuring specific clinical, programmatic requirements are met. The SP market will soon exceed \$100B in annual revenue opportunity and health systems across the United

care, limited and restricted drug protocols related to FDA-approved REMS requirements, narrow network payer agreements, and well-coordinated medication delivery to the patient's home. Each component of the services outlined requires intense investment in staff, their ongoing training and education, and technology in order to sustain the business.



Investment Required

The cost to establish a robust, credible and high-performing SP business can easily eclipse millions of dollars depending on where the organization is on the pathway to success. Operating expenses quickly absorb even the smallest gross margin generated by the most high-performing SP's. There are many financial variables at stake that are largely out of the hospital's control. In fact, more than 80% of the specialty pharmacy provider market is dominated by only a handful of industry providers and PBM's. The health system executive must consider all of these in order to make an informed decision on its SP strategy before going into this arena alone. As one experienced health system pharmacy leader indicated, "You can put yourself out of business by getting into the specialty pharmacy business!"

Capital Equipment, Space, and Technology

As illustrated, the number of personnel involved and varied work activities required necessitate significant investment in several thousand square feet of space, cubicles, telephony and call center operations, care management software, pharmacy management software, the fulfillment center, cold chain and supply chain facilities, monitoring systems, data center with appropriate redundancies, automation, tracking, and mail-order distribution center. Depending on the space requirements and the area of the country the SP is built in, these costs can easily exceed tens of millions of dollars.

or acute care pharmacy models many are familiar with. The SP operation tends to resemble that of the home health area wherein there is a segregated call center staff, a production staff, and a distribution team. Because the SP operation is a highly technical confluence of interrelated and dependent activities, it takes multiple pharmacists, technicians, nurses, care coordinators, social workers, and management FTE's to ensure the pharmacy is functioning properly. Any one breakdown in this multi-faceted process will result in poor patient outcomes and experiences, low provider satisfaction, and unnecessary waste and downstream costs. A certain component of staff FTE's are fixed while others are variable depending on the volume of the pharmacy. There is not always a linear, predictable relationship between the number of prescriptions filled and the number of FTE's required due to the fact that different patients have vastly differing disease burdens (i.e. cancer vs. multiple sclerosis) which will dictate the specific needs that the pharmacy must satisfy with more or less clinician time on the phone or multiple drug product shipments per month.

Drug Inventory

The cost of SP drug inventory is the largest direct and ongoing expense the hospital will have. Based on current drug manufacturer and wholesaler models, there are little if any discounts available to purchasers even through membership in a group purchasing organization. There

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Labor

Given the unique nature of the SP operation, this endeavor must be viewed as a new business venture, one where incremental FTE's must be added to the operation in order to dedicate them to the new service. Labor expense is substantial due to the high-touch demands of any SP operating model. Staff productivity operates under an entirely new and diverse model as compared to that of the community, retail

are also restrictions on what drugs can be purchased and returned that receive credit. Hospitals should anticipate being locked out of accessing multiple product SKU's, and for those they can obtain, only expect single digit gross margins based on payer reimbursement which result in razor thin margins to fund any new SP venture.



Access to Payer Network

As the SP market continues to grow, the competition for access to process these prescriptions for patients and populations is fierce. Despite largely unfavorable client and member satisfaction with PBM owned and operated SP's, these same PBM's are dictating to health plans how the SP pharmacy benefit is structured which results in locking out most pharmacies, including hospitals and health systems. In fact, more than 50% of the entire SP marketplace is processed through either CVS Caremark or Express Scripts.

their lack of skillset in the area of PBM contracting.

Access to Limited and Restricted Drugs

Obtaining access to many SP drugs is restricted to only those that can demonstrate an ability to meet certain manufacturer requirements. Even if a SP eventually does show the capability to meet these standards, it does not guarantee access to the drug today or into the future. In fact, out of ~150 limited or restricted drugs, there is not one pharmacy in the United States today that has access to all limited or restricted drug products. SP providers must

Hospitals must realize that what they have access to and can dispense in the inpatient setting IS NOT A GUARANTEE OF ACCESS OR USE IN THE OUTPATIENT SETTING.

Based on research, employers, coalitions, and self-insured health plans are willing to seek diverse SP models if the care and outcomes are as good as the large PBM operations; and it is at the same or lower total cost of care to provide similar SP products and services.

SP's must have capabilities that demonstrate their ability to improve quality, create positive patient experiences, and drive medication adherence. Developing such capabilities takes years, significant effort, and resources. As new SP entrants, hospitals are not guaranteed access to patient lives or payer networks. In fact, the trend is to continue to narrow SP networks to only a few contracted providers across the country. Hospitals may be able to leverage their existing contract relationships in the payer marketplace; however, most current and future SP drug spend falls under the pharmacy benefit, not the medical or hospital benefit, which makes existing contract relationships less valuable in hospitals.

In addition, having a payer contract does not ensure that your SP can actually dispense, due to an increasing trend in employer sponsored benefit plan designs that specify a specific SP, regardless of your being in network. Hospitals are finding themselves at a competitive disadvantage because of their late entry into the SP market, their inability to contract for hundreds of thousands of lives regionally and nationally, and

heavily invest in trying to differentiate themselves from what the current SP providers are performing today for drug manufacturers otherwise there is not a need to open up access. Some examples of this may include developing new or improved clinical programming that results in higher than average medication adherence rates or generating outcomes based research that could facilitate post-marketing surveillance data for the supplier.

At the end of the day, drug access can be an uphill battle in the outpatient setting. Hospitals must realize that what they have access to and can dispense in the inpatient setting is not a guarantee of access or use in the outpatient setting. There are distinctly different classes of trade. Furthermore, even if a hospital does gain drug access, that access can be taken away on a whim (and is increasingly occurring), as manufacturers further limit their SP networks. Lastly, it takes scale to compete with these supplier and payer network forces. Most hospitals and health system do not have the volume in this area to leverage and will fall short when attempting to do this on their own.

Reporting Requirements

Obtaining access to SP drugs from drug manufacturers and achieving approval to fill prescriptions for covered beneficiaries with an insurance company usually comes



with the requirement that the SP provide robust patient data back to both constituents. Setting up comprehensive data reporting capabilities can cost an organization millions of dollars and requires a dedicated information technology staff to maintain it. No two manufacturers or payers request the same information in the same format and routine so the data mart and corresponding analytics capabilities must be well thought out. Implementation and ongoing maintenance is expensive, but necessary, in order to continue to garner access to both current and future SP drugs for the patients that need them.

Marketing

In order to drive patient, prescription and revenue capture, a well thought out marketing strategy must be created. Internal marketing within a hospital is often times an overlooked or poorly funded resource and instead a colleague-to-colleague approach is deployed. An assumption is made incorrectly that all prescribers will support the new SP and send prescriptions accordingly to the hospital-owned SP. In reality, most clinicians don't care where patients obtain their prescription therapy, including SP drugs. This can be a cause for significant prescription leakage and failure to execute on a business plan with budgetary targets. A strong sales and marketing team must be invested in in order to mitigate such an opportunity loss.

Accreditation

Most payers are requiring dual accreditation of the SP through reputable organizations such as URAC, TJC, or ACHC. The investment in order to achieve this level of practice is two-pronged. There is the actual expense for the onsite survey that is not inconsequential. Also, there is extensive work in preparing for such as accreditation survey. This takes resources, time, and lots of intellectual effort to muster the training program, policy and procedures, a prepared staff, and the quality improvement program to not only pass the initial inspection, but then to maintain a constant state of readiness.

Clinical Program Development

Offering disease state management programs that provide high-touch clinical services is also a requirement of accreditation bodies, payers and manufacturers. Disease state management programs are important to promote medication adherence, optimize drug therapy and to ensure appropriate therapeutic outcomes are achieved for patients. Non-adherence to medication therapy, leads to poor outcomes, which then increase health care service utilization and overall health care costs. Medication non-adherence has attributed to between \$100 and \$300 billion of avoidable health care costs.

Disease management programs are managed by pharmacists and nurses that are clinically-trained and specialize in specific disease states. The programs are developed following evidence-based medicine, clinical guidelines and FDA REMS requirements and include high-touch clinical services, i.e. bi-monthly to monthly outreach calls that provide medication therapy management to promote adherence. Medication therapy management includes providing patient education/counseling, performing comprehensive medication reviews (assessing for possible drug-drug interactions), monitoring efficacy and safety of medication therapy, providing side effect management, collaborating with prescribers, and documenting and reporting clinical interventions captured.

Options Available

As illustrated thus far in this review, significant investment into building SP capabilities is unavoidable for any new entrant. As one studies the many important features and functions that are hallmarks of high-performing SP program, health system leaders should pause and consider all options when entering this space for the first time. What should be our go-to-market SP strategy? Simply put, there are a variety of options or approaches to consider; however, for the purpose of this review, a decision is usually centered on the idea to either insource or outsource some or all of these new SP services.



Option 1: Insource the SP solution – this solution requires the hospital to generate enough volume and revenue capture to offset the significant upfront capital investment to offer comprehensive SP services. Some health system pharmacy providers may try to utilize an existing outpatient or retail pharmacy that resides within one or more of its facilities. The focus in the outpatient pharmacy is on patients transitioning out of the hospital on the day of discharge or on patients that are accessing providers in clinics that are geographically close to the pharmacy. It may serve as a good initial dispensing location, but usually does not have the bandwidth to support robust patient care services, back-office services, a call center operation, or mail order distribution each of which would be necessary as a SP. Others without an existing outpatient pharmacy, may elect to accept all the financial risks involved and build the SP themselves.

Option 2: Outsource the SP solution – this solution requires much less upfront capital investment and risk on behalf of the hospital because there's available capacity to scale the solution via a SP partnership with a 3rd party vendor or provider. Many health systems utilize this solution either for some or all SP services for their patients. A formal service agreement is put into place outlining exactly what services and associated costs will be (if any). There is also agreement on data collection and reporting, 3rd party network contracting, limited/restricted drug access, among other business-related activities.

Each health system that is interested in pursuing a SP capability, either by insourcing or outsourcing, must be careful to weigh all of the risks and benefits of getting into this space. The SP market is a complex, demanding, and ever-changing business environment that is nothing like the acute care or retail pharmacy operating space.

Risks and Benefits Considerations

Risks and benefits of Insourcing SP

The risks to a hospital when electing to insource all of the SP business functions are many. First, the hospital must generate enough volume and revenue capture in order to offset the significant upfront capital investment to offer comprehensive SP services. Depending on the size and scope

of the business plan, estimates can easily exceed tens of millions of dollars in capital investment in order to create a dedicated space, team, automaton and technology, along with the necessary processes to be put into place and start up a brand new SP. The return on investment (ROI) is usually many years even for the most aggressive business plans.

Besides the pure financial risk, there is significant risk inherent with the number of “known unknowns” around SP prescription capture rates, which is largely a function outside the control of the hospital (i.e. accessing limited/restricted drugs by manufacturer, accessing third party payer network for patients locked out of local networks). Even if access to drugs and payer networks are granted, the hospital's SP must heavily invest in data capture and reporting. It is not good enough to simply buy and dispense drugs for these SP partners. Demonstrating clinical outcomes at a lower cost is the new normal.

There is also significant risk with class of trade (COT) confusion or potential for contract infringement based upon patients accessing the SP for prescription care upon discharge from the hospital and wanting to continue their care with the health system SP for prescriptions generated by non-employed health system specialty care providers.

If successful, the benefits to a hospital insourcing the SP business functions include the potential for bottom line financial success and having direct control over all of the people and processes of the pharmacy. However, proceed with caution here as entry into the SP space is wrought with financial and nonfinancial risk. Only with a thorough understanding of the SP business climate should the hospital attempt to navigate these industry challenges alone.

Risks and benefits of Outsourcing SP

The risks to a hospital when electing to outsource some or all of the SP business functions are few. The upfront capital is low, if not zero, depending on what the hospital desires out of the outsourced relationship. Most 3rd party SP providers charge a professional or administrative fee (per transaction) to meet the needs of the hospital while some elect to forego charging any fee in favor of collecting the revenue upon



dispensing. Other risks to the hospital of outsourcing are minimal and can be mitigated by partnering with a reputable SP provider that has a proven track record of success.

Benefits of the hospital outsourcing the SP to a trusted party include the following:

- Speed to market
- Quality of existing care programs
- Cost efficiency of not duplicating capital costs on technology such as call center telephony and data mart installation
- Appropriate accreditation day 1
- Standardized operating procedures
- Full front and back office operations already built
- Access to limited and restricted drugs
- Access to narrow payer networks
- Co-branding opportunity with SP industry leader

Financial Modeling Considerations

There are some important financial considerations the hospital must contemplate when trying to size the SP opportunity that is represented in their facilities.

These might include:

- Budget for thin gross margins ranging between 4 and 7%
- Anticipate gross margin compression to continue year over year
- Limit the analysis to top 5-7 specialty disease programs and estimates
- Identify the volume of the population in geographic area with disease burden
- Estimate total volume and capture rate per site
- Estimate number of fills per patient per year using average MPR
- Account for narrow network payer lockout rate
- Account for manufacturer restricted access to some drugs
- Approximate the expense to ship or deliver prescriptions
- Calculate labor cost for pharmacists, nurses, technicians and call center agents
- Cost of invested capital into facilities, equipment, refrigeration, back-ups, automation and technology

Many hospitals figure out quickly that the return on capital investment is very low and full of risk. By partnering with a reputable specialty pharmacy, their patients can receive the high-quality care they deserve while the hospital avoids the financial risk of this low margin business.



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