

# Considerations for Opening a Specialty Pharmacy



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## **SPECIALTY PHARMACY DEVELOPED**

as a segment of pharmacy to meet the needs of patients who didn't require hospitalization, but their medication, administration, training, and monitoring were more complex than most traditional retail pharmacies could provide. Specialty pharmacy is the fastest-growing pharmacy segment, as most new FDA approvals are for specialty medications. Specialty sales are increasing dramatically and are expected to approach 50% of all prescription sales in the next couple of years. Here we will highlight and discuss seven areas that an entrepreneurial pharmacist would need to consider before opening a specialty pharmacy.

Diligent preparation through these seven areas will put you on the right path to determine if you should open a specialty pharmacy.

## **DISEASE STATES**

**Defining the disease focus of the** specialty pharmacy will set the process in motion. The following questions will guide your disease identification process:

- What disease states do you want to provide services for?
- What will be your service niche that will differentiate you from other specialty pharmacies that are working in these disease states?
- How many patients receive treatment for these diseases and are in your target market area?
- What insurance coverage do these patients have, and will their insurance limit their access to your pharmacy?

- What is your likely capture rate?
- Are new specialty drugs in the pipeline for these diseases, or is the market mature and facing generic or biosimilar competition?
- Will you have access to purchase the drugs for your targeted disease states, or are the drugs only available via limited distribution?
- If there is a REMS (Risk Evaluation and Mitigation Strategies) program for the drug, what is involved for the pharmacy?
- Is there enough business to support a specialty pharmacy?

## **IT**

**The IT requirements differ for a specialty**

pharmacy when compared to a retail pharmacy, and should be factored into a budget for your business plan. As with any pharmacy, the specialty pharmacy will require a pharmacy management system to fulfill regulatory needs for prescription records and prescription claims submission. Additional required software components for specialty pharmacy include clinical functions, patient management, medical benefit billing, reporting, and an interface with suppliers. These components will support processes for benefits verification, adherence management and measurement, and data reporting to pharmaceutical manufacturers. A specialty pharmacy needs more extensive clinical documentation for reporting to pharmaceutical manufacturers, including patient interactions and clinical touchpoints. Requirements may include freezers for cold storage of drugs and shipping supplies to expand your reach beyond the local population.

## **PHYSICAL LOCATION**

**Will the pharmacy be freestanding or** located on a medical facility campus? The proximity should be a key consideration for determining the physicians who will be marketed to for directing prescriptions to your specialty pharmacy. Will your goal be to dispense all of your patients' medications, or limit dispensing to the specialty medications only? In most situations, you will be shipping medications

to the patient's home, so you will need to consider state board of pharmacy licensing requirements based on the location and states where your patients reside.

## REIMBURSEMENT

### Third-party coverage is essential for

high-cost specialty drugs because patients have difficulty affording this therapy if they must pay out of pocket. Furthermore, if the drugs are approved for coverage, what are the reimbursement rates? What ability will you have to secure contracts with the payers for the specified disease(s)? Commercial payers may lock out new specialty pharmacies from gaining network access. Any-willing-provider plans include Medicare Part D and fee-for-service Medicaid. Do the math and estimate your potential revenue and profit margin by the third-party payer. Consider the likelihood of negotiating more favorable pharmacy reimbursement rates with payers. Treatment affordability for the patient will be a key focus, so use of co-pay cards with commercial plans or patient assistance programs must be included as a specialty pharmacy service model.

## PURCHASING

### Verify that your wholesaler discounts

provided for brand drugs apply to the specialty drugs. We have seen situations where wholesaler discounts are less for specialty drugs compared to small-molecule nonspecialty brand drugs. This can severely impact the profitability of specialty medications. If possible, explore direct purchasing relationships with pharmaceutical manufacturers or join a buying group.

## Prospective specialty pharmacy owners should generate financial statements and prepare a business plan that realistically demonstrates the ability to be financially viable.

For rare diseases, some manufacturers may provide the drug on consignment, where you only pay for the product when it is dispensed.

## ACCREDITATION

### URAC (Utilization Review Accreditation

Commission) and the Accreditation Commission for Health Care (ACHC) were the initial accrediting bodies for specialty pharmacies. The Center for Pharmacy Practice Accreditation (CPPA) Specialty Pharmacy Practice Accreditation Program is the latest offering. Gaining accreditation is a requirement for your pharmacy. Accreditation ensures that specialty pharmacy services are documented and fulfilled (i.e., benefits verification and coordination are comprehensive and patient centered, and not just words on paper). The specialty pharmacy compliance with standards, quality, value, and patient-centered focus is verified through the accreditation process, instead of each payer or manufacturer performing its own rigorous review.

## PUTTING IT ALL TOGETHER

Once you have determined the targeted diseases that your pharmacy would focus on, assess how to acquire patients,

determine the pharmacy location, and determine the technology required. Prospective specialty pharmacy owners should generate financial statements and prepare a business plan that realistically demonstrates the ability to be financially viable. Obtain guidance from a trusted team of accounting, legal, and regulatory advisors before making a final decision on whether the business is feasible. Creating a pessimistic financial projection is worthwhile to see if the business can survive this projection, at least in the short term.

Entering the specialty pharmacy sector requires more than adding specialty drugs to your inventory. Specialty pharmacies have more hurdles and challenges with payers and manufacturers, and gaining prescriptions from physicians, all while assisting patients through the process. Diligent preparation through these seven areas will put you on the right path to determine if you should open a specialty pharmacy. **CT**

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