Guide to Selecting the Appropriate Specialty Pharmacy

10 Elements a Payor Should Consider in the Decision Process













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Specialty medications have become a significant factor in drug expenditures, accounting for 30% of total drug spend for the typical commercial plan sponsor in 2012.¹ According to recent reports from the Pharmaceutical Research and Manufacturers of America (PhRMA), pharmaceutical research and biotechnology companies have over 900 drugs in development to treat several types of cancers, 45 to treat HIV/ AIDS, 200 to treat infectious diseases, and several hundred drugs to treat other chronic conditions such as Rheumatoid Arthritis, Cystic Fibrosis, and Multiple Sclerosis.²

Many of the 1,200+ drugs in the pipeline will be classified as specialty drugs based on their characteristics, including their cost, dosage form, distribution channel, storage requirements, side effect profile, and/or monitoring needs. Specialty drugs are prescribed to treat complex and chronic conditions and patients require relatively extensive education and utilization review during their course of treatment.

The selection of a specialty pharmacy should be based on its capacity to address each specialty drug's unique requirements, to provide comprehensive, quality clinical services to patients, and to meet manufacturers and providers' data and utilization review needs. Making the correct decision affects all stakeholders, including patients, physicians, and payors, and has long-term implications. Customer satisfaction, adherence, access to specialty drugs, cost containment and waste management can all be positively shaped by partnering with the right specialty pharmacy.



1. Access to Limited Distribution Drugs

A specialty pharmacy's positive, ongoing relationship with pharmaceutical manufacturers is extremely valuable as it may determine the pharmacy's access to certain specialty drugs. Manufacturers often elect to limit the number of specialty pharmacies that can dispense their drugs to maintain close control over inventory. Their specialty drugs may require special handling, such as temperature control, and not all pharmacies have the expertise or infrastructure to adhere to those controls.

Manufacturers often publish scorecards that illustrate a specialty pharmacy's performance relative to a specific specialty drug. Manufacturers provide data regarding the pharmacy's dispensing turnaround time in comparison to its peers. A specialty pharmacy should perform favorably and should be transparent and willingly provide its scorecard.



The Cost of Specialty Medications:

Healthcare analysts project that specialty drugs will account for approximately 40% of a health plan's drug spend by 2020, due, in large part, to hundreds of drugs in the pipeline.

(Kaiser Family Foundation, 2010)



2. Specialty Medication Therapy Management

Specialty drugs are generally prescribed for patients with complex, chronic conditions. Patients' adherence to their drug regimen is critical to their clinical improvement, whether arresting the progression of their disease as in Multiple Sclerosis, or preventing the rejection of a transplanted organ. A specialty pharmacy should offer an array of programs and services that help patients comply with their drug regimens.

a. Specialty Pharmacist Counsel

Patients who are empowered about their condition, treatment, and potential side effects are more likely to be compliant.³ Specialty pharmacists should counsel patients before the initiation of therapy, reinforcing and complementing the information received from physicians.

b. Strategically Timed Communications

Many specialty drugs are not available at local retail pharmacies. Several specialty drugs are under strict FDA guidelines and patients must have blood tests performed prior to their drug shipment. A specialty pharmacy should offer strategically timed communications with patients to ensure that the patient receives their refills before running out and/ or have complied with the guidelines outlined by the FDA.

c. Patient Education

Pharmaceutical manufacturers often offer starter kits to patients at initiation of therapy. However, patient education should go beyond starter kits. Patients with chronic conditions may be on their drugs for life. One starter kit will be of minimal value after a few months. Periodic educational brochures or fact sheets that are relevant to patients' condition and ways to mitigate their drug's side effects will reinforce the need to be persistent and compliant. Specialty pharmacies should have the capacity to create educational material that is unique for each disease state.

d. Technological Tools

Adherence tools are not "one size fits all" solutions. For many patients, an interactive or dose-related adherence tool is more compelling. A text message as a reminder to take their drugs is very powerful to some patients. If they are busy and tend to forget to take their drug, a text message is a gentle, minimally intrusive tool that prompts them. The bidirectional text messaging program includes:

- Daily drug reminders
- Refill reminders
- Hydration and good nutrition promotions
- Motivational messages for patients to adhere to and finish their therapies



What is a Specialty Pharmacy?

Specialty pharmacy consists of a high-touch comprehensive care system of pharmacological care wherein patients receive expert therapy management and support tailored to their individual needs.⁴

(URAC, 2011)

A more interactive technological tool to promote adherence is GlowCap,™ an innovative electronic drug reminder. The GlowCap is placed on the prescription bottle and a wireless reminder light plugs into a kitchen or bathroom outlet. The cap pulses and glows orange at a predetermined time. It is a subtle reminder for a patient to take their drug. If disregarded for two hours, the reminder escalates to a telephone call with the message, "It's time to take the pill in your green GlowCap."

e. Experiential Support Groups

There are also psychosocial benefits gained from patients' interaction with individuals who share a diagnosis. Experiential support groups provide networking opportunities among patients with similar backgrounds where they can share experiences, support, and encourage each other. Not only do patients experience others' empathy, they often gain insight into remedies for side effects. These support groups can take place in person or online as webinars.



3. Customer Service

Patients taking specialty drugs face challenges that are unimaginable to individuals taking traditional drugs. Payors regularly encounter new specialty drug-related challenges. The diversity of a specialty pharmacy's services to support patients and payors will facilitate and simplify both patients and payors' experiences.

a. 24/7 Clinical Support

Patients' access to clinical pharmacists during their specialty drug regimen may prevent an emergency room visit due to a side effect and likely non-adherence in the future. A pharmacist can often provide a solution for patients to mitigate side effects when confronted with a side effect. In other situations, the clinical pharmacist may recognize a side effect that demands medical attention, may instruct the patient to seek medical attention, and then contact the patient's physician. Around-the-clock access to clinical pharmacists offers patients peace of mind.

b. Financial Assistance/Copay Assistance for Patients

One of the primary characteristics of specialty drugs is their expense. According to the 2012-2013 Specialty Drug Benefit Report by the Pharmacy Benefit Management Institute (PBMI), a research organization located in Arizona, the average monthly cost for a specialty drug is \$2,000. PBMI reported that the mean specialty pharmacy copay in retail was \$84 in 2011, with copays ranging from \$10 to \$250. For many patients, copays for specialty drugs are prohibitive. Their adherence and persistence may suffer due to the cost of their drugs. ⁵

Many pharmaceutical manufacturers offer copay assistance and/or financial assistance programs to ensure that high out-of-pocket costs do



GlowCaps:

Once activated, the plug in reminder light and cap connect to the AT&T Mobile Broadband network, giving patient both light and sound indicators for scheduled medications.

not prohibit patients from accessing their drugs. There are also several nonprofit organizations that offer financial aid to patients who cannot afford their copays. Patients are often unaware of these resources and are frequently overwhelmed by the applications and enrollment processes. A specialty pharmacy must have in depth knowledge of these programs and routinely inform patients of their availability and initiate the process, thus assuring access for patients to obtain their drugs.

c. Customer Satisfaction

Customer satisfaction is the primary indicator of a specialty pharmacy's ability to meet patients' needs. Customer satisfaction surveys traditionally require respondents to rate various types of interactions with the specialty pharmacy. A specialty pharmacy that continually conducts surveys demonstrates its interest in its patients' experiences and will share its customer satisfaction survey results.



4. Accreditation

Specialty pharmacies invite outside accrediting agencies to inspect and test their products and to review their policies and procedures. These independent agencies have set very aggressive standards or benchmarks that a company must meet for their products or services to receive the agency's accreditation. Accredited companies distinguish themselves from their non-accredited competitors.

a. Pharmacy Compounding Accreditation Board Accreditation

Compounding, the expert creation of a personalized drug, is required when a patient's prescribed dosage is not manufactured by a pharmaceutical company. A compounding pharmacist combines the appropriate ingredients, often under sterile conditions, to create a drug that is patient specific. The Pharmacy Compounding Accreditation Board (PCAB®) is the nation's recognized accrediting agency for compounding pharmacies. Compounding pharmacies voluntarily invest substantial time and money to prepare for and maintain PCAB accreditation, the gold standard for compounding pharmacies.

b. URAC Accreditation

Utilization Review Accreditation Commission (URAC) accreditation is healthcare's largest and one of the most prestigious accrediting bodies with over 600 organizations and companies accredited worldwide. URAC is a nonprofit organization that is independent of any particular stakeholder healthcare group, cementing its credibility as an accrediting agency. Committees of experts, including physicians, healthcare organizations, insurers, and individuals representing the public interest develop URAC standards.

Accreditation signifies to consumers that they can be confident in a product or service's safety and quality.





5. Quality

In addition to accreditation from outside independent agencies, a specialty pharmacy should have an internal Quality Assurance Department (QA) whose goal is to continuously improve quality throughout the organization. The QA Department should be designed to not only detect quality issues, but as a tool to improve and maintain high quality. A specialty pharmacy's QA Department should have quality check points, starting with a patient's initiation of therapy through its conclusion. In the event that an issue is identified, the QA Department works with the individual department on a corrective action plan to prevent future reoccurrences.



6. Waste Management

The inherent expense of specialty drugs demands that specialty pharmacies have policies and procedures to manage waste.

a. Quantity Limits

A specialty pharmacy may collaborate with a payor and perhaps initially dispense only a two-week supply of drug to determine if a patient can tolerate a new drug. This reduction in doses can prevent potential waste.

b. Elimination of Auto-Refills

Traditional pharmacies automatically refill prescriptions for patients to alleviate the need for patients to remember to call when their supply of drug is nearly exhausted. With specialty drugs, auto-refills are contraindicated. There are many reasons that a refill could be wasted, including temporary or permanent termination of drug treatment or patient hospitalization. Therefore, it is significantly more cost effective to contact each patient prior to their need for a refill to verify the continuation of treatment.



7. Data Management/Reporting

Data is a critical tool to analyze historical utilization and to predict future usage. Data is immensely helpful but only if the data management system has the capacity to capture relevant data points and to generate meaningful reports with that data. Standard reports have proven their value and have widespread use in the specialty pharmacy industry.

A specialty pharmacy should have state-of-the-art Information Technology (I.T.) capabilities, including file transfers, utilization of FTP sites, and secure e-mail/file transfer.



Quality Assurance:

The demand for specialty and compounded medications is growing due to the medical community's move toward personalized medicine as well as advances in pharmaceutical technology. Protect your patients and research your options for a specialty pharmacy provider as thoroughly as you would research any other component of their care.



8. Cost Containment

A specialty pharmacy should offer competitive pricing and have the flexibility to base pricing discounts on various industry standards such as AWP, or WAC. Specialty pharmacies should have procedures in place to maximize generic substitution and formulary adherence. Additional services offered by specialty pharmacies include prior authorization management and formulary management.



9. Internal Resources

Customer satisfaction is a direct result of the specialty pharmacy's infrastructure, program, services, and corporate sophistication. Customer satisfaction is not based exclusively on patients' experiences with their specialty pharmacy. Payors, PBMs, and physicians are also specialty pharmacy customers and internal departments and programs must be in place to support them as well as patients. Among the many support services and departments, the following are critical.

a. Call Center

Patients must have easy access to call center staff members. Call center hours should accommodate all time zones and patients' work hours. Call center staff must have expertise in the complex disease states of the patients it serves.

b. Prior Authorization Services

Prior authorizations are extremely common in specialty pharmacy due to the high cost of the drug prescribed. A prior authorization team should assist physicians and patients through the process with clinical pharmacists available to provide clinical data/information in support of the specialty drug prescribed. The specialty pharmacy should facilitate the prior authorization approval and should communicate with the patient and physician at all times during the process.

c. Billing

A patient's benefit plan determines if a specialty drug is billed under medical or pharmacy benefits. The specialty pharmacy should have the internal ability and competence to bill a member's medical benefit when necessary. Knowledge of J-Code billing with appropriate diagnosis codes and billable units is required as well as expertise in performing thorough benefit verifications.

d. Legal/Regulatory Oversight

A specialty pharmacy's legal department should be diligent to ensure that the company is in compliance with all states' unique regulations



Data Management and Reporting:

A specialty pharmacy data management system should have the flexibility to generate ad hoc, customized reports in several formats, such as Excel, XML, RTF, Word, and PDF as well as web-based.

regarding drugs and pharmacies. Additionally, the legal department must guarantee that pharmacy operations, policies and procedures are in compliance with all FDA rules and regulations. The legal department crafts contracts for specialty pharmacy services with payors and manufacturers.

e. Regional Account Management

Account managers are a specialty pharmacy's on-the-ground facilitators. Inside and outside sales team should cover all 50 states, support physicians, and expedite communications among all stakeholders. Payors are major stakeholders in specialty drug utilization and dedicated account managers at the specialty pharmacy can be invaluable resources for them. Account managers should assist in analyzing utilization data and helping stakeholders realize their goals of achieving optimal outcomes while containing costs.

f. Marketing Department

A specialty pharmacy's marketing department works closely with payors, manufacturers, account management and customers to develop patient educational material and other co-branded materials to help communicate the value of the organization.

g. Formulary Management

A specialty pharmacy must work with physicians and payors as a member of a patient's treatment team to promote cost-effective and appropriate treatment that will optimize patient outcomes.



10. Corporate History, Community Standing and Distinctions

Investing time to research prospective specialty pharmacies will prove invaluable in the long-term. A specialty pharmacy should have a rich history providing specialty pharmacy services.

A company whose sole business is specialty pharmacy has dedicated 100 percent of its resources to specialty pharmacy. Its core competency is specialty pharmacy and specialty pharmacy is not an add-on service.

Specialty pharmacies that collaborate on scientific projects with respected academic institutions and their affiliated medical centers demonstrate their involvement in the dynamic and evolving arena of specialty pharmacy. Such specialty pharmacies may have access to research options, such as innovative adherence tools in testing, for patients.



Account Management: Account managers offer frequent in-office support and coordinate educational programs to the medical professional community.



Specialty drugs are expected to account for 40% of a health plan's drug spend by 2020. The selection of a specialty pharmacy should be based upon its primary business, history and infrastructure, range of programs and services provided to all stakeholders, and its access to limited distribution drugs. Selecting a specialty pharmacy that will be a true partner to patients, physicians, and payors will clearly create a culture of collaboration. As a member of patients' treatment teams, a specialty pharmacy is a trusted and invaluable resource for all stakeholders and will ultimately benefit patients, physicians, and payors clinically and financially.



About Avella Specialty Pharmacy



Avella Specialty Pharmacy's (Avella) blended business model differentiates it from other specialty pharmacies by combining high volume national distribution facilities and community-based specialty pharmacies with an extensive account management organization. Cost-containing programs that support all stakeholders are embedded in Avella's daily operations.

Drug utilization review (DUR) at Avella begins with the receipt of a prescription, continues through to dispensing and persists throughout a patients' treatment. Clinical pharmacists ensure there are no drug redundancies, saving payors from unnecessary drug costs. Comprehensive DUR prevents life-threatening adverse events, whether due to an oversight in the drug prescribed for a patient's condition, a reaction due to an allergy



What our patients are saying:

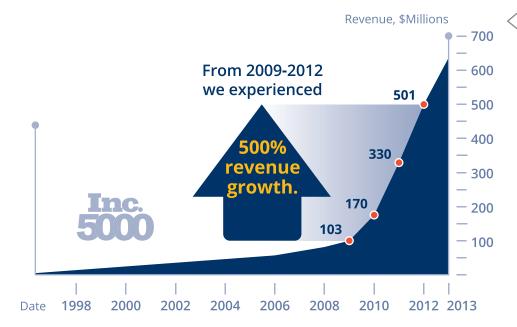
"Every staff member I interacted with in order to fill my prescription was very helpful and patient. They offered me solutions, options and extreme courteous attention which made my whole experience a lot less stressful. I tried different pharmacies but the only constant choice where they showed me respect and sincere interest was Avella."

- Maria C. (February 2013)

or a drug-drug interaction. Regardless of the cause, the patient suffers a preventable reaction that is costly to the payor.

Avella is recognized for its unparalleled high-touch Specialty Medication Therapy Program. Avella embedded its Specialty Medication Therapy Program into its operations from receipt of prescription through the patient's completion of therapy. Avella's high-touch Specialty Medication Therapy Program incorporates:

- Ongoing, strategically timed communication
- Counseling by clinical pharmacists
- State of the art technology tools
- Patient education
- Extensively trained call center specialty care coordinators
- Community-based education/support



The variety of Avella's clinical interventions, all aimed at increasing patients' adherence to their drug regimens, prevent/minimize adverse reactions and side effects, and empower patients to recognize and treat adverse effects. Avella is a member of every patients' clinical team.

Avella's clinical pharmacists have completed residencies in one or more specialties and are conduits to all stakeholders. They are always available to advise physicians about specialty drug pharmacodynamics and pharmacokinetics. Avella clinical pharmacists collaborate with payors in the development of educational tools for patients. Avella clinical pharmacists counsel every new patient about their specialty drug before the patient initiates therapy, reinforcing the information provided by the physician.

Avella's prior authorization team assumes responsibility for acquiring prior authorizations for patients, thereby freeing up that time for physician practices. Avella's clinical pharmacists will submit supporting data and information that are needed to receive approvals for specialty drugs. Avella's on the ground and in-house account managers will work on behalf



We were the fastest-growing privately held company in Arizona in 2012.



of physicians and their clients to eliminate delays due to prior authorization documentation requirements.

Avella's financial assistance team has extensive training in assisting underinsured patients to minimize their financial risk. Avella team members work closely with several non-profit agencies that offer financial assistance to patients with conditions that demand expensive specialty drugs.

Avella's proprietary specialty pharmacy data management offers payors and physicians unequaled reporting flexibility. Standard and custom designed reports document individual patient histories, prescribing trends, and patient adherence. Report consultations with account managers and clinical pharmacists can guide stakeholders in their goal to achieve optimal outcomes while containing costs.

For more information please contact us at: marketing@avella.com



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