

Specialty Pharmacy: High Tech, High Touch

by Marsha Millonig, R.Ph., M.B.A.

The specialty pharmacy market continues to grow, and with 60% of the drugs in phase 3 clinical trials considered specialty drugs, 47% of the pharmacy industry's revenues are projected to come from specialty drugs by 2022, according to the "2018-19 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors" (Adam J. Fein, Ph.D., Drug Channels Institute, October 2018). While there is not a single definition of what a specialty drug is, they generally are described as prescription drugs that are difficult to manufacture and require special handling or administration, have limited distribution, target a narrow group of chronic diseases, are costly, and require ongoing clinical support. What are the current market dynamics, and what technology needs are required to be successful in the specialty space? *ComputerTalk* set out to explore this question through interviews with some specialty pharmacy players.

Specialty Market Trends

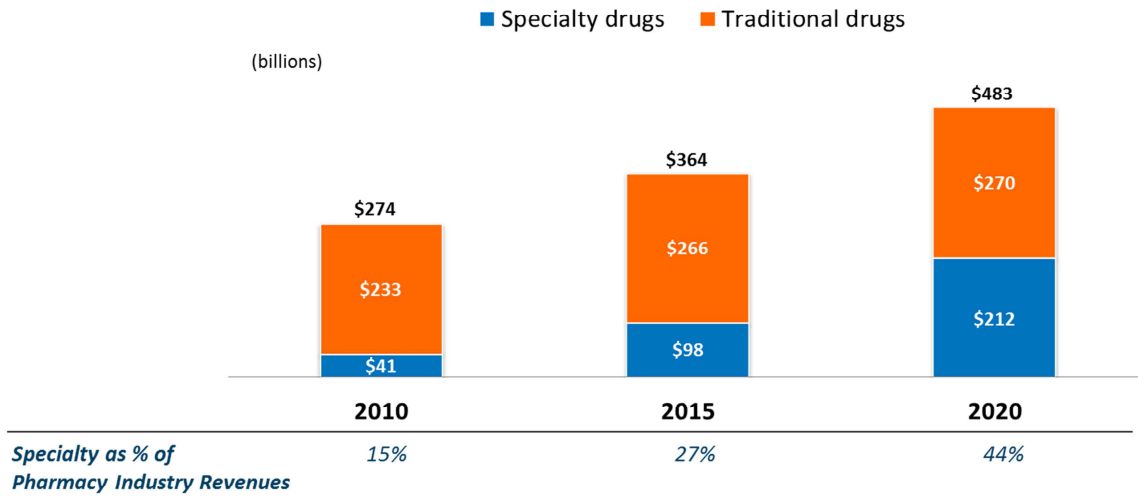
In its report, "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA provides insights into the specialty market space (www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf). Key highlights include:

- Spending continued to shift from traditional to specialty medicines, with that segment accounting for 46.5%, or \$407, of the \$876 per person per year spent on medicines.
- The specialty share of net spending across institutional and retail settings grew from 24.7% in 2008 to 46.5% in 2017.
- Medication spending growth is projected between 2% and 5%, with 1% to 4% growth in retail and mail-order prescription drugs.
- Growth will be driven primarily by the large number of new medicines, many of which will be specialty and orphan drugs.
- Specialty drugs compose 1.9% of total prescription volume, but account for 37.4% of spending within the retail and mail-order distribution channels.
- In the nonretail setting, specialty drugs account for 60% of invoice spending and 2.3% of standard unit volumes.
- The largest percentage of new medicines launched in the last five years has been specialty drugs, and specialty share of spending has risen.
- Net specialty medication revenue was an average of 23% below invoice sales, a difference that was found to be twice as large for traditional drugs.
- New brand spending has experienced a dramatic shift to specialty, driving \$9.8 billion of the \$12 billion net growth.

- Of 42 new active substances launched in 2017, 32 were for specialty treatments.

Adam Fine of the Drug Channels Institute estimates that specialty spending will reach \$483 billion by 2020:

Pharmacy Industry Revenues, Traditional vs. Specialty Drugs, 2010-2020



Figures in billions
Source: Pembroke Consulting estimates

This table appears as Exhibit 34 in: Fein, Adam J., *The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies*, Drug Channels Institute, January 2016. Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/



In his article “The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning” (April 9, 2019; www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html) Fine estimates that in 2018, retail, mail, long-term care, and specialty pharmacies dispensed about \$146 billion in specialty pharmaceuticals. Clearly the specialty market has come of age since its early beginnings, and significant consolidation is happening in the marketplace. In his blog, Fein notes that the top four companies’ share grew from 66% in 2017 to 70% in 2018. He attributes this growth partly to: (1) the pro forma combination of Express Scripts and Cigna, (2) CVS Health’s acquisition of five specialty pharmacies, and (3) OptumRx’s acquisition of Avella Specialty Pharmacy and Genoa Healthcare. Avella and Cigna had both appeared on their 2017 list of the largest specialty pharmacies. He further notes that independent specialty pharmacies in 2018 faced slowing growth and mounting competitive pressures. Smaller specialty

pharmacies struggled to access specialty medications within payer and PBM (pharmacy benefit manager) networks.

Specialty and the Community Pharmacy

The management of the specialty drug spend continues to be a top priority for plan sponsors, according to the April 2018 “EMD Serono Specialty Digest: Managed Care Strategies for Specialty Pharmaceuticals.” This includes determining the value of specialty therapies and ensuring their clinically appropriate use. Plans are increasing their use of utilization management and prior authorization to control specialty spend. The services the plans report valuing the most include specialty dispensing and patient services. Perhaps not surprisingly, specialty pharmacies employ high-tech, high-touch means to address clinical outcomes, and their operational requirements are different from the traditional distribution environment.

“The specialty pharmacy business is not an assembly line. It requires a lot of high touch,” notes Dorinda Martin, R.Ph., Pharm.D., a partner in Martin’s Specialty Pharmacy in Austin, Texas; this community pharmacy has been in the neighborhood for 61 years. The specialty practice, which was established in 2015, currently occupies approximately one-third of the building and has dedicated staff, technology, and inventory. Martin’s has two other Austin-area locations in Dripping Springs and Bee Cave, Texas.

Martin’s moved into the pharmacy space in partnership with a manufacturer of a specialty product that needed to build a distribution network. “There are really two primary independent providers for that manufacturer in Texas,” notes Martin.

“As we moved into the specialty space, we had to build out a number of services,” she says. These include:

- Prescription confirmation.
- Co-pay assistance and benefits investigation, including denial and appeal programs.
- Refill reminders to patients.
- Side-effect management.
- Lab coordination and treatment updates.
- Monthly patient status reports.

Initially, the operation used a pharmacy technician who was trained specifically in specialty pharmacy. They now have three pharmacy technicians and three pharmacists who rotate through the specialty pharmacy. “Our business has grown to over 500 specialty prescriptions a month,” notes Martin, “and we primarily have grown the business by marketing our services to area physicians so we can continue to care for our patients on these medications.”

Services cross a variety of therapeutic areas, including, cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders, and encompass about 25 specialty medications. “For us, any drug with a cost of more than \$1,000 is automatically driven from the community pharmacy to the specialty pharmacy environment,” says Martin.

“We started our specialty practice from ground zero; the slow and steady growth allowed us to transition into many of the high-touch activities that we now provide on a larger scale. We incorporated these activities without really realizing what they were going to cost in the future on a larger scale,” she says. Specific areas of operation that Martin’s addressed as it developed its specialty pharmacy included:

- Accreditation, certification and training (Martin’s is accredited by the Accreditation Commission for Health Care).
- Pharmacist education and training.
- Patient care services, counseling, and training.
- Tracking and reporting patient adherence and outcomes.
- Storage, handling, and delivery.
- Reimbursement requirements.
- Website forms.
- Computer software and additional specialty software.
- Staffing.

“At the beginning we had a manual system in place to document care plans, timetables, and follow-up. We called it our war room. It did not take long for us to realize we could not continue to operate in a paper environment. Imagine when you go to a physician or dentist’s office and observe the walls of patient records. We didn’t have room to do that,” says Martin.

They used their Computer-Rx pharmacy management system to process the prescriptions, but it did not have the capability to manage patient care plans and the needed follow-up for specialty prescriptions. Martin and her partner decided to participate in a specialty pharmacy conference to explore possible solutions. “We decided to purchase software to support the specialty pharmacy patient care process,” she says. A long-term contract was not required, and the flexibility of a month-to-month fee allowed them to determine if the technology was a fit. Martin’s Specialty Pharmacy is not integrated back to any physician practice EMRs (electronic medical records) or EHRs (electronic health records), and so staff members communicate patient care information by phone, fax, or email, based on the physician’s preference.

Product dispensing requires double data entry in both the Computer-Rx system and the specialty pharmacy software system, because they are not integrated and the specialty pharmacy system cannot adjudicate claims.

Across the industry, the average time it takes for patients to receive their specialty medication from a large specialty pharmacy operation is three to six weeks after it is prescribed, according to Martin. “This statistic demonstrates the intensity of the fill process,” she says. “However, an independent pharmacy can turn these prescriptions around a lot faster. We are usually able to do so in two days. It all depends on the drug and the plan, and how much info is required on the prior authorization. Another factor is the disease state; if the patient has to have a failed attempt on another product, that’s a big delay.” Going through the exercise of measuring actual time required to fill a specialty prescription brings attention to and heightens awareness of the cost. “This is very helpful when trying to calculate the true return on investment of staff time. It takes us over two hours to refill a specialty prescription,” says Martin.

Martin’s uses its own delivery service as well as UPS, depending on where the patient is located. Manufacturer reports are completed at the manufacturers’ web portals and populated with data that is tracked in the specialty pharmacy software system.

Martin and her partner are exploring additional technology solutions that could be integrated, now that the business has grown. “We definitely operate at a much higher level of customer touch and one-on-one service with specialty patients versus community pharmacy patients,” she says, “And that requires a different technology solution.”

Scaling up with Specialty Pharmacy

PANTHERx has taken a different approach to its specialty business. PANTHERx ranked as the twelfth largest specialty pharmacy in 2018, with estimated revenues of \$0.7 billion, according to Drug Channels. The company was founded in 2011 with a specific focus to be *the* rare disease specialty pharmacy. This independently owned specialty pharmacy has been honored as the fastest-growing company in Pittsburgh, where it is headquartered. It is a closed-door pharmacy with three locations in Pennsylvania and Ohio.

Senior Vice President and Head of Business Tim Davis shared PANTHERx’s story at an American Society for Automation in Pharmacy (ASAP) conference. He noted the company’s focus on being service-oriented, nimble, and efficient, as it primarily grows through partnerships with manufacturers. PANTHERx’s mission is to transform lives by delivering medical breakthroughs, clinical excellence, and access solutions to patients afflicted with rare and devastating conditions.

PANTHERx is accredited by the Accreditation Commission for Health Care, the Center for Pharmacy Practice Accreditation, and URAC, and also carries the National Association of Boards of Pharmacy's VIPPS accreditation, indicating an online pharmacy's compliance with state and federal laws and regulations.

What began as a retail operation with a retail pharmacy management system and basic telephony and accounting platforms has evolved to a paperless specialty pharmacy with a specialty pharmacy management system with specialty workflow technology (SWFT), integrated telephony, hardened security, internal and external dashboards, and expanded contracting alignment. "Flexibility is important," notes PANTHERx's Senior Vice President of Technology Carlos Correa. "We have to be able to make changes to our systems to meet our manufacturer partner requirements. We can set up our systems with forms and documents that meet those needs and then guide how patients are onboarded into the system by our patient care coordinators."

PANTHERx has a number of specialized roles within the specialty pharmacy workflow, including:

- Patient care coordinator.
- Insurance resolution specialist.
- Provider relation liaison.
- Clinical pharmacist.
- Clinical nurse specialist.
- Order management technician.
- Fulfillment technician.

"Core to our operation is specialty software and a custom built system we call Specialty Workflow Technology (SWFT). The specialty software is our patient record and SWFT is a workflow solution that guides our staff's interaction with our patients. The two systems are tightly integrated. Together, these systems manage all interactions with the patient." says Correa.

Like Martin's, PANTHERx systems are not integrated back into any physician EMR or EHR systems. Prescriptions are primarily sent to PANTHERx via eScripts or fax and entered into the specialty software system. Prior to scheduling an order, an Insurance Resolution Specialist ensures any needed prior authorizations or other data necessary for the patient's insurer is entered into the patient's record. Once completed, the patient is entered into a SWFT queue for the appropriate patient care coordinator to call and begin working the order. SWFT will guide the responsible PANTHERx staff through our process. If this is a new patient, the process is a complete on-boarding process to gather required information. If it is an existing patient, it can be as simple as confirming insurance information and shipping address. SWFT is configured to include any scripting that the partner requires when

PANTHERx staff interact with the patients (e.g., any specific questions to ask or information to provide).

All medications PANTHERx that manages are stocked in inventory based on the number of patients on each medication and refill metric and tracked in the specialty software. "One of the biggest differences in our operation from a typical retail pharmacy is that we are closed door, and all patient medications are shipped. The shipping and tracking process is very intense, and we have systems set up for our patient care coordinators to view and confirm delivery," says Correa. PANTHERx partners with Federal Express for its medication fulfillment shipping. Product shipping is tracked frequently within the fulfillment side of the operations, often every 10 minutes.

The integrated specialty software and SWFT systems were designed to allow monitoring of patient adherence metrics and adverse drug reactions while also providing clinical support and clinical/medication education so that patients receive the best care possible.

Patients report high satisfaction with PANTHERx's services. The company was named the top overall specialty pharmacy in patient satisfaction for two consecutive quarters in 2017 in the Zitter Health Insights Patient Satisfaction Survey, which assesses all specialty pharmacies in the United States. It was also the winner of the Specialty Pharmacy Patient Choice Award in the non-PBM/payer category for 2016 and 2017. Most recently, PANTHERx was awarded the National Association of Specialty Pharmacy (NASP) Specialty Pharmacy of the Year in 2018. Company leadership notes that the awards reflect PANTHERx's mission, vision, and values. That vision is that PANTHERx will become the national leader in specialty pharmacy for rare and devastating conditions by providing unrivaled care to its patients, service to its providers, and attention to its partners.

"Our solutions are customized for our partners in order to provide the best service possible for our patients," notes Correa. PANTHERx Specialty's focus is to partner with manufacturers of medications for rare disease. They are the exclusive specialty provider for numerous companies and medications. "We collect data based upon our contracts with individual manufacturers. Data may be reported daily, weekly, or monthly, depending on the manufacturer's need. Data is collected and sent electronically to the manufacturer through data aggregators contracted by the manufacturers, or directly to the manufacturers," Correa says. "There is no standard format or EDI [electronic data interchange] transaction set. Data is encrypted and sent via SFTP," he notes. "The requested data is not always unique when you look at different

aggregators/manufacturers. We do work with the manufacturers to define data file formats. It can be time-consuming to set up reporting for an aggregator.”

Correa notes that “pharmacy management systems aren’t necessarily built for the specialty pharmacy space,” and that “a lot has to be done to make it happen.” As Tim Davis observed at the ASAP 2017 Midyear Conference, “Partners are looking for better ways to solve patient dilemmas and drive outcomes.”

The specialty pharmacy business is expected to continue significant growth in the coming years, driving toward half the prescription marketplace. Different systems are required to meet data needs and drive patient outcomes than in the traditional pharmacy marketplace. In this high-tech, high-touch growing business sector, flexibility and customization are keys to success.

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