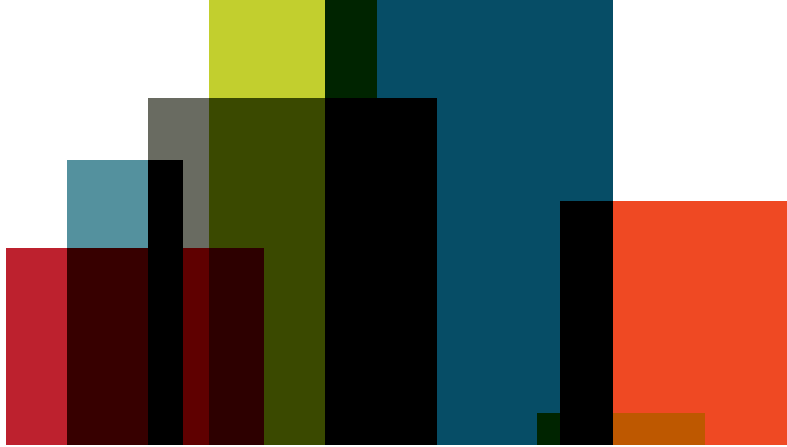




SPECIALTY PHARMACY:

Succeeding in a
Shifting Landscape

AUGUST 2021



It's called specialty pharmacy for a reason.

This growing segment of health care requires specific expertise, superior service and extraordinary attention to detail. It also offers singular hope to many patients living with life-altering and often devastating conditions.



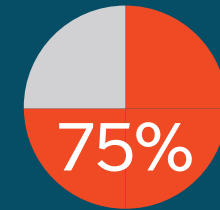
Specialty pharmacies across the country have always been driven by a desire to improve patients' lives. Now they have become an integral part of the care team, collecting, analyzing and sharing data and partnering with patients, providers, manufacturers and other stakeholders to deliver outstanding care to patients.

Organizations and individuals with a passion for patient care gravitate to this field. Pharmacy practice can be an all-consuming occupation, especially as the health care landscape, and specialty pharmacy in particular, continues to shift and change—and grow. The term “specialty pharmacy” didn't even exist until 20 to 25 years ago. Accrediting organizations instituted programs for this area and have seen major growth in the last five to 10 years.

In 2015, there were 378 accredited specialty pharmacy locations in the country. In 2020, the number topped 1,200. The top 15 specialty pharmacies—mostly central-fill mail and specialty pharmacies operated by pharmacy benefit managers and insurers—currently account for 75 percent of prescription revenues from specialty drugs.¹ Independent and provider-owned specialty pharmacies are growing too. Accredited provider locations have nearly tripled in the last five years to 39 percent of locations in 2020—just behind independents (42 percent). Mergers and acquisitions are also on the rise, especially

 1200

Accredited specialty pharmacy locations in the country in 2020



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among the larger independent specialty pharmacies. Payers and PBMs are ramping up their expectations, further increasing the importance of accreditation from at least one organization, and often two.

Meanwhile, the number of specialty drugs continues to grow. The FDA approved 140 new specialty drugs between 2013 and 2020, but estimates put the number of specialty drugs in the pipeline at more than 900. Gene therapies and biologics make up a growing proportion of pipeline therapies, but the majority are new molecular

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entities. The biggest categories are oncology, inflammatory diseases and multiple sclerosis. Established names include Keytruda, Humira and Enbrel with millions of prescriptions each year.

On the other end of the spectrum, many specialty medications target rare and ultra-rare diseases. In the U.S., a rare disease is defined as one that affects fewer than 200,000 Americans.² Approximately 7,000 diseases fall into this category, and while

 \$600B

Total in 2021, U.S. pharmaceutical spending is expected to reach



some of these conditions may affect only a few thousand or hundred people in the country, together they affect a significant portion of the population—up to 1 in 10 Americans. Many of these diseases are genetic, and two-thirds are diagnosed in children. Most—up to 95 percent—have no treatments. Specialty medications are changing that—and changing lives.

“Five-ten-fifteen years ago, we didn’t have any treatments for these patients,” says Sheila Arquette, President and CEO of the National Association of Specialty Pharmacy. “Now we’re seeing manufacturers that are focused on bringing drugs to the market for the treatment of orphan and rare conditions.”

The dollars going to specialty pharmacy are also rising sharply. In 2021, U.S. pharmaceutical spending is expected to reach \$600 billion. Even though specialty prescriptions make up only 2.2 percent of the overall number of prescriptions filled, they account for about 50 percent of drug spending.³

Clearly, this is a time of tremendous expansion in the specialty pharmacy segment of health care. More importantly—it’s a time of new possibilities for people with serious health conditions such as cancer, multiple sclerosis, cystic fibrosis, hemophilia, rheumatoid arthritis and Crohn’s disease.

What does this mean for organizations entering or already in this burgeoning area of health care?

Challenge. Opportunity. Innovation.

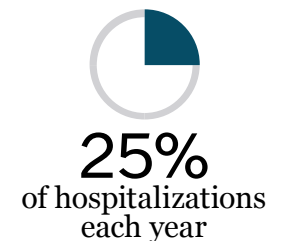
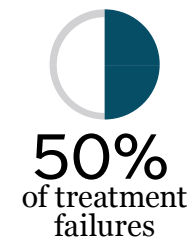
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Essentials of Specialty Pharmacy

In general, specialty pharmacies dispense specialty drugs – medications that require a high level of patient monitoring and more clinical support than traditional therapies. They also provide a high level of patient monitoring and more clinical support than a traditional pharmacy practice. There isn't much argument that drugs in this category are intricate therapies for chronic or complex conditions and require special attention in some way, either in monitoring, dose adjustment, storage, distribution, administration or other areas. Some specialty drugs require additional data reporting, patient education and other precautions under the FDA's Risk Evaluation and Mitigation Strategies program to help ensure that a medication's benefits outweigh its risks.⁴ Specialty medications tend to be expensive, with costs for some that range from \$10,000 to \$7 million per patient per year. URAC, which offers a wide range of pharmacy accreditation programs, defines specialty as one that dispenses specialty drugs and provides a high level of patient monitoring and more clinical support than a traditional pharmacy practice.

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deaths



Effective specialty pharmacy operations build their models on close patient relationships and monitoring.

Nearly all health care professionals agree that these drugs can't help people if they don't take them—and that dispensing drugs that don't get used or don't have the desired effect is a waste of precious health care resources. Non-adherence is a significant concern in pharmacy in general, accounting for up to 50 percent of treatment failures, 125,000 deaths and up to 25 percent of hospitalizations each year.⁵ The risks rise with the complexity of the treatment as well as the severity of the condition being treated. Monitoring effectiveness is another part of the specialty pharmacy picture. While the goal of all health care is improved outcomes and quality of life for patients and their loved ones, achieving that goal in specialty pharmacy can require several extra layers of resources to address the inherent complexity.

As a result, effective specialty pharmacy operations build their models on close patient relationships and monitoring. Leaders in the field have developed a variety of innovative and evidence-based models of care that use data, expertise, empathy, outreach and ingenuity to overcome challenges and deliver exceptional care to patients.

The Patients' Voice

Heritage Biologics

There's no shortage of passion for patient care and quality services in the specialty pharmacy area. But the founders of Heritage Biologics have very personal reasons for their focus on the patient and the patient journey. Founder Tom O'Neill is the parent of someone with a rare disease; Christopher Quesenberry is a rare disease patient himself. Their personal experiences navigating the complexities of rare diseases drove their model that puts the patient and their quality of life at the center. Their ambitious goal: changing health care for the better.

Chief Operating Officer Amanda Walker is very clear: Heritage Biologics is not like other specialty pharmacy organizations. Although licensed to serve patients in all 50 states, they have fewer than 1,000 patients nationally. The company specializes in home-infusion therapies for patients with chronic and rare diseases. "We are not a one-stop shop type of pharmacy. We only take care of the disease states that we're clinical experts in. We have a very select few therapies," says Walker.

Patient experience is at the core of the company. That means helping patients navigate a complicated,

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segmented health care system and manage their disease and their medications for optimal results and quality of life. “These patients are on very expensive medications that they are going to be on for the rest of their lives,” says Walker. “It’s really figuring out how we can help these patients do the best they are able to do in their day-to-day life and not be defined by their disease or the medication that they are taking.”

Through a software package they developed for their patients, Heritage Biologics attempts to unify the fragmented health care system and collect data in real time from infusions and dispenses, as well as from the physician’s office and from the patients themselves. In addition to clinical information, they also collect information on the patients’ quality of life using the SF-12, a validated health-related quality-of-life questionnaire as well as a custom survey called “Rare Voice” that they developed in-house.

Listening to patients and addressing quality of life can mean

connecting them with financial assistance or with

support groups and educational opportunities related to their disease state. But it can also mean dealing with other aspects of building a full and fulfilling life. “We’ve helped patients with their resumes and helped



Their goal is to make patients' lives better and enable them—through specialty medications and other types of support—to live fuller lives.

them look for jobs. We've connected them to housing assistance.” Their goal is to make patients' lives better and enable them—through specialty medications and other types of support—to live fuller lives. In fact, says Walker, dispensing medication is almost the smallest part of what Heritage does.

To make this work from a business standpoint, the company must be innovative and find reimbursement beyond dispensing medication. For example, Heritage works directly with employers to figure out how best to care for their employees who are rare disease patients to help them manage their disease state. They also partner with manufacturers to provide de-identified patient data that helps them improve their products. “You have to get creative in today's marketplace to figure out how you can bring money through the door beyond just the margin on the drug,” Walker explains.




Health Systems Caring for Their Own

University of Kentucky
Healthcare

In 2015, about 50 percent of large hospitals had a specialty pharmacy program. By 2020, more than 90 percent had a formal program to dispense specialty drugs and support patients taking these medications.⁶ These programs have increased access to specialty medications and increased support for clinicians and patients within their health systems.

In 2013, just a handful of academic medical centers had received accreditation in specialty pharmacy, says Debbie Duckworth, PharmD, Senior Director for Specialty Pharmacy at University of Kentucky (UK) Healthcare. But Dr. Duckworth, then an on-call pharmacist who had recently joined the health system, saw the potential in this area. Previously, as the owner of a pharmacy and durable medical equipment company, she had witnessed the increasing tendency of insurers to require certain medications be filled by specialty pharmacies. She also knew that Kentucky ranked lower than other states in health outcomes, especially in its rural areas. She saw an opportunity to increase access to specialty medications and impact health in the state. “We wanted to make sure we could gain access to those therapies for patients and not hand that over to someone else,” she says. UK Healthcare is now URAC-accredited in specialty pharmacy with rare disease designation.

In addition to positioning UK for payer approval to dispense these drugs, Duckworth also saw an opportunity to build on the trust



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residents already have in their in-state academic medical center. The accreditation process also helped drive best practices that she believes are making a real difference in the health of her fellow Kentucky residents. “When a patient calls us and they have a problem, they know that we’re going to be fully invested in providing a solution for them and making sure their therapy works, that we are communicating immediately with their provider,” she explains. “That’s just something another specialty pharmacy can’t do for our patients because they’re not in our health record, they don’t work shoulder to shoulder with our providers.”

Overcoming Barriers to Access

University of Washington

Specialty Pharmacy Manager Erica Diamantides, PharmD, at University of Washington (UW) in Seattle defines specialty pharmacy not so much by the cost or complexity of the drug but by the many barriers to access: logistical, financial, clinical, etc. She sees the role of the UW Specialty Pharmacy as removing or helping patients navigate those barriers by assisting with prior authorization, connecting patients to assistance programs and providing expanded clinical pharmacist education around the therapies. Her department fills the role of ensuring that all those in the care team follow policies and protocols, which increases the chance of treatment success. They serve this role even if the medication (for insurance or other reasons) is actually dispensed by another pharmacy.





Before this program started in 2014, Diamantides says that providers had little way of knowing whether the patient ever got their prescribed medication. Depending on the patient's insurance, the prescription might move back and forth from pharmacy to pharmacy, and providers might not find out until their next appointment with the patient that they were never able to get the medication. Now, Diamantides says, providers know every step of the way where the patient is in the treatment path.

The electronic health record (EHR) is a key component of this. Pharmacy team members—just like the clinicians and other members of the care team—are all using the same medical record. To meet the requirements for URAC accreditation, Diamantides and her team worked with UW's EHR vendor to implement a patient management program that's built right in.



Proving Outcomes

Vanderbilt University
Medical Center

Vanderbilt University Medical Center (VUMC) has gone even further in integrating specialty pharmacy into the care team, actually embedding full-time specialty pharmacists into clinics that have high volumes of patients who need specialty medications. The pharmacist sees patients in-person when possible, especially before the start of a new therapy or a change in therapy. Clinics with lower volume use a centralized model.

The result? Better outcomes, says Tara Kelley, PharmD, executive director of Vanderbilt Specialty Pharmacy (VSP). “We feel strongly that our model of integrated specialty pharmacy really does improve patient outcomes.” But VUMC wanted proof.

“We wanted to see how the model improves care and reduces provider burden,” says Autumn Zuckerman, PharmD, Outcomes Program Director for VSP. She first started by forming an outcomes committee to research and demonstrate the value of the VUMC model. They looked at outcomes for hepatitis C patients and saw that more patients were accessing the medication faster as a result of the program. In

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2017, the committee became an outcomes program and since then the group has published 36 peer-reviewed manuscripts analyzing outcomes from the program. The program also conducts multi-site studies and provides training opportunities to enable pharmacists to conduct their own research. They have also actively shared best practices with other health systems through a national conference they host. Nearly 150 health systems participated in 2019 and 190 attended the virtual 2020 conference. Several other health systems—including UK—are now dedicating a staff member to outcomes research in specialty pharmacy.



Narrowest of Markets

PANTHERx Rare

While some of the latest specialty medications clearly fall in the blockbuster category, PANTHERx Rare pharmacy has gone in the exact opposite direction, focusing on rare and ultra-rare conditions. Back in 2015, PANTHERx won its first exclusive contract with Alexion to be the sole specialty pharmacy to dispense Strensiq which is FDA approved to treat hypophosphatasia, an inherited disorder that affects bone development in 1 in 100,000 newborns. This contract set them on a path to pursue these limited and exclusive distribution medications. Now, more than 90 percent of the company's revenue comes from these types of arrangements.

Most of the therapies PANTHERx manages have fewer than 1,000 patients—and some have as few as 200 patients total nationwide.

All require intensive education and support to get the best possible outcome from the medication. In order to serve this area, PANTHERx holds not only

specialty pharmacy accreditation but also rare disease designation from URAC and ACHC.

Richard Faris, PhD, RPh, Senior Vice President and Head of Pharmacy for PANTHERx points out that the original idea behind specialty pharmacy was to provide that intensive guidance and enhanced

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service to patients who require complex therapies. Now, he says, the reimbursement on some drugs have diminished over years to the point that they may not even cover the cost of the medication, let alone the time required of the pharmacist, the insurance specialist, the patient care coordinator, and others. But focusing on exclusive and limited distribution arrangements allows PANTHERx to return to that original specialty care focus.

Under limited and exclusive distribution models, manufacturers often pay for enhanced services for patients to receive additional assistance and to empower them to use the medication properly. This may include follow-up phone calls, specialized welcome kits and other services. The fees that the manufacturer pays makes up for otherwise thin margins that characterize the pharmacy business, he says. “Exclusive and limited

distribution arrangements allow you to provide these additional services, which are about value to the patient and the healthcare system. Our job is to specialize in the disease state and medication in a way that helps patients achieve outcomes that are important to them.”

In late 2020, the managed care company Centene acquired PANTHERx as a complementary, high-growth asset to other specialty pharmacy assets. According to Faris, Centene intends to keep PANTHERx separate from its other specialty pharmacy businesses. “Our job isn’t to service all of Centene’s patients who need specialty medications.”



Instead, PANTHERx will focus on the rare disease therapeutic categories exclusively, serving patients with all types of insurance and payment arrangements. “Rare and ultra-rare disease really require

a different thought process” from the blockbuster portion of specialty pharmacy.

Faris believes that the number of medications with exclusive and limited distribution arrangements will continue to grow. Even though this might seem like good news for PANTHERx and other

rare disease specialty pharmacies that are able to deliver the expertise and intensive services needed by these patients, Faris looks beyond the business case.

“I actually pray that we go out of business because nobody needs our medicines,” Faris says. “What a wonderful world that would be. But as long as people require medicines of this type, we have an opportunity to help them to live different lives.”



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Specialty pharmacies are at the heart of patient care and are a critical resource when patients need these providers the most.

While organizations and individuals entering this field may take different approaches to specialty pharmacy, they share that kind of dedication, expertise and attention to detail. The complexity of the medications—and the conditions they are designed to treat—demands all that, and more.

Specialty pharmacies are at the heart of patient care and are a critical resource when patients need these providers the most. They provide treatment that can be lifesaving to patients, as well as much needed supplemental support to families and caregivers. Patient care is not just something pharmacies do, but rather is an opportunity for them to be at their very best with each new patient who comes through their doors. Specialty pharmacies think about the big picture, consider the details, see each patient as unique, and develop innovative methods for treating the whole patient and not just the disease. They partner with other organizations, learn from their patients, take risks, and try to do it all better than they had before.

That is how specialty pharmacies embrace innovation to meet the challenges and opportunities they face. ■



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