



COMPETING

IN THE *Specialty Pharmacy Market*

Achieving Success
in Value-Based Healthcare

The explosion of the specialty drug market has forced the pharmacy industry into a new era of heightened competition. Specialty drugs for individuals with chronic or complex diseases and disorders now comprise nearly one-third of the pharmacy industry's revenue, and are expected to account for up to 50 percent by 2020.¹ The dramatic increase in the supply and demand for specialty drugs has attracted a wide range of organizations to the market. Organizations ranging from small, independent pharmacies to huge publicly traded retail pharmacy chains now dispense specialty drugs to patients in every state of the U.S., resulting in wide variation of quality and expertise among these providers.

With the healthcare delivery system continuing to move toward value-based reimbursement, health plans, pharmacy benefit managers (PBMs), practices and hospitals are seeking to partner only with pharmacies that have a proven ability to deliver better care at a lower cost. To successfully compete, specialty pharmacies not only must improve their processes, create sustainable transformation, but also collect and share data that demonstrates their ability to improve patient adherence and outcomes.

Accreditation helps organizations achieve this competitive advantage and provides external validation that they have the clinical, operational and logistical expertise to deliver higher value at a lower cost. By continuously measuring and improving performance through rigorous adherence to best practices, accredited specialty pharmacies advance patient-centered care beyond the "Five Rights" of safe medication administration to include a crucial "Sixth Right": the right result.

It's not enough for specialty pharmacies to provide the right drug to the right patient at the right time. That's why every standard in URAC's Specialty Pharmacy Accreditation program focuses on how pharmacies can help patients with the highest needs and the highest costs achieve the intended result from their medication therapies—and why payers, PBMs and pharmaceutical manufacturers now require specialty pharmacy accreditation among their contracted partners.

This industry insight report explores the specialty pharmacy landscape, discusses key competencies essential to achieve the "Right Result," and looks ahead to the near-term future.

*Exponential
market
growth has
resulted
in operational
variability*



The specialty pharmacy industry has grown exponentially over the past five years, influenced in part by a plateau in the generic dispensing rate, increased utilization and a steady pipeline of specialty drugs hitting the market.²

While total drug spending in the United States increased 8.5 percent in 2015, to \$310 billion, after adjusting for rebates and other price concessions by manufacturers, spending on specialty drugs jumped 15 percent, to \$121 billion, according to research by QuintilesIMS.³ In fact, spending on specialty drugs nearly doubled between 2010 and 2015, contributing more than two-thirds of overall growth in drug spending. With more specialty treatment options in development, this trend is expected to continue.

Not surprisingly, the number of organizations competing to dispense specialty therapies has skyrocketed as well. These organizations include PBMs, retail chains, health plans, pharmaceutical wholesalers, physician practices, hospital systems and small, independent pharmacies. But because there is no “official” specialty pharmacy definition—specialty pharmacies aren’t defined by state pharmacy boards or even by CMS—the definition continues to change as the industry segments itself from traditional pharmacy.

The National Association of Specialty Pharmacy offers the most comprehensive definition, which includes: “A specialty pharmacy is a state-licensed pharmacy that solely or largely provides only medications for people with serious health conditions requiring complex therapies.”

The diversity of specialty pharmacies has resulted in tremendous variability in all operational areas, including, tracking adherence, educating patients, dispensing medications and ensuring medication safety. A pharmacist at a community-based pharmacy may meet with patients in person to discuss their therapies and educate them about possible side effects, for example, while a central-fill mail pharmacy may engage in this interaction via telephone.

URAC’s Specialty Pharmacy Accreditation program recognizes and accommodates these differences by empowering organizations to develop customized workflows that align with their business model and meet the needs of their patient populations.





The move to value-based healthcare and the role of specialty pharmacies

As the healthcare delivery system continues its transition to a value-based reimbursement model, pharmacies face many of the same market pressures as other healthcare providers to improve patient outcomes and patient experience while controlling costs.

Because complex therapies and medications are expensive and require intense patient management strategies, payers rely on PBMs to manage utilization and reimbursement of specialty drugs. Many PBMs, in turn, seek out accredited specialty pharmacies to provide an elevated degree of competency—one that focuses on medication adherence and patient outcomes.

“The need for managing patient care throughout the course of therapy will never be greater,” says Kylanne Green, URAC’s president and CEO. “Pharmacists and pharmacies that begin to adopt fundamental elements of the new value economy, those who position themselves as an essential part of the care team, will succeed.”

In a 2016 survey of 58 commercial health plans, 88 percent of respondents identified drug dispensing as the most valuable service provided by specialty pharmacies, followed by (82 percent) providing such patient services as coordinating eligibility and reimbursement, helping patients obtain financial assistance and educating patients about treatment adherence. Eighty-one percent placed a high value on a specialty pharmacy’s ability

to track patient interventions and outcomes and document expenditures and savings.⁴


Consider the new pressures physicians are facing. The value-based reimbursement established under MACRA (Medicare Access and CHIP Reauthorization Act of 2015) will fundamentally change how providers are paid by rewarding physicians for improving outcomes.

“Physicians are care team leaders under MACRA,” Green notes. “If physicians benefit financially by partnering with top-performing pharmacies who help them improve quality, they will seek them out.”

To demonstrate their value as a care team partner, specialty pharmacies must measure and report performance. Some measures commonly tracked include medication possession ratio; portion of days covered; viral load; accuracy and turnaround time of dispensed prescriptions and customer satisfaction.

Specialty pharmacists also must display a deeper knowledge and understanding of complex disease states and medications, and have the competency to make therapeutic recommendations, assess/reassess patients and collaborate with the patient’s physician.

“Pharmacists and pharmacies who can demonstrate their ability to manage medication and thus demonstrate their value will be recruited by accountable care organizations, clinically integrated networks and patient-centered medical homes,” says Green. “Pharmacists will no longer play supporting roles. They will be vital leads.”



Demonstrating value by measuring and tracking outcomes



Validating improvement through performance measurement is critical in today's value-based market. To demonstrate value, specialty pharmacies must have data that connects their interventions directly to patient outcomes.

And perhaps no measure is more important than adherence. Countless studies have demonstrated its impact on outcomes and avoiding unnecessary hospitalizations and other expenses. A 2013 study, for example, found that patients were 60 percent more likely to achieve optimum adherence with their Hepatitis C drug therapy if they used a specialty pharmacy rather than a retail pharmacy.⁵

Driving medication adherence is a constant challenge, but one at which specialty pharmacies particularly excel. Integrated refill reminders and comprehensive care management programs are among some of the most effective strategies. When it comes to serving patients with complex co-morbidities that require costly therapies, this kind of hands-on intervention can mean the difference between an adherent, low-cost outcome and a non-adherent, high-cost readmission. One study found patients were 46 percent more likely to achieve optimum medication adherence with their leukemia drug therapy—which can cost upwards of \$92,000 annually—if they used a specialty pharmacy that offered refill reminders, care management and educational programs.⁶

“That’s what makes specialty pharmacies so vital,” Green says. “They’re not just managing the drug, they’re managing the whole process. The pharmacist connects with the patient and the pharmacy collects the resulting data, analyzes it and makes it actionable so that it can inform future efforts.”

URAC’s Specialty Pharmacy Accreditation promotes outcomes reporting in two ways. First, the standards require that accredited organizations evaluate their clinical services by tracking clinical, financial, patient satisfaction, and quality-of-life outcomes. Each specialty practice can define which outcomes within these categories are most meaningful to their practice. In this way, the standards provide pharmacies with a framework for gathering data to demonstrate their value. Second, all accredited specialty pharmacies track and annually report to URAC the same five measures:

- Drug-drug interactions
- Call center performance
- Dispensing accuracy
- Distribution accuracy
- Prescription turnaround time

Pharmacies also can also choose to report three additional “exploratory” measures:

- Proportion of days covered
- Fulfillment of promise to deliver
- Primary medication non-adherence:

Through this tracking, pharmacies can more effectively work as part of patient’s care team and have outcomes data ready to demonstrate their value.

“This quality data can and should be used as a competitive tool that exhibits a specialty pharmacy’s expertise,” says Aaron Turner-Phifer, URAC’s director of government relations and policy. “They’re part of the organized system of care that centers around the patient.”

Taking the Five Rights of medication administration one step further



The “Five Rights” of medication administration — right patient, right drug, right dose, right time, and right route — are embedded in URAC’s Specialty Pharmacy Accreditation standards. But also embedded in URAC’s accreditation standards is tracking patient outcomes. This is the sixth right — the right result for the patient — according to Green.

“The high-price of specialty pharmaceuticals and the potential impact on patient safety requires specialty pharmacies to have specific competencies for tracking how patients respond to a drug therapy and ensuring patients have the appropriate outcome,” says Green.

At the core of URAC’s Specialty Pharmacy Accreditation is a focus on achieving the right result for the patient. Every standard in URAC’s accreditation program is focused on this principle. Achieving the right result is critical for promoting positive patient outcomes, preventing hospitalizations and keeping costs low. Nearly 18 percent of Medicare patients are readmitted to the hospital within 30 days of the initial discharge, often due to medication misuse, mismanagement or nonadherence.⁷

Under pay-for-performance, those readmissions will translate into an average reduction of 0.74 percent of Medicare inpatient payments in 2017.

This will equate to \$528 million in lost revenue, a \$108 million increase over 2016. (The increase is primarily due to the inclusion of more medical conditions being measured.)⁸

Patients with more than one chronic condition have the highest readmission rates. Specialty pharmacies, with their high touch points and strategic patient outreach, are uniquely poised to help break this cycle.


Unlike most traditional prescriptions, specialty medications require strategic care coordination between pharmacists, physicians, nurses, allied health professionals and the patient and caregiver. From comprehensive teaching prior to beginning their drug therapy to continuous monitoring and outreach throughout the treatment, specialty pharmacists provide an essential drug management program for each patient.

“This patient management piece is what distinguishes specialty pharmacies from other pharmacies,” says Green. “It’s not just about the drug, it’s about the entire management of the process. The significant follow-up they provide is one of their critical areas of function.”

The Six Rights, therefore, serve as a blueprint for URAC’s standards and constitutes what is required for success in a value-based healthcare economy.

The growth of lower reimbursement models that penalize poor outcomes has drug manufacturers, health plans and PBMs seeking specialty pharmacies that can deliver quality care at a lower cost. Accordingly, most now require specialty pharmacies to be accredited by a nationally recognized accrediting organization as a way to externally validate quality and competency.





Accreditation as a tool for competing in today's market




URAC's accreditation program is considered the premier choice and "gold standard" for specialty pharmacy accreditation.⁹

"The overarching goal of accreditation is to serve as a mechanism to drive best practices, which is inevitably going to be at the forefront of the healthcare evolution as the industry continues to focus on value-based care," according to a 2016 report on specialty pharmacy best practices.¹⁰

In today's value-based landscape, medication adherence and medication management not only drive outcomes, they're driving specialty drug payment.

Consider a pair of game-changing value-based contracts announced by Cigna in May 2016, when the insurer established contracts with Amgen and Sanofi/Regeneron that tie drug prices with patient outcomes. The agreements modify the price of costly new cholesterol-lowering drugs based on how well customers respond to the medications, aligning incentives by linking financial terms to improved patient health.



If Cigna's enrollees aren't able to reduce their LDL-C levels at least as well as what was experienced in clinical trials, the two pharmaceutical companies will further discount the cost of the drugs. If the drugs meet or exceed expected LDL-C reduction, the original negotiated price remains in place. Cigna has similar value-based contracts in place with medications designed to treat heart failure, diabetes, multiple sclerosis and Hepatitis C.

These types of value-based arrangements will continue; reimbursing for drugs based on value was among the three most important strategic priorities identified by payers for 2017.¹¹ Accredited specialty pharmacies are strategically poised to partner with these organizations and their provider networks to help patients realize these improved outcomes.



What the future holds

While therapies for “the big three” disease states (multiple sclerosis, cancer and rheumatoid arthritis) will continue to account for a substantial share of specialty drug utilization, the next generation of “pharmaceutical blockbusters” may actually belong to orphan drugs—specialty drugs developed to treat diseases that affect smaller patient populations that often have substantially higher costs.

This will further expand market opportunities for specialty pharmacy providers—as the clinical, logistical and operational expertise necessary to help patients manage these therapies becomes more complex, the need for exceptional specialty pharmacies will only increase.¹²

With specialty drug spending projected to comprise from 35 to 50 percent of all U.S. drug spending over the next three years, healthcare providers are already realizing the potential. In fact, they’re the fastest growing category of accredited pharmacy locations. One in five hospitals already offers a specialty pharmacy service and an additional 38 percent are considering it, according to a survey by Baird Equity Research.¹³

Mail-order pharmacies, national retail chains, independent community pharmacies and regional drugstore chains will likely continue their push into this market as well. But such rapid growth will bring more market consolidation.

“There’s a tremendous amount of interest because of the sheer dollars going into specialty drugs. That trend is here to stay,” says Green. “With

consolidation, there will be increasing sophistication in operations and care management.”

Payers will continue to seek out the best of the best. Among their top strategic priorities this year: coordinating specialty drug management across pharmacy and medical benefits.¹⁴ The pharmacy market has a significant role to play in creating a more collaborative model of care, particularly in the types of high-touch therapies provided by specialty pharmacies. Accredited, patient-centered specialty pharmacies will be best positioned to win some of this lucrative business. The coming year will bring expanding opportunities for pharmacy to highlight the critical role they play.

“Pharmacy practice is undergoing a transformation: from an operational focus to providing more value-based services. This is a positive trend for patients as well as the industry,” says Heather Bonome, URAC’s director of pharmacy. “URAC understands what’s necessary to make this transition, and our accreditation program facilitates the process.”

Endnotes

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