



Specialty pharmacies flourish, but could they be facing hidden risks?



Meeting the operational challenge

Countless prescribing laws across the United States affect the prescription claims process. From prescriptive authority to the growing restrictions on prescribing controlled substances, the rules are becoming more complex at both the federal and state level.

At the same time, healthcare reforms have led CMS to continue its oversight of prescription reimbursements for Medicaid patients. Together, these and other issues make validating every prescription a necessity. That validation process can present an operational challenge for specialty pharmacies, even more so for small, community-based specialty pharmacies that may have limited resources and data-based tools.



The role of specialty pharmacies

Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis and multiple sclerosis. They're expensive—often exceeding \$1,000 per month.¹

Because most specialty drugs have specific handling and administration requirements (typically injection or infusion), they're often not available at traditional consumer drugstores. They're dispensed by specialty pharmacies, which can offer patient care services for these high-cost, high-touch medications. Specialty pharmacies must provide patient education, promote medication adherence and help monitor the patient for side effects and efficacy.

According to *Specialty Pharmacy Times*, “Specialty pharmacies serve as a vital component to the success of a medication newly approved by the FDA. Through interactions with prescribers, patients and manufacturers, specialty pharmacies function as a valuable intermediary for distribution of drug information, provision of exceptional care for clinically complex patients and engagement in post-marketing surveillance.”²



Growth in the specialty market

The specialty pharmacy landscape is rapidly changing as the balance of pharmacy industry revenues shift from traditional brand-name drugs to specialty drugs, a surge not expected to subside in the near future. In fact, over the next four years, over 40% of medication spending will be on specialty drugs.³

According to Paul Urick, President of Diplomat Pharmacy, Inc., which published a report⁴ on the current state of specialty pharmacy, “The specialty pharmacy industry continues to show exceptional growth. The development of new drugs, as well as expanded indications for previously approved treatments continues to make the robust specialty drug pipelines one of the major drivers of growth.”⁵

In the *Specialty Pharmacy Continuum*, Adam Fein, PhD, the CEO of Drug Channels Institute, noted the past three years have seen “astounding growth” in the number of unique accredited specialty pharmacies. In 2015, there were 381 unique specialty pharmacy locations, a number that grew to 499 in 2016 and 729 in 2017. “I predict that next year, we’re going to see this number approach and maybe exceed 1,000,” Dr. Fein said.⁶

Confirming prescription validity

While large chain pharmacies have systems in place for prescription validation, many specialty pharmacies have not yet invested in these solutions. Often they’re relying on mixed-and-matched data and technology components that are ineffective.

Specialty pharmacies must be able to perform real-time, comprehensive prescription compliance checks within their existing workflows if they’re to ensure reimbursement, which is especially critical when dispensing ultra-costly specialty medications. These compliance checks, when done right, also mitigate the risk of regulatory fines related to prescriptive authority, federal licensing, state credentials and controlled substance regulations.



The specialty pharmacy landscape



¹ <http://www.drugchannels.net/2017/06/trends-and-challenges-in-specialty-drugs.html>

² <http://www.drugchannels.net/2017/06/trends-and-challenges-in-specialty-drugs.html>

³ <http://www.wolterskluwer CDI.com/blog/pharmacy-trends-2018/>

⁴ <https://www.healthinsurance.org/glossary/specialty-drug/>

⁵ Pharmacy Benefit Management Institute® Specialty Drug Benefit Report, p. 17

⁶ <http://www.drugchannels.net/2017/06/trends-and-challenges-in-specialty-drugs.html>

⁷ Pharmacy Benefit Management Institute® Specialty Drug Benefit Report, p. 35

Pharmacies must check that the prescriber has:

- A valid license
- No sanctions
- No exclusions from Medicaid
- Prescriptive authority for controlled substances
- No irregularities that might suggest fraud or abuse

A compliance-based, data-driven solution

Specialty pharmacy, which once represented only a small segment in the pharmaceutical market, has become a burgeoning industry. Scientific advances and innovation promise to add to the cures and treatments coming on the market in the next few years. With more medications available and more patients to service, specialty pharmacies will need to step up their operations to protect against risk.

The right data-driven validation solution can help specialty pharmacies perform real-time compliance checks on all prescription transactions before they are transmitted to payers, reducing regulatory risk and increasing the percentage of paid prescription claims.

Most importantly, an efficient, effective solution allows specialty pharmacies the time needed to offer patients the skilled counseling and care they deserve.

For more information on a real-time, compliance-based validation solution designed specifically for pharmacies and PBMs, call 866.396.7703 or visit risk.lexisnexis.com/products/verifyrx.



Health Care

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¹ <https://www.healthinsurance.org/glossary/specialty-drug/>

² <https://www.specialtypharmacytimes.com/publications/specialty-pharmacy-times/2018/january-2018/new-therapies-and-the-role-of-specialty-pharmacy-providers>

³ <http://www.wolterskluwer CDI.com/blog/pharmacy-trends-2018/>

⁴ https://issuu.com/diplomatrix/docs/2016pipelinerecapfinal_web?e=15248128/42785885

⁵ <https://www.specialtypharmacytimes.com/news/specialty-pharmacy-drugs-2016-approvals-and-2017-forecasts>

⁶ <https://www.specialtypharmacycontinuum.com/Article/PrintArticle?articleID=48582>