Navigating the specialty pharmacy landscape: Considerations for health systems and opportunities for patient care

Five trends are shaping the specialty pharmacy landscape

1. **The market for specialty drugs has grown rapidly, with medication costs increasing and the complexity of medication therapy evolving.** In 2023, 80% of novel drugs approved were specialty, and at least 75% of the 7,000 drugs under development in 2024 were specialty.[1] Health plan specialty drug costs are expected to increase by 13.3% in 2025.[2] As of December 2024, specialty pharmacies in the US span across 440 pharmacy and health system networks (half of which are integrated delivery networks).[3]

2. **Scrutiny of accessing 340B pricing for specialty medications is increasing.** Compliant participation in a 340B drug pricing program yields increased cost savings and revenue for safety net hospitals, serving as a key contributor to maintaining robust patient care services in underserved communities. But more than 35 manufacturers have imposed contract pharmacy restrictions that limit health system utilization of 340B program benefits.

3. **Payers are establishing contract requirements for specialty pharmacies and access to specialty drug coverage.** Many payers are requiring specialty pharmacies to achieve accreditation to contract with them. (Two-thirds of payers prefer accreditation through URAC. At least one-quarter of specialty pharmacies hold accreditation with more than one body to maintain competitiveness and access with payers.[4]) To contain costs, payers are also looking to restructure their specialty drug coverage.

4. **Health systems will see increasingly complex medication orders, coupled with continued limited distribution networks and reporting requirements.** These heightened complexities increase the need for multidisciplinary collaboration with clinical pharmacists, who can provide the required in-depth knowledge of these drug therapies. Medically integrated dispensing pharmacists can also use medication adherence tools and adverse event monitoring to support patients throughout their journey.

5. **Regulatory requirements and scrutiny associated with specialty drugs is increasing.** As innovative complex therapies come to market, manufacturers often establish strict handling and distribution requirements, and specialty pharmacy operations and distribution processes must adapt. Similarly, accreditation requirements continue to evolve to ensure the proper stability and efficacy of drugs throughout their journey from pharmacy to patient. Since 2017, the presence of hospital and health system-accredited specialty pharmacies has increased from 15% to 27%.[5]

What this means for health systems

- **Payers will add layers of requirements for access and coverage of specialty pharmacy drugs.** As payers try to prioritize cost-effective value-based care, they are instituting patient outcome reporting requirements as a gateway to specialty payer contracts and a means to justify the increased cost of prescribed specialty drugs. Prior authorization requests are expected to increase as these drugs become more prevalent. Additionally, financial coverage and patient assistance programs are becoming essential to ensure medication adherence and optimal outcomes. For patients with chronic specialty diseases, payers often require cost-effective alternatives as the primary treatment.

- **A greater need for clinical expertise, patient education, and adherence monitoring for access to limited distribution drugs (LDD).** Nearly 70% of specialty drugs are subject to limited distribution.[6] Manufacturers utilize limited distribution networks to streamline access and support for drugs with US Food and Drug Administration (FDA) requirements and to ensure safe use, data reporting, and targeted distribution. Pharmacy benefit managers (PBMs) and health-plan-aligned pharmacies report greatest access to limited distribution drugs (LDDs), followed closely by health system-owned pharmacies. The ability to provide clinical services and data reporting on outcomes and adherence is critical to LDD access.

- **Evolving accreditation and manufacturer requirements that will require adapting pharmacies' operational and clinical processes.** This involves closely monitoring specialty drug fulfillment and distribution, as well as meticulous audits to monitor changes and adapt regulatory processes accordingly. Additionally, pharmacies need to perform frequent audits of clinical documentation within the patient management platform to ensure optimal compliance and patient care.

- **Additional barriers to maintaining 340B program benefits for safety net hospitals.** As manufacturer contract pharmacy restrictions on high-cost specialty drugs continue, along with the new proposed pilot of the 340B rebate model, safety net hospitals may have limited leverage from 340B program savings for patient care initiatives. The continued evolution of the 340B program also necessitates ongoing evaluation of compliance practices.

What health systems need to do now

- **Prioritize implementation or expansion of your specialty pharmacy strategy.** This will promote continuity of patient care and manage rising medication costs. By optimizing specialty pharmacy services for employees and patients, health systems can advance drug access for high-touch, high-cost, and newly approved medications. It requires integrating clinical pharmacists, patient advocacy programs, adherence monitoring, and patient-centric care. Additionally, strategies like electronic health record (EHR) integration can improve prescription capture rates, and centralized prior authorization processes can help launch or grow a specialty pharmacy.

- **Consider implementing clinical pharmacist-led programs.** As part of a specialty pharmacy strategy, health system leaders should consider implementing a high-touch clinical medication management program. This is integral to successful accreditation, payer and LDD access, optimal patient outcomes, and the potential for enhanced 340B savings.

- **Build and maintain a compliance-based, well-developed, and fully integrated 340B program.** This is fundamental to a health system's specialty pharmacy growth strategy. For increased cost savings across the enterprise, health systems should consider enhancing their 340B program with leading-edge strategies such as eligibility expansion methodologies, in compliance with Health Resources and Services Administration (HRSA) requirements. Leveraging these strategies in combination with a health system specialty pharmacy is integral to offsetting 340B manufacturer contract pharmacy restrictions and maintaining community patient care initiatives.

- **Establish dual accreditation and implement clinical interventions associated with optimizing patient outcomes.** Dual accreditation (e.g., URAC and Accreditation Commission for Healthcare [ACHC]) and clinical outcome reporting by disease state can enhance payer contracting and limited distribution drug access. Implementing clinical interventions for optimized patient outcomes will demonstrate high-quality standards of care and clinical capabilities, as required for accreditation. Together, these actions can increase the number of specialty patients served with excellent care. This capability is especially important as the population of specialty patients grows—60% of Americans have a chronic disease, and 14 million more are expected by 2030.[7]

- **Implement a quality management committee (QMC) to ensure optimal health system pharmacy operations and patient safety.** The QMC helps identify specialty pharmacy quality improvement initiatives to highlight positive patient care and clinical outcomes. The QMC can ensure specialty pharmacy excellence by identifying quality improvement initiatives based on audit findings and accreditation requirements.

Are you ready?

We can help. Contact us to learn more about how to implement and grow your specialty pharmacy services to yield increased financial performance and quality of patient care.

Sources

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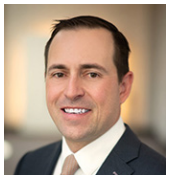

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