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The 340B specialty pharmacy

The challenging prognosis, the prescription for success

As care transitions from inpatient to ambulatory settings, health systems frequently consider operating specialty pharmacies. While access to the 340B drug discount program is complex and detailed, the advantages can far outweigh the challenges. It's important, though, to understand the obstacles and risks, and have the right tools in place to overcome them.

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Specialty drugs represent **less than 2%** of prescriptions, yet they account for

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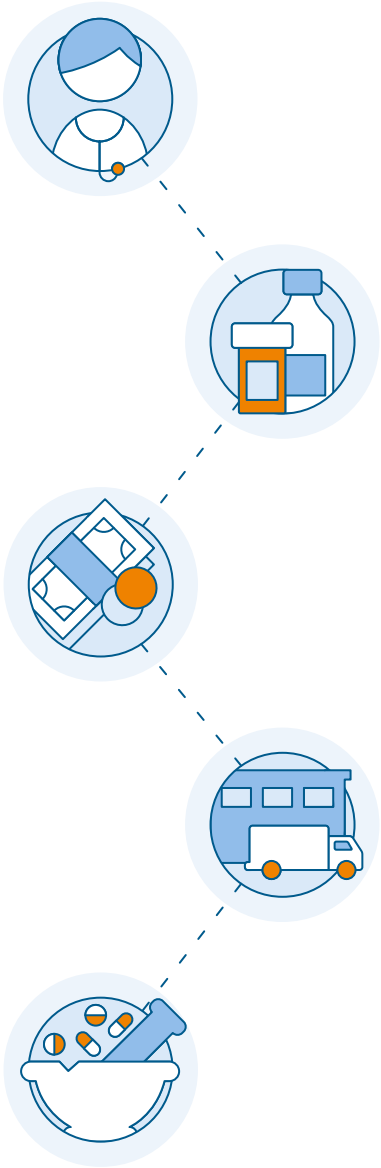
of consumer spending in the same channels.

A lot has changed since 1992, when Congress passed Section 340B of the Public Health Service Act requiring drug producers to provide certain safety-net healthcare providers with discounted outpatient drugs.[1] Healthcare systems have grown more complex, frequently blending covered entities with non-covered hospitals and clinics. Advanced therapies have allowed caregivers to shift the site of care from inpatient to ambulatory settings for many patients with chronic conditions. Specialty drug costs have skyrocketed, even as the total percentage of specialty drugs prescribed remains low. And over the years, the program itself has become more difficult to navigate. By taking a well-informed and well-resourced approach to specialty pharmacy operations, however, healthcare systems with 340B-eligible sites of care can stretch federal resources more effectively to do the most good in their communities.



What constitutes a specialty drug?

While there is no single definition of what constitutes a specialty drug, a product with five or more of the following characteristics has historically earned this designation:[2]

- Targets complex, chronic or rare medical conditions
- Prescribed by a physician specialist
- Is generally an injectable, inhalable or infusible (exceptions: hepatitis C, oral chemo, HIV)
- Requires special handling, such as refrigeration
- Has a unique distribution model (narrow networks, direct ship) and is usually not stocked at retail pharmacies
- Has a high monthly cost or cost per treatment
- Requires extensive patient training/follow-up
- May require patient reimbursement assistance

The specialty category may also include so-called "orphan drugs" — drugs intended to treat diseases so rare that their production would not be financially viable without subsidies. It takes an average of 10 years and tens of millions of dollars from the time a new molecule of this type is discovered until the time it hits the market. And that's just for the ones that are ultimately found to have a therapeutic benefit. Only 1 of every 10 molecules tested is generally found to be beneficial. It's no wonder, then, why drugs with such a slim demand make it virtually impossible to recover the costs of research and development.[3]

Since the definition of a specialty drug can be somewhat subjective, most health plans and PBMs create unique specialty drug lists to define specialty items in an agreement. The drugs included in these lists vary between different plans and PBMs. 340B contract pharmacy agreements also often utilize a list to define what items are considered "specialty," since dispensing fees often differ between specialty and traditional prescriptions.

Specialty drugs may be difficult to define in black-and-white terms, but their financial impact is clear — these products represent less than 2% of prescriptions, yet they account for nearly 40% of consumer spending in the same channels.[4] And with new product approvals on the rise in this category, it's more critical than ever for 340B-participating organizations to get their programs in order.

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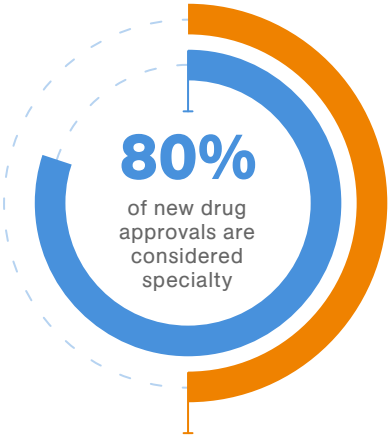

By 2020, specialty medication is expected to increase to

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The Rx equation is changing

According to a report by *Specialty Pharmacy Times*,[5] 80% of new drug approvals are considered specialty.[6] In addition, specialty medication is expected to increase to 50% of drug costs by 2020,[7] driving the growth of the specialty pharmacy segment to $500 billion by 2020.[8] As the number of specialty and orphan drugs continues to grow, so does the challenge of verifying patient eligibility and managing eligible sites of care — especially as outpatient-consumers prefer (and expect) access to their medications through clinics or retailers near their home, versus traveling back to the certified 340B hospital, in order to get specialty prescriptions filled.

The importance of self-auditing and compliance

The purchasing requirements surrounding specialty drugs are dictated by the manufacturer and can change at any time. If the HRSA conducts an audit and finds that serious oversights or missteps occurred in 340B program management or applying eligibility guidelines, it can require corrective action to restore compliance and direct repayment of unearned 340B discounts. HRSA can suspend an institution's 340B participation, which can make it difficult for some organizations to survive.

For patients that qualify and receive a 340B-purchased drug, a drug manufacturer may contact the covered entity and ask it to provide an assurance or specific information to support that medications purchased at a 340B price actually were dispensed to eligible patients. If not, pay-back terms will be developed.

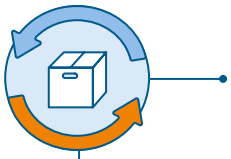
Creating a new site of care? Expect a long 340B lag.

As health systems continue to grow, it's not uncommon for organizations to build or acquire new facilities that may be similar, if not identical, to existing 340B-covered sites of care in their healthcare continuum. Yet before these organizations can extend these valuable benefits to new facilities, they must first run the gauntlet of qualifying each new site independently.

For a new site to qualify, it must appear on a health system's cost report, which is filed only once a year. For example, if a new clinic or pharmacy is opened or incorporated into a healthcare system in January, the system's cost report will likely not be completed until July or August, after which it goes to external auditors, whose review generally delays the finalized cost report until October or November. Then, because the Health Resources and Services Administration (HRSA) mandates that new sites can be registered only during a 15-day period at the beginning of each calendar quarter, it will take from January 1–15 to ***register*** a site that opened a full year before. ***Qualifying*** for 340B drugs requires yet another calendar quarter, extending the process into March or April.

All sites of care are not created equal

Another significant issue for systems and patients is the site at which care is delivered. There are multiple entities within any given healthcare system, including hospital-based clinics (whose prescriptions would qualify for 340B) and clinics overseen by a system's larger physician employment group (whose prescriptions would only qualify for 340B under specific circumstances, e.g., a hospital discharge prescription). Paying the lowest cost possible for drugs is best for the health system and patient alike, and most care providers work diligently to assure that 340B patient and prescription eligibility is managed effectively to ensure that costly medications that qualify for 340B are identified.

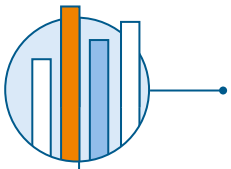


Multiple care settings exponentially increase the complexity, cost and effort associated with a health system's supply chain infrastructure.

Enhancing infrastructure: Technology to the rescue

To address the paradigm described above, software developers have gone to work creating and refining effective tools to help specialty pharmacies validate eligible sales and help healthcare systems gain valuable insights into their specialty/orphan drug market.

With applications like Macro Helix 340B Architect,™ EPIC Willow,® Verity340B® and others, contract pharmacies can quickly confirm whether a patient qualifies for 340B pricing. In split-billing 340B software, a sophisticated logic matrix pinpoints the prescriber, the location where a prescription was generated, and the last time the patient was seen in a 340B-qualified medical center, along with ensuring that a wide array of rules are met that allow 340B pricing. By automating these variables, organizations are able to minimize the risk of errors at any number of points along the complex 340B supply chain, which helps to ensure compliance while supporting optimal pricing and reimbursements.



Analytics identify trends to help improve compliance, increase reimbursements and capture revenue while improving staff efficiency.

Diminishing complexity: 340B savings at a glance

Further up the value chain, health system administrators can use the same software to quickly see the revenue generated by their specialty pharmacies as a result of the 340B arrangement and confirm their 340B savings across the organization — even in systems that include larger contract pharmacy networks and/or prescribers that engage with patients in 340B non-qualifying, as well as 340B-qualifying, facilities. For large healthcare systems, those savings can add up to a substantial sum, which can be used to optimize care of vulnerable populations.

Through process and technology consulting, drug spending declines and drug utilization increases to improve both a health system's performance and patient outcomes.

Fueling performance: How 340B benefits can outweigh challenges

The 340B program is incredibly complicated — almost as complicated as today's multifaceted healthcare systems. When the two are combined, they can make 340B compliance and management a challenging endeavor. With the right people, the right tools and the right mindset, though, streamlined oversight and administration are possible.

The first step: It's important for hospital system administrators to define drug procurement and reimbursement internally as something more than just two steps in the supply chain. Supply chain management has far fewer regulatory mandates and rapidly changing components — and certainly does not pose the significant legal risks and ramifications for falling short. As such, drug procurement and reimbursement also require the coordinated effort of a team of experts — caregivers, pharmacists, internal auditors, compliance officers, general counsel, IT specialists, a dedicated 340B program manager, and others — to obtain approval from third-party payers to make these expensive specialty and orphan medications available through a 340B program.

The next step: Don't under-resource it. While 340B certification represents a huge benefit to patients, it can be an equally huge compliance risk for healthcare systems if not done right.

CONCLUSION

At the end of the day, thorough preparation, attention to detail, and meeting the seemingly endless details of specialty pharmacy management and compliance are more than worth it. Specialty and orphan drugs help people and — often — save lives. The more a healthcare system adheres to the mandates, the more it can save on its own bottom line. And the more a care system saves, the better prepared it will be to deliver quality care to even more people in need.

Advanced technology designed by and for health system pharmacists provides actionable, data-driven insights to help you make intelligent, impactful decisions.

This white paper was authorized by McKesson Corporation.

Sources:

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