Understanding and evaluating deal considerations in the specialty pharmacy sector

An update for private equity investors

This issue explores certain strategic, financial, and tax issues that private equity investors should consider when evaluating investments in specialty pharmacies.

Strategic considerations

Growth in specialty pharmaceutical spending and pipeline—While the overall rate of growth in total drug spend averaged in the low single digits, the rate of growth for specialty drugs was almost 20 percent over the last eight years. Specialty drug spend was approximately $87 billion in 2012 and is anticipated to be approximately $400 billion in 2020, which represents approximately 9.1 percent of the nation's total healthcare spend. There appears to be increasing interest from manufacturers to develop drugs as evidenced by the increase in FDA approvals. Specialty medications make up at least 60 percent of the drugs slated for approval for marketing in the US. The growth in specialty pharmaceutical spending and pipeline of drugs can provide a significant opportunity for private equity investors.

Pressure on specialty drug prices—Less than one percent of all prescriptions were written for specialty drugs, but accounted for approximately 32 percent of total drug expenditures. To combat the increasing price of specialty drugs, many governmental and commercial payers are negotiating with manufacturers to obtain rebates and reduce prices in addition to coordinating with pharmacy benefit managers ("PBM") to impact the designs of certain programs. There will likely be greater coordination between manufacturers, third party payers, and specialty pharmacies to control costs of specialty drugs within the overall healthcare system, which may lead to lower reimbursement on specialty drug sales.

Healthcare reform and impact on service revenue—Traditionally, specialty pharmacy revenue is derived from drug sales and rebates earned from PBM and manufacturers. Increasing costs of specialty pharmaceuticals and healthcare reform change have driven many specialty pharmacies to engage with patients and other providers by managing drug utilization in order to increase adherence and effectiveness. Depending on the services provided and the insurance carrier of the patient, specialty pharmacies may be able to bill third party payers for such services. Billing for these services is incremental to the revenues generated through drug sales and may result in additional revenue streams. Understanding the services provided by specialty pharmacy practitioners in conjunction with performing a compliance and regulatory analysis to understand whether such services can be billed under payer contracts may identify additional revenue streams.

Narrow networks driven by PBM and other large players—The specialty pharmacy sector experiences a high level of competition especially from large national players, many of which have specialty pharmacy offerings in addition to owning their own PBMs. This combination can allow them to limit the access of smaller pharmacies to distribution and payer networks, which can be seen as a barrier to entry. Additionally, there is an increasing trend of PBMs and payers alike to limit patient access to various products and pharmacies in order to combat the rising costs of drugs. These trends may result in down-side risk to earnings to the extent smaller specialty pharmacies are not able to negotiate favorable terms or become part of the network.

Financial considerations

Revenue cycle—Specialty pharmacies are typically reimbursed at pre-authorized rates from commercial and government payors. Each payer contract is different and can require differing amounts of patient responsibility. Due to these complexities, there may be variations between gross amounts charged and contractual rates with insurers. The proliferation of high deductible plans has been increasing the burden on patients, which may increase the risk of bad debt. Significant judgment can be required to estimate future expected cash collection and the value of accounts receivable. Investors should consider performing additional procedures related to accounts receivable to assess whether historical accounts receivable estimates have been realized through subsequent cash receipt and whether historical trends indicate current accounts receivable may be collectible. Understanding historical billing and collection experience is typically a key focus of the specialty pharmacy due diligence process.

Rebates and other discounts—Most specialty pharmacies receive a high level of rebates and discounts from manufacturers either directly or as a pass through from PBMs and other contracted distributors. The ability of the pharmacy to account for rebates is typically dependent on the availability of information provided from the PBM or manufacturer. Often, pharmacies record rebates on a cash basis but should accrue rebate revenues as earned. Rebate and discount structures vary by specialty drug, manufacturer, and PBM, and can be complex. Understanding various vendor contracts is key to the due diligence process in order to assess timing and amount of cash flows associated with rebates and discounts. To the extent the specialty pharmacy engages in a prime vendor agreements, the pharmacy may experience shifting levels of discounts depending on purchasing volumes. Specialty pharmacies may also be incentivized to accelerate purchases or speculate through inventory to achieve higher levels of rebates and discounts or take advantage of published price increases. The impact of all of these factors on reported revenue and margins should be considered as part of the due diligence process.

Impact of patent expiration on branded drugs—When branded pharmaceuticals lose patent protection ("the conversion period"), specialty pharmacies typically experience a significant spike in profit margin during the conversion period. The spike in profit margin per script is primarily due to the temporary incentives that payers provide to encourage the conversion from the branded drugs to the lower cost generics. The impact of branded to generic conversions should be considered when analyzing gross margin trends and normalized levels of earnings as part of the due diligence process.

Inventory considerations—Tracking and managing inventory is a significant component of operating specialty pharmacies. Investors should understand contracts with manufacturers and distribution networks and specific terms associated with guaranteed returns for obsolete, slow moving, and returned scripts. Furthermore, additional complexities may arise to the extent pharmacies engage in speculative buying where large amounts of inventory are purchased before scheduled or suspected price increases by manufacturers. Understanding historical inventory levels, gross margins, and inventory costing methodologies is imperative as changes may result in an impact to EBITDA and working capital.

340B Drug Pricing Program—The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. Covered entities have the option of contracting with specialty pharmacies to provide 340B pharmacy services to their patients. Pharmacies earn a fee from the 340B entity for dispensing drugs under the program but do not hold the inventory or include cost of drugs within cost of goods sold. Revenue streams associated with the 340B Drug Pricing Program should be analyzed as part of the due diligence process as revenues may not be recurring in nature.

Regulatory and compliance considerations—Most drug distribution agreements between manufacturers, distributors, and pharmacies are constantly under scrutiny by enforcement agencies particularly as related to the Anti-Kickback Statute. Penalties can be being levied against stakeholders which pay or receive "kick-backs" in form of referrals or higher performance-based bonuses. Additionally, downside exposure may exist to the extent pharmacies are inappropriately billing and coding for drug sales. Due to extraordinary growth in the marketplace, many specialty pharmacies are gaining significant visibility with government regulators and enforcement agencies. Investors should consider performing regulatory and compliance due diligence in order to evaluate whether any potential downside exposure exists due to inappropriate practices.

Tax considerations

Operating taxes—Various operating taxes apply to specialty pharmaceutical businesses. To the extent a company is not reporting for these taxes correctly, a buyer could become liable for an underpayment of historical operating taxes. Further, underreporting operating tax liabilities could also have a negative impact on reported EBITDA.

- **Sales and use taxes**—While most jurisdictions do not impose a sales tax on the sale of prescription pharmaceuticals, a limited number of jurisdictions (e.g., Illinois and local parishes in Louisiana) do impose such a tax. Further, certain jurisdictions may impose sales tax on the sale of ancillary products often sold with prescription pharmaceuticals (e.g., needles and epi pens), as well as non-prescription pharmaceuticals. Finally, certain jurisdictions impose a use tax to the extent sample prescription pharmaceuticals are provided to customers at no cost.

  As mentioned above, specialty pharmacies often provide services to customers; these services include, but are not limited to, dispensing of the medication, management of adherence to medication protocol, benefits investigation, and financial assistance. These services may be subject to sales taxes in certain jurisdictions. A buyer should assess whether a target is properly remitting applicable sales and use taxes.

- **Gross receipts taxes**—A limited number of states (e.g., Ohio and Washington) impose a gross receipts tax on gross revenues in lieu of a business income tax. To the extent a specialty pharmacy could be acting in more than an agency capacity (e.g., taking title to pharmaceuticals or accepting risk with respect to reimbursement), as is generally the case, a buyer should assess whether a target is appropriately reporting and remitting applicable gross receipts taxes based on its gross revenues rather than its gross revenues less the cost of pharmaceuticals. Certain of these gross receipts taxes are not treated as income taxes and therefor underreporting of such taxes could have a negative impact on reported EBITDA.

Traveling employees—Specialty pharmacies may employ or contract with individuals who travel to a number of jurisdictions on a regular basis (e.g., to dispense the pharmaceuticals to customers). Depending on the activities performed and the amount of time spent in any particular jurisdiction, a target may have additional state and local income and/or operating tax filing and payment requirements in jurisdictions outside of its retail or office locations. A buyer should assess whether a target is properly remitting applicable taxes in jurisdictions where the activities of its employees or representatives create a filing obligation as a buyer could be liable for an underpayment of historical taxes in jurisdictions where it has not historically filed tax returns. Further, underreporting operating tax liabilities could have a negative impact on reported EBITDA.

Revenue recognition—As mentioned above, significant judgment can be required to estimate future expected cash collection and the value of accounts receivable of a specialty pharmacy. Contractual allowances and bad debt reserves that are based simply on estimates may not be currently deductible for tax purposes. As such, certain specialty pharmacies may have unrecognized book-to-tax differences attributable to revenue recognition that could result in pre-closing cash tax exposures.

Cash basis—Specialty pharmacies may be filing income tax returns on a cash basis. Depending on the tax structure that financial investors pursue, retail pharmacies may be required to report taxable income using the accrual-basis of accounting during post-closing tax periods. The conversion from the cash-basis of accounting to the accrual-basis of accounting may trigger taxable income, creating adverse tax implications for buyers and/or sellers. Accordingly, these tax implications should be addressed in the letter of intent so that the parties understand who is responsible for the taxable income that may have been deferred as a result of cash-basis accounting.

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