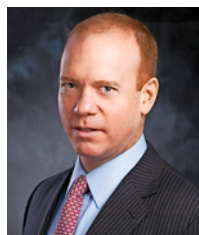


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Pharmacies

A Special Type of Government Scrutiny: Pharmaceutical Manufacturer Relationships with Specialty Pharmacies: Part I



BY GARY F. GIAMPETRUZZI, JONATHAN STEVENS,
REGINA GORE CAVALIERE AND EVAN BARTELL

An area that has garnered considerable government scrutiny of late is the relationships between pharmaceutical manufacturers and specialty pharmacies. In this two-part series, we explore the development of the specialty pharmacy market and the risks associated with these relationships and outline reasonable controls to mitigate the risks based upon recent enforcement actions.

I. What Are Specialty Pharmacies Anyway?

A. Specialty Drugs. To understand the nature of specialty pharmacies, one must first start with specialty drugs. The specialty drug market has grown substan-

tially in the last twenty-five years. It is estimated that there were as little as ten specialty drugs on the market in 1990 compared to nearly 300 in 2015. Approximately 40% of the 650 drugs under development are considered specialty drugs and at least 60% of new drugs expected to be approved for marketing in the United States in the near term are also considered specialty drugs. By 2020, specialty drugs will account for almost 50% of pharmaceutical industry revenues and 9% of total domestic health care spending.

Despite its common use, the term “specialty drug” still lacks a consensus definition. Specialty drugs, at least historically, have typically been characterized as medications that are both high cost and highly complex. Common characteristics of specialty drugs have generally included:

- Drugs that cost in excess of \$600 per month
- Drugs that are approved to treat complex, often chronic, illnesses such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, human growth hormone deficiencies, hemophilia, and similar disorders
- Drugs that are prescribed or administered by a specialized physician or healthcare professional
- Drugs that require a high degree of patient management, like increased supervision or counseling
- Drugs that have special handling, storage, distribution, or inventory management requirements

Gary Giampetruzzi is global vice-chair of the Investigations and White Collar and Life Sciences Departments and a partner in the Litigation Department at Paul Hastings in New York. Jonathan Stevens is an associate in the Litigation Department at Paul Hastings in Washington, D.C. Regina Gore Cavaliere is a principal in KPMG’s Compliance Risk Management practice in New Jersey. Evan Bartell is a director in KPMG’s Compliance Risk Management practice in New York.

- Drugs that are highly regulated and require physician certifications, diagnostic results, or pharmacist training, and other requirements that must be met prior to dispensing

Historically, specialty drugs have been available at either the physician's office or a traditional retail pharmacy. However, the percentage of specialty drugs dispensed at retail pharmacies has dropped significantly over time. The high overhead costs associated with these expensive drugs and the high degree of supervision and oversight required to dispense them conflicted with the volume-driven retail pharmacy business model. In short, specialty drug prescriptions are often time consuming, high-maintenance transactions. Another pharmacy option was needed, and developed over time.

B. Specialty Pharmacies. In the mid-1990's, a small group of specialty pharmacies emerged to service the needs of this unique segment of the market. Like specialty drugs, there is no universally accepted definition for the term "specialty pharmacy" and there is no unique licensure or industry-accepted standard used to designate a specialty pharmacy. Specialty pharmacies have generally been distinguished from traditional retail pharmacies in that they stock a limited number of high-cost specialty drugs and coordinate various aspects of patient care and prescription management that are unique to those drugs. Today's specialty pharmacies offer a comprehensive suite of patient services for a fee that extend beyond distributing and dispensing pharmaceuticals. Specialty pharmacies may:

- Employ health care professionals to provide patient education and counseling services related to specialty drugs and the complex conditions they treat

- Promote adherence through refill reminders and other services

- Offer mail-order /drop-shipment services to efficiently deliver medications with specialized handling, storage, and distribution requirements

- Provide data reporting and other services for a fee to assist manufacturers, payers, and health care professionals track important metrics related to highly regulated drugs, such as the FDA's Risk Evaluation and Mitigation Strategy ("REMS") program as well as better insights into patient use and market dynamics

- Offer benefit verification, prior authorization, and other reimbursement support services and assist patients locate financial assistance resources for out-of-pocket costs for expensive specialty drugs

- Furnish "enhanced" patient services such as follow-up calls and appointment reminders, product use training (e.g., injectable training)

- Administer coupon/co-pay card programs if providing "hub services"

C. Specialty Pharmacies and Drug Channel Intermediaries. The rapid growth of the specialty drug market, and the rise of specialty pharmacies to service that market, caused other drug channel intermediaries to take notice. Payers, pharmacy benefit managers ("PBM"), wholesalers, and large retail pharmacy chains recognized that certain aspects of the specialty pharmacy model aligned with their economic interests. Over time,

that model has evolved as increasingly consolidated drug channel intermediaries have positioned themselves to capitalize on specialty drug growth.

1. *Specialty Pharmacies and Payers and PBMs.* For example, large institutional payers such as United Health Group, Aetna, Blue Cross Blue Shield, and Cigna, either directly or through wholly-owned PBMs, own some of the largest specialty pharmacies. Direct ownership of specialty pharmacies is attractive to payers for a number of reasons. First, it adds an additional revenue stream and puts downward pressure on drug acquisition costs. The vast majority of large payers have a closed specialty pharmacy network and a single preferred specialty pharmacy. Consolidating the specialty drug distribution channel allows the payer to capture the dispensing margin it used to pay pharmacies to fill specialty drug prescriptions and also increases its purchasing power and leverage with manufacturers on pricing and rebates. Second, payer-owned specialty pharmacies improve the payer's implementation of medication therapy management tactics and the coordination of reimbursement which arguably reduces inappropriate utilization and reduces costs. Third, payers benefit greatly from specialty pharmacy services such as patient education and counseling services, which ensure appropriate dosage, adherence services, which reduce the likelihood of further complications or catastrophic conditions, and data reporting, which improve utilization management and benefit design.

Not to be outdone, the PBMs are in on the action too. The largest independent PBM, Express Scripts, also owns one of the largest specialty pharmacies. Direct ownership of a specialty pharmacy is attractive to an independently operated PBM like Express Scripts for the same reasons it is to payers. It allows the PBM to recapture margins within the drug distribution channel, curb overutilization by controlling medication therapy management and reimbursement coordination, and benefit from specialty pharmacy services such as adherence services and data reporting.

2. *Specialty Pharmacies and Wholesalers.* The three largest pharmaceutical wholesalers, AmerisourceBergen, Cardinal Health, and McKesson, all own and operate specialty pharmacies. As payers and PBMs began incentivizing and requiring patients to use their payer- or PBM-owned specialty pharmacy, specialty drug sales shifted to the largest specialty pharmacies which have the smallest margin for wholesalers. Moreover, many manufacturers are electing to bypass wholesalers and sell directly to large specialty pharmacies. Thus, wholesaler participation in the specialty pharmacy space may be considered a largely defensive measure that allows them to continue to compete in the lucrative and growing specialty drug market.

3. *Specialty Pharmacies and Retail Chains.* The most dominant retail pharmacy chains CVS/Caremark and Walgreens currently own two of the three largest specialty pharmacies. Through various acquisitions of independent regional specialty pharmacies, these retail pharmacies have positioned themselves to compete in the specialty drug space. Direct ownership of specialty pharmacies is attractive to retail chains for a number of reasons. First, as payers and manufacturers began to limit and manage the pharmacies that were eligible to dispense expensive specialty drugs, retail pharmacies were forced to find a specialty pharmacy solution.[1] Second, it allowed them to separate and retain their

volume-driven brick and mortar locations and simultaneously provide the mail order specialty pharmacy services to which specialty drug patients were accustomed. Third, large retail chains centralized the specialty drug challenges associated with handling, storage, and distribution into a handful of mail-order specialty pharmacies. Thus, ironically, while the earlier move away from the dispensing of specialty drugs by retail pharmacies itself led, in part, to the establishment of specialty pharmacies, the world has come full circle, and we now see those same retail pharmacies back in the specialty pharmacy space.

4. *Specialty Pharmacies and Drug Manufacturers.* Like drug channel intermediaries, manufacturers, while not establishing their own specialty pharmacies, recognized that the specialty pharmacy model aligned with their specific interests as well. For a number of reasons, specialty drug manufacturers are increasingly opting for narrow distribution channels through a limited number of specialty pharmacies. In particular, manufacturers began to leverage the unique attributes and services associated with such pharmacies to improve their own operational and financial positions around:

- abandonment of prescriptions due to stocking issues,
- improved clinical outcomes, data reporting and patient experiences
- mitigation of logistical issues by selling to a limited number of specialty pharmacies that are accustomed to specialized handling, storage, and distribution requirements; and
- greater access to pharmacy benefit verification, prior authorization, and reimbursement support services to assist patients with insurance related issues and use of the manufacturer's copay support programs.

II. Specialty Pharmacies: Legal Risks and Enforcement Environment

Manufacturers should be mindful that certain arrangements and relationships with specialty pharmacies may pose conflicts of interest and, if improperly structured or implemented, may be susceptible to civil or criminal enforcement actions under applicable fraud and abuse laws, including the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). Similarly, certain practices that are closely associated with specialty pharmacy services pose specific risks of violating fraud and abuse laws. Civil and criminal enforcement agencies are currently very active in the specialty pharmacy space as evidenced by the recent string of settlements and the growing number of companies that have publicly disclosed criminal subpoenas and civil investigative demands.

A. Execution of Copay Support Programs that Fail to Exclude Federal Healthcare Program Beneficiaries. Specialty pharmacies have played, and continue to play, a critical role in managing certain aspects of manufacturer copay support programs through their existing suite of services. In 2014, there were 561 copay support programs for more than 700 brand name drugs; during that time, approximately 35% of specialty pharmacy prescriptions were offset by copay support programs.

Not every copay support program is designed the same. Manufacturers may use various mechanisms to administer and adjudicate copay support claims, including tangible and electronic copay cards, as well as customized pharmacy claims management software solutions that either notify the pharmacist that the claim is eligible for copay support or automatically convert the claim into an applicable manufacturer offer. Even if a manufacturer's copay support program is managed and administered by a third party vendor, manufacturers often rely on specialty pharmacy technicians to properly adjudicate copay cards and correctly administer offers in the pharmacy claims management system. The execution of these programs often requires a high degree of interaction, collaboration, and oversight among manufacturers and specialty pharmacies. This is especially true for manufacturers that have elected for a narrow distribution channel with a limited number of specialty pharmacies.

Manufacturers that operate copay support programs with the assistance of specialty pharmacies must ensure that those programs, both by design and in practice, exclude federal healthcare program beneficiaries. The Office of Inspector General, U.S. Department of Health and Human Services ("OIG") has publicly opined that cost concessions, and cost-sharing subsidies such as copay vouchers, cards, or coupons provided by pharmaceutical manufacturers to patients insured by federal healthcare programs pose a heightened risk of fraud and abuse under the AKS. In its 2005 Special Advisory Bulletin (SAB), OIG explained that "the subsidies would be squarely prohibited by the [AKS] statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product. Where a manufacturer patient assistance program ("PAP") offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs."

The same SAB also noted that "[o]ccasional, inadvertent cost-sharing subsidies provided . . . to a [federal health care beneficiary] should not be problematic under the anti-kickback statute (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D)." "Notwithstanding a pharmaceutical manufacturer's compliance with the foregoing, the Government will take enforcement action in cases where there is evidence of unlawful intent." Whether prosecutors, who have relentlessly pursued the pharmaceutical industry, will agree that "occasional, inadvertent" government leakage is not problematic remains to be seen.

The 2014 OIG study on Manufacturer Safeguards to Prevent Copay Coupon Use for Part D Drugs and a recent enforcement action signal that even a small proportion of government leakage may be problematic. OIG acknowledged that the copay support processing edits currently used by pharmacies may not stop all coupons from being processed for drugs paid for by Part D because manufacturers cannot identify a beneficiary's Part D enrollment status with complete accu-

racy. Manufacturers rely on claims processing edits using proxies that are substitutes for, but do not replicate, actual enrollment information. OIG clarified that manufacturers “ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that sponsor copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services.” In 2016, for example, a Nashville pharmacy agreed to pay \$7.8 million to settle allegations that the pharmacy routinely and improperly waived Medicare co-payments without an individualized assessment of those beneficiaries’ inability to pay, and improperly used pharmaceutical manufacturers’ copayment cards to pay the co-payments of certain Medicare recipients for thirteen Medicare beneficiaries in violation of the AKS and FCA.

Pursuant to the 2014 OIG study, and illustrated by the recent Nashville Pharmacy settlement, the risk that copay support provided to federal healthcare beneficiaries under a manufacturer’s copay support program would rise to the level of an unlawful inducement under the AKS would likely depend on whether the subsidies could be considered “occasional” and “inadvertent,” and whether, despite diligence, the manufacturer did not know, or should not have known, that such subsidies were being provided to federal healthcare beneficiaries claims reimbursed by federal healthcare programs.

B. Conversion and Switching Programs. Manufacturers that operate copay support programs with the assistance of specialty pharmacies and manufacturers that operate a narrow distribution channel with a limited number of specialty pharmacies need to ensure that these arrangements do not unlawfully induce pharmacists from, overtly or covertly, converting or switching patient’s prescriptions to the manufacturer’s products.

The AKS prohibits manufacturers from offering financial incentives to pharmacies to effectuate “product conversion” or “switching” programs that financially incentivize a pharmacist to recommend that a prescribing physician convert a patient from one drug to another, where even one purpose is to induce increased use of prescription drugs covered by federal healthcare programs. The OIG, through a Special Fraud Alert, has noted that manufacturers “have increased their marketing activities among providers, patients and suppliers such as pharmacists Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.”

In 2013, a California-based biotechnology company agreed to pay \$24.9 million to settle AKS and FCA claims alleging that the company paid performance-based rebates to pharmacies in long-term care and skilled nursing facilities to steer Medicare and Medicaid beneficiaries away from a competitor drug to the company’s specialty drug. The civil complaint specifically alleged that the company entered into rebate contracts with these pharmacies that were based on volume and market share of the drug.

In 2013, a New Jersey-based pharmaceutical company signed a \$149 million settlement related to allegations that it entered into quarterly market share rebates, where the percentage amount of the rebate on each drug increased as market share of that drug increased, and market share was determined based on the pharmacy’s purchases of each drug in comparison to its purchases of competing products. The rebate agreements also included performance rebates based on the pharmacy’s ability to “appropriately shift market share” to the company’s product.”

In 2015, a Swiss-based pharmaceutical manufacturer agreed to pay \$390 million to settle allegations that it paid kickbacks in the form of patient referrals and rebates to specialty pharmacies in an effort to promote the dispensing of its drugs in violation of the AKS and FCA. The government alleged that the company implemented a strategy to leverage its rebate and discount relationship with certain specialty pharmacies to have the pharmacies implement growth strategies designed to switch patients to their drug. The government further alleged that the strategy for growing the product line was to “partner with specialty mail order pharmacies on conversion.”

Both OIG guidance and recent enforcement actions make clear that switching and conversion programs that include claims reimbursed by federal healthcare programs violate the AKS and FCA. The structure, contractual terms, business rationale, and execution of specialty pharmacy arrangements are critical in determining whether one purpose of the arrangement is to unlawfully induce pharmacists to engage in pharmacy switching or conversion schemes.

C. Educational, Counseling, or Reminder Practices that Rise to the Level of Biased Product Promotion. Manufacturers should structure arrangements with specialty pharmacies that protect the professional independence of pharmacists and pharmacy technicians and ensure no undue influence is exerted over their professional judgement. The AKS was enacted to protect patients and federal healthcare programs against fraud, waste, and abuse associated with healthcare transactions tainted by conflicts of interest. Specifically, its passage arose out of congressional concern that remuneration provided to those who could influence health care decisions would result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to patients. Likewise, educational and counseling services could lead way to off-label promotion, puffery, or superiority claims.

For example, the government alleged that the above-mentioned Swiss-based manufacturer directed specialty pharmacy technicians to call patients and “under the guise of offering ‘clinical counseling’ or ‘education’ [to] encourage them to order more refills.” These calls allegedly emphasized the benefits of getting refills and downplayed the significance of the drug’s potentially serious side effects. The government further alleged that the company was aware that its closed network of specialty pharmacies was performing “marketing tasks to increase [company] sales behind the façade of patient-oriented clinical activities run by an independent healthcare provider.” The government allegations reference communications suggesting that the company reviewed and approved pharmacy practices and telephone scripts as well as sworn testimony that the re-

fill reminder practice was financially-driven as opposed to clinically-driven.

Similarly, government allegations against the New Jersey-based manufacturer referenced internal presentations in which the pharmacists were referred to as an “extension of the [the company] sales force” and acknowledgments that the pharmacy was “highly motivated based on economics,” which depended “less on net costs [to payers], and more on quality of product and ‘spread’ (their margin).” Manufacturers should ensure that specialty pharmacy arrangements are void of any aspects that may be considered a sales, marketing, or promotional function.

D. Closed or Captive Pharmacy Networks that Make Patient Referrals Performance-Based. Manufacturers that operate a narrow distribution channel with a limited number of specialty pharmacies should be mindful that prescription referrals to these pharmacies may be considered remuneration under the AKS. If manufacturers are in a position to control or steer these prescriptions, they should ensure the methodology for doing so is not based on metrics that account for the potential volume or value of federally reimbursed business at the specialty pharmacy and should take caution and prevent instances in which it may be exerting control or excessive influence over a specialty pharmacy’s operations or the pharmacist’s independent professional judgment.

The government emphasized the Swiss-based manufacturer’s “Paying for Performance” initiative that tied the volume of patient referrals from the company to the

pharmacy’s performance in delivering higher refill rates. The government alleged that the company had unfettered control over how its intermediary allocated approximately half of all new patients whose insurers and physicians did not specify a choice of pharmacy. To determine how the referrals were allocated, the company purportedly used certain success and market share metrics that tracked pharmacy performance with “scorecards” and “adherence scores.” Of particular note, the government alleged that the company put one specialty pharmacy on a performance improvement plan due to low “levels of refills as compared to the other two . . . pharmacies.” After that pharmacy increased its refill rates using the refill reminder script mentioned above, the pharmacy’s refill rate surpassed the other two pharmacies and the company awarded the pharmacy with 60% of the referral base thereafter.

Thus, if the provision of referrals is performance-based and tied to the potential volume or value of a manufacturer’s business at a specialty pharmacy, and those referrals include claims that are reimbursed by federal healthcare programs, such an arrangement may implicate the AKS.

In Part I of this two-part series, we have covered the evolving and wide-ranging role of specialty pharmacies in the dispensing of specialty drugs, and the increased risks of government scrutiny and enforcement around them. In Part II of the series, we will provide answers to the critical questions around how manufacturers might reasonably mitigate the risks associated with this area of business.