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Your Special Relationships – Specialty Pharmacies and 5 Thoughtful Controls to Consider

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The Government and other regulators are now focusing more on initiative relationships between pharmaceutical companies and other customer entities, beyond those relationships with individual healthcare professionals (HCPs). One area of increased focus involves specialty pharmacies. This article explores those relationships and suggests controls that compliance officers should consider.

After years of focusing on the pharmaceutical industry's relationships with physicians, including dozens of Corporate Integrity Agreements (CIAs) centered on alleged off-label promotion or potential kickback arrangements, Government regulators, public advocates, and the media are now focusing more on initiatives and relationships between pharmaceutical companies, their distribution channels, other healthcare providers and patients.

As pharmaceutical companies continually work to assist healthcare providers and patients in gaining

What is a Specialty Pharmacy?

According to the American Pharmacist Association, a "[s]pecialty pharmacy focuses on high cost, high touch medication therapy for patients with complex disease states. Medications in specialty pharmacy range from oral to cutting edge injectable and biologic products. The disease states treated range from cancer, multiple sclerosis, and rheumatoid arthritis to rare genetic conditions."

https://www.pharmacist.com/specialty-pharmacy

The authors of this article are all consultants with Huron Consulting Group, which serves the continuum of life sciences organizations to deliver unique solutions that bridge the process of scientific discovery and sustainable business-model creation with strategies that reduce the risks associated with regulatory and government scrutiny. Views expressed in this article are that of the authors and not necessarily those of Huron Consulting Group, or its clients, and should not be interpreted as legal advice. If you have questions about specialty pharmacy relationships or any other considerations, please feel free to contact Jack Tanselle @ (317) 319-8237; jtanselle@huronconsultinggroup.com or Mark DeWyngaert @ (646)-277-8817; mdewyngaert@huronconsultinggroup.com

Specialty Pharmacy Risks

The list below details several of the risks that have been highlighted in recent settlements and media coverage.

1. Specialty pharmacies might fill a prescription for a branded product of a pharmaceutical company with whom they have a contractual and financial relationship, without providing or making available to the patient balanced information and less expensive alternatives.

2. Specialty pharmacies may distribute products for only one pharmaceutical company; with the pharmaceutical company representatives encouraging physicians to have patients only fill prescriptions through that one specialty pharmacy.

3. Pharmaceutical companies may get too deeply involved in the claims/co-pay adjudication process associated with fulfilling prescriptions, including potentially altering the physician's orders, as a way of reducing the administrative burden on physicians and patients.

4. Pharmaceutical companies may come to rely upon specialty pharmacies for products that do not meet the generally accepted criteria for such special handling and patient care.

access to drugs (e.g., drug samples, vouchers, co-pay cards, patient assistance programs), specialty pharmacies have grown in quantity and importance. The growth in accredited specialty pharmacy locations is significant with fewer than 20 in 2009 and now as many as 250 at the end of 2015.[1] While patient demographics and product portfolios at many pharmaceutical companies align with this increase in specialty pharmacies, recent allegations, and media scrutiny during the latter half of 2015, suggest that some of the increase in the use of the specialty distribution channel may be perceived as an inappropriate driver for unnecessary drug utilization.

Potential Risks Posed by Relationships with Specialty Pharmacies

With the increased use of specialty pharmacies, there has been a corresponding increase in the potential risks associated with this distribution model. Some of these risks are inherent to any relationship within the pharmaceutical industry. However, certain risks are specific to this type of relationship.

Many specialty pharmacies are incentivized through metrics involving volume thresholds or share of the market, typically in the form of adherence or refill prescription targets agreed upon with the manufacturer. These thresholds may incentivize the pharmacy to manipulate the information provided to the patient (i.e. alternative therapy options, misleading or removal of key product information, etc.) and ultimately can result in over-utilization. Recent litigation shows this is a growing concern and has resulted in false claims being submitted to federal health care programs.[2]

Additionally, there is a high risk for rejection of lower cost alternative therapies by the patient due to the manufacturer and specialty pharmacy relationship. Potential lower-cost alternative therapies can be in the form of a generic product or a lower-cost brand alternative. This is a growing concern, with an emphasis on lowering prescription costs as a whole in the healthcare landscape.

Specialty pharmacies can be appropriately incentivized to place adherence communication calls as part of operating disease-management programs to improve clinical outcomes. Agreements with the pharmacies that specifically preclude informing patients of generic or lower-cost brand alternatives, with a similar efficacy as the specialty product they have previously been prescribed, may present a conflict of interest risk.

The claims/co-pay adjudication process often is outsourced to third parties or handled internally by major pharmaceutical companies. Patients are referred to a division called "Patient Services," with the goal being to make sure a patient receives, and stays, on the appropriate drug as set by the patient's physician. The legitimate intent of the pharmaceutical company is to provide assistance to patients and make it easier for them to access therapy.

However, such actions also come with the potential risk of perceived or real conflict of interests for two possible reasons. First, offering too much assistance to any customer (e.g., specialty pharmacy, patient, physician), without receiving compensation for it, might be perceived as a kickback. Offering assistance may also lead to perceptions of driving an unnecessary increase in the utilization of your branded products, which in turn could lead to allegations associated with the False Claims Act.

5 Controls to Consider

To better manage risks within your company, there are controls that can be implemented to help account for existing and future activities. One such external control is already occurring as it relates to these specialty pharmacy operations. Leading pharmacy benefit managers have started excluding certain specialty pharmacies called out by recent media attention, thereby cutting off this pathway downstream from the patient and physician.

The key question to ask within your organization is what controls does your company have in place to help mitigate these risks with specialty pharmacy relationships, or with identifying the next risk that emerges in the never-ending search for creative approaches to improving product development and patient care.

For specialty pharmacy relationships, below are five controls your company should consider to potentially address current and future risks.

1. Justify the Need: Assess current specialty pharmacy relationships and establish or update standard processes to help ensure that each arrangement with any customer can be appropriately justified.

The industry has come to understand the concept of a "needs assessment," that was first included in the CIA's with several of the world's leading orthopedic manufacturers. Subsequent settlements with pharmaceutical manufacturers have included similar requirements, whereby at an aggregate-level annually (e.g., annual needs assessment), and per each activity (e.g.,

rationale documents), a company assesses the actual need for each customer arrangement, as well as the type and volume of HCPs involved, and frequency of the activity, to be sure there is a legitimate business need prior to commencing the engagement.[3]

Based on this idea, one immediate action to consider is assessing the legitimate business needs associated with each specialty pharmacy relationship and the services your company is requesting to be performed. In conducting such an assessment, first determine if the products involved in such relationships warrant the special handling or patient care involved with the use of specialty pharmacies (see definition provided earlier). Also, assess the requirements of both parties outlined in each specialty pharmacy contract and determine if either party is required to perform activities, such as those outlined earlier, that may be creating unnecessary risk for your company, the specialty pharmacy, or both.

On a go-forward basis, it is important to justify each customer engagement and manage that justification throughout the life of the contractual terms. With proposed and recent changes from the Centers for Medicare and Medicaid Services (CMS) regarding itemization and scrutiny from a variety of regulatory agencies, companies may want to reevaluate how they are determining the need for, negotiating, and drafting their third-party distribution agreements to reflect properly the specific activities the third parties, or your company, will be performing, the metrics for measurement, and the expected deliverables that will support FMV payment for these services.

2. Catalog All Customer Activities: Include in your annual risk assessment a catalog of all of the different types of business arrangements your company has in place with all of the different types of customers, including specialty pharmacies, with which your company does business.

In addition to assessing the legitimacy of any activity, the risks associated with conducting those activities should also be routinely assessed. As a participant in the U.S. Federal Health Care system, your company faces potential scrutiny for any type of arrangement you make with any entity involved in the prescribing or dispensing of your products. Your company likely has numerous types of existing arrangements with prescribers and dispensers of your products, and those individuals in your company involved in commercializing products will continually be challenged with creating new types of arrangements going forward that support improved healthcare delivery. Does your company have an existing catalog or database of all such customer activities to leverage in an ongoing manner as part of your current and future risk assessment process?

While there are multiple facets to a strong risk-assessment process, successfully summarizing the triangle of company products, customers (e.g., physicians, specialty pharmacies, other distributors), and associated business arrangements is a critical first step. Each time a risk assessment process begins (e.g., annually), the summary should be revisited and updated based on input from commercial, medical, clinical, financial, legal and compliance colleagues. This does not guarantee risk prevention, but not maintaining such a list may greatly increase the

chances that you find out about such risks when it is too late to mitigate them quickly.

3. Justify the Value: Establish or update standard processes to help ensure that fair market value (FMV) is being paid for any bona fide services specialty pharmacies might be providing to your company as part of any contract or engagement.

In addition to justifying the conduct of any activity with a customer, it is also critical to justify the value of the specialty pharmacy arrangement and to be sure that your company has documented policies and procedures that are followed to determine the fair market value of all such arrangements. There is a further consideration regarding the bona fide nature of the services that may impact government price reporting calculations. Consider a review of the payment process as well, to ensure that contracted services were actually performed.

It is also important to assess whether your company is directly or indirectly providing additional services to customers, such as getting involved in the claims/co-pay adjudication process, as described earlier (i.e., helping providers and patients with completing paperwork or assisting with clearing prior authorization hurdles associated with many healthcare plans). In order to mitigate the risk of conducting activities that may be perceived as kickbacks, your company should consider conducting a careful analysis of exactly what types of support are being provided and the impact on third-party payers.

4. Other In-Process Controls: Consider implementing other specific controls to manage off-label and anti-kickback risks (e.g., reviewing compensation plans, utilizing inclusion/exclusion lists).

The CIAs of the last decade provide guidance to some specific controls that can potentially be applied to your specialty pharmacy relationships. For example, for companies assisting with prior authorization and other patient support services, either directly or through a third party like a specialty pharmacy, any compensation plans for those employees or agents of the company should be closely reviewed and approved by your company's Legal department on an annual basis. If leveraging a third party, contract terms should consider your company's right to review compensation plans as one of your company's controls in the overall effort to mitigate risk with specialty pharmacy relationships.

Just as sales representatives should not be incentivized to sell to physicians whose specialties do not align with the indication(s) on product label(s), scrutiny should be given to the idea of any employee or agent of a company being incentivized on the volume of patients receiving reimbursement assistance and clearance for their company's drugs. That volume should be driven by physician prescriptions to their patients.

Specialty pharmacies should also potentially be evaluated with an inclusion/exclusion list, akin to those used by companies under CIAs in order to control the specialties sales representatives call on and provide samples to. In the case of specialty pharmacies, such a list would indicate

any products in the portfolio that may not warrant special care or attention to go through that channel. In having such a list, individuals involved in the approval processes for various contracts with specialty pharmacies and other customers can be trained to help assess for such misalignment and stop such agreements from being executed in the first place.

5. Audit and Monitor: Consistently include in your company's auditing and monitoring activities those activities that cover the full range of products, customers, and activities?

The first four controls can help mitigate risk because they are controls built into the processes at the earliest stages of creating various business activities. Compliance auditing and monitoring is another control that allows for assessing risk as activities are taking place, or after they have taken place. If your company has specialty pharmacy relationships, and you are uncertain about the risks associated with them, auditing one or more of those contracts should give you an indication of the risks, either at the level of one or more of the specific specialty pharmacies, and/or your company's systemic processes for establishing and managing those relationships.

The auditing and monitoring plan should be derived annually from the risk assessment output, such that identifying new activities that carry risks untested should then be included in the subsequent year's auditing and monitoring plan for more in-depth review. In turn, the output from a quality auditing and monitoring program should be used as input to the next cycle of risk assessment, such that a virtuous cycle is created and maintained to contribute to the continuous improvement that any effective compliance program will demonstrate.

Conclusion

Acting on some or all of the recommended controls outlined in this article should allow your company to mitigate better risks associated with specialty pharmacy relationships. Understanding that new business activities and arrangements will be created in the future, creating new risks, it is important to consider the controls outlined in this article for more than just managing specialty pharmacy relationships. Specifically, the fundamentals involved with managing an effective compliance program should not change because the customer activities conducted by commercial, R&D or medical affairs departments evolve over time.

If companies are not implementing consistent risk assessment processes designed to ask questions across the entire customer continuum

Summary: 5 Controls to Consider

1. Justify the need
2. Catalog all customer activities
3. Justify the value
4. Other in-process controls
5. Audit and monitor

(i.e., all activities conducted with all customers for all brands), as well as conducting appropriate monitoring controls throughout the lifecycle of each customer relationship (i.e., from strategic and budgeting planning to payment and reporting), the next creative, yet questionable, approach to managing this hyper-competitive and highly regulated marketplace may surface within your company, but may not be identified and controlled until it is too late.

1 *See Deena Beasley, Specialty pharmacies in spotlight as Valeant ties questioned, Reuters (Oct. 22, 2015) at http://www.reuters.com/article/2015/10/22/us-valeant-pharmacies-industry-idUSKCN0SG02320151022#ApHjcXzoUZDh9TQk.97; see also Kaitlin Fallon, Specialty Pharma in the Spotlight – Novartis Settlement Finalized, Life Science Compliance Update (Jan. 2016) at https://www.lifescicompliance.com.*

2 *See Tom Moylan, Another Specialty Pharmacy Settles Exjade False Claims Allegations For $45 Million, LexisNexis (May, 1 2015) at http://www.lexisnexis.com/legalnewsroom/litigation/b/litigation-blog/archive/2015/05/01/another-specialty-pharmacy-settles-exjade-false-claims-allegations-for-45-million.aspx.*

3 *See Calisha Myers, Now You See It, Now You Don't – A Review of CIA Provisions from 2009 to 2015, Life Science Compliance Update (Jan. 2016) at https://www.lifescicompliance.com.*

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