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

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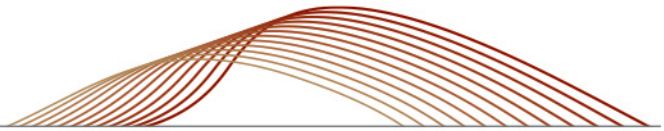
The manufacturer/specialty pharmacy relationship and attendant risks should be on the agenda of every compliance officer in the life sciences industry. Specialty pharmacies are uniquely positioned to connect manufacturers, prescribers, and patients. In Part I of this two-part series, we covered the wide-ranging role of specialty pharmacies in the dispensing of specialty drugs, and the increased risks of government scrutiny and enforcement around them. The risk areas potentially implicated by these relationships include inappropriate inducements, off-label promotion, switching/interference with clinical decisions, underreporting of adverse events or product quality complaints, misuse, overuse, and privacy. These risks warrant a tailored compliance program directed at specialty pharmacy activities, as we will now cover in Part II of this series.

I. Business Case

A formal business case process for any *potential* specialty pharmacy activities is a leading practice. Such a process allows the business to vet a proposed arrangement before various stakeholders (e.g., general counsel, compliance officer, medical affairs, pharmacovigilance, quality) and affords these disciplines the opportunity to understand the business objectives and strategies at the outset, to analyze the risks, to meet regulatory requirements, and to partner with the business on mitigation options and controls. A thorough business case should include:

- Business objective;
- Description of proposed services, staffing model, use of hub services, specialty pharmacies' roles;
- Plan for data purchases, pricing, proposed use and responsibility for data validation and maintenance;
- Proposed compensation for the services and fair market value analysis;
- Policies, procedures and training internally and at the specialty pharmacy;



- Material review process;
- Service level metrics; and
- Monitoring and auditing plans.

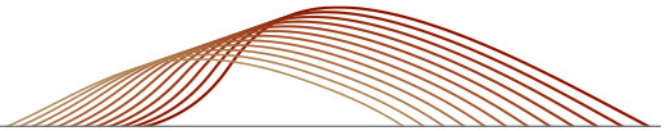
A thorough business case will reflect *who* the specialty pharmacy is, *what* services are being proposed, *why* the arrangement benefits the patients, and *how* risks will be managed. Approval of the business case by legal counsel, in consultation with the compliance officer and other functional areas, should then be required, in order to complete the initial business process.

II. Due Diligence

At some point in the cycle but preferably before signing a contract, an assessment of the specialty pharmacy's capabilities, compliance savviness, people and culture is necessary, with the proviso that the level and nature of the due diligence will vary based on the maturity of the specialty pharmacy. For example, due diligence for a specialty pharmacy that is a sophisticated entity with a well-established compliance program will be different than that for a new entrant to the marketplace. The number of specialty pharmacies that will source the product also impacts due diligence efforts. As we have seen, mere expertise with handling products in a certain therapeutic area is not enough; the specialty pharmacy must satisfy both operational and compliance expectations. Some steps for consideration:

- Conduct background checks on the specialty pharmacy, owners, and/or management;
- Ensure the presence of qualified pharmacy personnel to support the program;
- Provide periodic compliance training to the specialty pharmacy;
- Interview the specialty pharmacy's compliance officer (or equivalent) to gauge culture;
- Review Code of Conduct, policies, procedures and training on laws and risks;
- Review controls, including those around purchasing, data protection and cybersecurity, to ensure the delivery of services will occur within a high-quality compliance framework;
- Assess process for handling adverse events and product quality complaints;
- Understand the specialty pharmacy's capabilities for implementing the business rules; and
- Review specialty pharmacy's process for monitoring and auditing operations.

Confirm there is an adequate "speak up" process for raising concerns. Due diligence is most effective when it's a collaborative, cross-functional effort. Since the storage and handling of the specialty medication along with other quality systems under current Good Manufacturing Practices ("cGMP") and the handling of adverse events are of paramount importance, the manufacturer's Quality Assurance and Pharmacovigilance teams—at a minimum—should also be involved and weigh in on the due diligence of the specialty pharmacy. Compliance can leverage those relationships and align on the timing and process to be followed for due diligence.



After a specialty pharmacy is vetted and ready for contracting, collaboration between the compliance and legal teams on the agreement's terms and conditions will support compliance initiatives by addressing training, policies, procedures, and prohibited remuneration. A key contract provision is the manufacturer's right to monitor and audit the specialty pharmacy. Another consideration is obtaining a written certification from the specialty pharmacy that it will not violate the Anti-Kickback Statute ("AKS").

III. Code of Conduct, Policies and Procedures

A Code of Conduct, policies and procedures reflect the manufacturer's overall compliance framework, values and "commitment to compliance." Policies and procedures that address the services to be provided by specialty pharmacies as well as the interactions among the specialty pharmacies, other vendors, the manufacturer, prescribers, payers and patients, are needed.

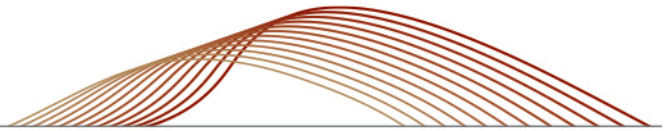
When developing policies and procedures, careful consideration of the manufacturer's business model allows the policies and procedures to be targeted to the exact nature of its specialty product business. Areas suitable for policies or procedures include:

- Training obligations for the manufacturer's staff;
- Interactions with patients, prescribers and payers including the handling of off-label requests;
- Identifying and handling patient complaints, such as adverse events, product quality complaints and unsatisfactory service;
- Privacy considerations and data breach process;
- Product handling and distribution;
- Fair market value ("FMV") methodology for data and service purchases and approval process;
- Risk Evaluation and Mitigation Strategy ("REMS") requirements, if applicable;
- Monitoring and other oversight controls; and
- Audit procedures.

Additionally—and dually applicable within the *Due Diligence* section—the manufacturer should ensure that each specialty pharmacy has implemented *its own* policies and procedures applicable to the business and services the specialty pharmacy will be providing. Part of ensuring the specialty pharmacy has the right infrastructure, processes and controls necessary to administer a program or service on behalf of the manufacturer is assessing the existence and appropriateness of the specialty pharmacy's policies and procedures, aligning these policies and procedures to those of the manufacturer, and addressing any gaps through the agreement and/or business rules.

IV. Business Rules

Business rules established by the manufacturer define the services the specialty pharmacy will provide and outline the specific operational details of each program. For example, setting product distribution limits would be an appropriate business rule to implement if the specialty pharmacy is administering a



free-trial or bridge program. Establishing clear operational instructions and boundaries at the outset and delineating contact individuals and their roles and responsibilities, as well as escalation procedures will help mitigate compliance risks by reducing subjectivity. Further, business rules should encompass the specialty pharmacy's internal and any outsourced operations involved in administering the program.

Key areas to consider for business rules:

- Communication guidelines (e.g., require the use of approved call scripts for interactions with patients, payers and providers);
- Scope of and limitations on services to be rendered;
- Database/recordkeeping requirements;
- Implementation of system-implemented "hard controls" rather than user judgment;
- Federal healthcare program beneficiary verification and/or exclusion processes; and
- Metrics and reporting requirements.

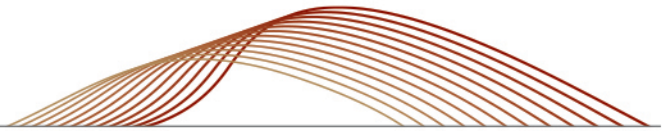
Those who are supporting the program—either at the specialty pharmacy or the manufacturer—should be intimately familiar with all business rules and should have frequent communications about them.

V. Training

Training is the opportunity to bring the manufacturer's policies and procedures to life for employees of the manufacturer and specialty pharmacy. Training should provide direction on how to handle specific situations as well as gray areas. Training by the specialty pharmacy on their own systems and policies is in order, but so is training by the manufacturer on the manufacturer's business rules and compliance requirements. A specialty pharmacy should understand the correlation between the services provided and regulatory risk.

Examples of areas to emphasize in a specialty pharmacy-focused training program include:

- Protocols around making product claims;
- AKS and penalties;
- Health Insurance Portability and Accountability Act ("HIPAA"), data protection, and security compliance;
- Adverse events and product quality complaints;
- REMS program and FDA requirements;
- Interactions with external parties;
- Eligibility rules as well as benefits investigations related to determining government versus commercial patients; and
- Recordkeeping/document retention.



VI. Monitoring

Monitoring is typically a combination of ongoing assessments of data and metrics combined with live observations of actual interactions with healthcare professionals, payers and patients. Monitoring provides real-time insights on areas for improvement. Reviewing and assessing the specialty pharmacy's performance and key controls allows the manufacturer to identify and address potential red flags associated with the provision of services in close proximity to the event. A compliance program cannot be fully effective without regular monitoring.

There are two levels of monitoring. First, the specialty pharmacy should have its own program in place to monitor its business and potential compliance risks. Second, monitoring of the specialty pharmacy's activities by the manufacturer, as well as the interactions between manufacturer and pharmacy personnel, provides a different and valuable perspective. Since specialty pharmacies are independent entities, thinking ahead about the need for monitoring and oversight during the contracting phase will allow the manufacturer to implement clauses that address monitoring and provide access to the specialty pharmacy's operations, personnel, and records. Roles and responsibilities of stakeholders in connection with monitoring the specialty pharmacy's operations should be clearly delineated.

The specialty pharmacy and manufacturer relationship often involves the exchange of data and reports and is a treasure trove for monitoring and testing. Analyzing the business data with a compliance lens can highlight potential compliance risks and trends for further inquiry. A robust monitoring program will combine data analytics with live monitoring of interactions with third parties.

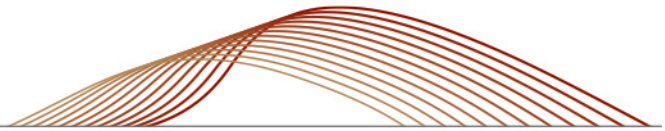
VII. Auditing

As with monitoring, the specialty pharmacy should have its own audit program in place. Notwithstanding, the right to audit clause is critical and is a must have in all agreements with specialty pharmacies. And most important is exercising the right to audit. An audit is a key mechanism for assessing quality and ensuring specialty pharmacy activities are aligned with the business rules and legal and regulatory requirements.

Avoidance of standard boilerplate language is recommended. With the support of legal counsel, the manufacturer should tailor the audit clause to its specialty pharmacy program but draft it broadly to withstand shifting business arrangements. The audit clause should sufficiently grant the manufacturer, and its auditors, access to all relevant data, personnel and systems required to conduct its audit.

Specialty pharmacy audits are conducted to review compliance with business rules, nature and content of interactions, handling and distribution of the medication, federal healthcare program exclusion checks for coupons and co-pay cards, handling of adverse events and product quality complaints, privacy and security compliance, and financial accuracy. As a result, specialty pharmacy audits may sometimes uncover critically high risk or potentially illegal activities. Manufacturers should consider retaining a law firm for ongoing advice during the audit as well as a consulting, accounting, or auditing firm to tailor audit work plans to its specialty pharmacy program to ensure the completeness, independence and thoroughness of the audit.

An audit should cover all objectives and risks associated with a specialty pharmacy contract including financial, operational, and regulatory concerns. Engaging an auditor, and perhaps with the support of legal resources, who understands the business model as well as its nuances will give the business comfort that (1) fees paid to the specialty pharmacy are substantiated and consistent with contract requirements, (2) the specialty pharmacy has the infrastructure to support and administer programs



effectively, and (3) the specialty pharmacy is not posing risk to the manufacturer in connection with legal and regulatory requirements.

Following the audit, the specialty pharmacy must develop action plans to address any observations and those plans should be vetted by the manufacturer to determine whether they will sufficiently mitigate the finding. Having a plan to conduct regular audits of the specialty pharmacy will afford the manufacturer the opportunity to conduct effectiveness checks on the prior commitments to ascertain whether they truly worked.

An effective compliance program will also include a monitoring and auditing plan for the manufacturer's internal team responsible for overseeing the specialty pharmacy's activities. Conducting audits of the manufacturer's team and related processes and the specialty pharmacy is more effective when done in parallel since it provides a holistic overview of the program and attendant risks.

VIII. The Future of Specialty Pharmacy

The pharmaceutical industry has depended upon specialty medications for its growth, creating additional dispensing demands for these medicines. The partnership opportunities for specialty pharmacies and manufacturers are likely to deepen, given the expanded level of services involved with dispensing the drugs, reimbursement, and other patient support. The high costs associated with these drugs are certain to lead payers and regulators to demand greater transparency about the costs of these medicines and the support programs associated with them, and to lead potentially to more costly government inquiries. Having a compliance program specifically tailored to the relationship between the specialty pharmacy and manufacturer, conducting regular monitoring and auditing, and course correcting as necessary will position a manufacturer well for whatever the future brings.

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