

PATIENT ASSISTANCE PROGRAM/VENDOR ASSESSMENT

OVERVIEW

CIS was retained by a top ten pharmaceutical manufacturer to proactively assess the management of its patient assistance program (PAP). The manufacturer developed a PAP to provide pharmaceutical products to patients who are either uninsured or otherwise cannot afford the prescriptions. The assessment was based on the manufacturer's established business rules and key control documents for the PAP. The objectives of the assessment were to:

- Assess vendor compliance with the manufacturer's established business rules
- Assess vendor compliance with contractual obligations, including billing and reporting requirements
- Provide recommendations to improve the administration of the PAP

The manufacturer looked to CIS to review activities, including application intake, eligibility determination, enrollment, periodic reassessment, claims processing and reporting. The business rules were in place to ensure adherence to HIPAA, fraud and abuse, product diversion and anti-kickback requirements.

SCOPE

CIS focused its assessment on two PAP programs managed by one specific vendor. CIS reviewed the manufacturer's business rules governing the administration of the PAPs to understand the requirements of the program. To thoroughly evaluate the vendor, CIS reviewed the vendor's policies and procedures applicable to the manufacturer's business rules and re-calculated activities to determine the accuracy of the randomly selected invoices. To accomplish the objectives of this assessment, CIS interviewed key stakeholders of both the manufacturer and the vendor.

METHODOLOGY

To effectively evaluate the management of the manufacturer's PAP, CIS performed the following review functions:

- Reviewed the manufacturer's business rules and the vendor's policies and procedures regarding the patient assistance programs
- Interviewed key stakeholders from both the manufacturer and the vendor to identify any gaps in activities



PROVEN EXPERTISE

Compliance Implementation Services (CIS) is a consulting firm specializing in Commercial Sales & Marketing compliance strategies for pharmaceutical companies. Our experts identify, assess and prioritize your organization's exposure to compliance risks, subsequently developing and implementing risk evaluation and mitigation techniques to ensure adherence to legal and regulatory requirements..

Our service areas of commercial compliance are:

- State Compliance & Reporting
- Compliance Program Development & Maintenance
- Business Assessment and Profiling
- Policy & Procedure Development
- Auditing & Monitoring
- Risk Mitigation/Implementation
- Supplemental Resourcing
- Training
- Vendor Compliance
- System Implementation & Validation
- Investigation/Litigation Support

- Reviewed the contract and invoices to determine if the manufacturer was charged the appropriate fee for managing the PAP
- Identified compliance gaps and missing documentation controls

DELIVERABLES

CIS provided the manufacturer with the following deliverables to describe the results of the assessments and recommendations to improve the PAP administration:

- Assessment Report
 - Findings
 - Transactional Testing Approach
 - Recommendations
- Summary and Prioritization of Assessment Findings and Recommendations
- Assessment Presentation

BENEFITS

The manufacturer benefited from the assessment performed by CIS in the following ways:

- By identifying gaps in standard operating procedures (SOPs), as well as in activities that did not follow the manufacturer’s business rules, CIS staff were able to update the SOPs accordingly. This ensured that business rules were followed, which in turn increased the likelihood that the program would remain compliant with state and federal laws.
- By identifying gaps in the application and approval process, CIS staff aligned the PAP application with the SOPs, assuring the manufacturer that the program was administered appropriately.
- By identifying those communications that were sent directly to physicians, but were not approved by the manufacturer, CIS staff was able to assist the manufacturer in better tracking its communications...an important step in ensuring that the PAP is not promoting off-label indications.
- By identifying errors in invoicing, CIS staff discovered a refund/credit for the manufacturer.



“Aligning the PAP application with the standard operating procedures assured the manufacturer that the program was administered appropriately.”