

STATE COMPLIANCE AND REPORTING ASSESSMENT

BACKGROUND

State compliance and reporting about interactions with Healthcare Practitioners (HCPs) is mandatory. In some states, penalties for non-compliance can escalate up to \$10,000 per infraction. Therefore, it is imperative that pharmaceutical manufacturers ensure that their state compliance and reporting program meets the requirements of each state. This case study highlights the importance of evaluating and improving established policies, procedures and processes through a state compliance and reporting assessment.

It was this assessment for which a pharmaceutical manufacturer retained Compliance Implementation Services (CIS). The client wanted to evaluate its compliance with individual state requirements, as well as determine the integrity of its data based on its current processes. By performing an assessment, CIS was able to make observations and develop recommendations to identify compliance and business risks. CIS was also able to provide recommendations for mitigating any risks and improving the overall program.

SCOPE AND OBJECTIVE

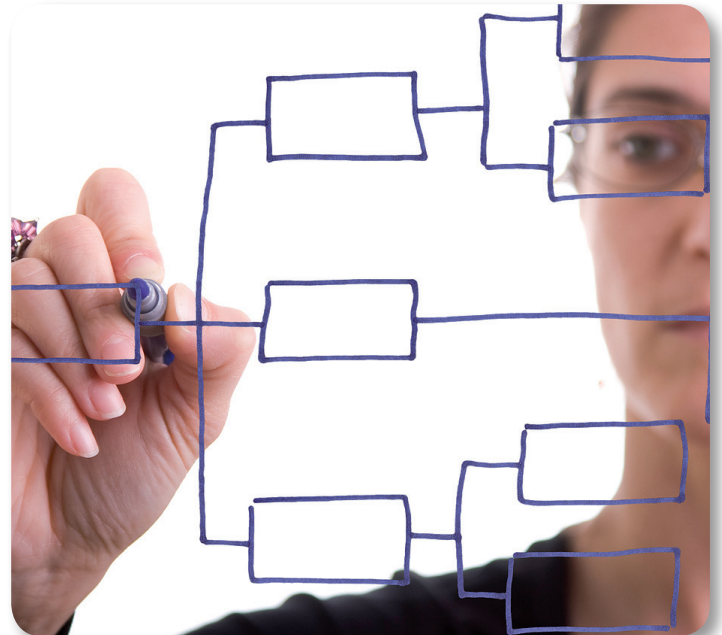
The scope of this project included an assessment of adherence to existing state compliance and reporting requirements and corporate policies and procedures. In addition, the data capture systems were evaluated and a compliance gap analysis conducted.

The objective was to identify manufacturer-to-HCP interactions for which states require documentation, tracking and/or reporting, and to identify existing and potential data feeds for those reports.

METHODOLOGY

Since state compliance and reporting is complex, the assessment took into account the departments and activities that were impacted by the reporting process, as well as the compliance requirements for each. CIS employed the following methodology for the assessment:

- Reviewed existing policies and procedures to ensure compliance with state requirements
- Interviewed key stakeholders from each impacted business area to evaluate awareness of the individual state requirements, as well as their awareness of corporate policies and procedures



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

- Evaluated existing training programs for compliance with state requirements
- Reviewed the data collection processes across various business units for promotional, marketing and advertising expenses in accordance with state-specific requirements
- Interviewed field-based employees to evaluate compliance
- Evaluated the HCP license verification process for reporting purposes
- Evaluated the overall state reporting process

DELIVERABLES

CIS’ state compliance and reporting assessment report provided the client with observations and recommendations for a thorough and compliant state reporting process. Acknowledging that each state has different requirements, and recognizing the limited resources available to the client, CIS recommended a standardized approach to data capture to simplify state reporting efforts. The project deliverables included a path forward to achieve compliance in future reporting processes. The specific area included in the state compliance and reporting assessment report included:

- An executive summary of the overall assessment
- Detailed observations and recommendations
- A state compliance and reporting calendar identifying state deadlines, summary of requirements, and website links to the regulations and state-issued reporting forms
- A *CIS Compliance Risk Matrix and Compliance Roadmap* identifying the non-compliance risk areas and prioritizing each item based on a risk classification and the logical workflow for implementation
- Marketing data collection templates for standardizing data reported through vendor-managed activities
- Narratives of each interview performed during the assessment



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BENEFITS

Through the assessment process, CIS was able to educate key stakeholders about the nuances of various state reporting requirements and pointed out activities that would benefit from certain process changes. CIS identified specific risks for the client within their existing processes and the organization was able to mitigate those risks through a clearly defined implementation plan. The observations and recommendations in the assessment report allowed the client to develop and implement compliance policies and procedures that aligned with its existing activities and systems. As a result, the client was successful in implementing a state reporting process that was efficient and cost-effective, while non-compliance issues were addressed and existing gaps eliminated. Mitigating operational risks at the state level will now allow the client to approach the implementation of federal transparency and reporting requirements with a well-established, compliant process in place.