

## STATE REPORTING AND THE LESSONS LEARNED FROM PREPARING STATE REPORTS

### BACKGROUND

State compliance and reporting is mandatory. In some states, penalties for non-compliance can escalate up to \$10,000 per infraction. Therefore, it is imperative that pharmaceutical manufacturers establish, maintain and continuously monitor an efficient state reporting process system. This case study highlights some of the “lessons learned” by one manufacturer going through the process of preparing state reports for the first time.

### OVERVIEW

A pharmaceutical manufacturer retained Compliance Implementation Services (CIS) to assess its state compliance and reporting processes. While CIS was conducting its assessment, several state reporting deadlines loomed. Because the company’s compliance department was limited in resources, meeting the state reporting deadlines became challenging. Consequently, the company asked CIS to prepare its state reports and conduct the audits required for state mandated declarations of compliance.

### SCOPE

The scope of the project included addressing and ensuring compliance of all aspects of each individual state’s reporting and declaration requirements. CIS directed the various departments concerning: (1) the data necessary for reporting; (2) data analysis and auditing; (3) compliance documentation review; (4) report(s) and declaration(s) compilations; and (5) process documentation. CIS applied the information that it learned through its initial assessment to ensure accuracy and integrity of the reports, audits and declarations.

### METHODOLOGY

Through the initial assessment, CIS learned where compliance gaps existed in information and expense data documentation methods. As a result, CIS created and implemented the following methodology to safeguard the integrity of the manufacturer’s final state reports filed in 2010:

1. Identified key business areas impacted by state requirements
2. Directed, guided and advised the finance department to gather appropriate data, such as (1) expenses; (2) marketing and advertising costs; (3) employee compensations; (4) call notes; (5) fee for service payments
3. Researched Massachusetts (MA) Healthcare Practitioner (HCP) licensing
4. Identified state regulations requiring interpretation and



### 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

- business decision considerations by the manufacturer’s legal and compliance departments
5. Analyzed data for reportability
  6. Aggregated reportable data as needed
  7. Audited data for compliance and investigated questionable activities
  8. Reviewed corporate compliance documentation for state requirement alignment
  9. Aggregated marketing expenses based on state requirements
  10. Aggregated employee compensation as needed
  11. Compiled state reports and state declarations

### DELIVERABLES

The following deliverables allowed the client to not only meet state reporting deadlines, but when reviewed in conjunction with assessment observations and recommendations, served as a means for the client to reach a standardized approach to state reporting.

- Completion of declarations of compliance and disclosure reports for each state
- Submission and fee process information for each state report
- Due diligence documentation describing the process followed when reports and/or declarations for each state were compiled
- Electronic files of all communications, documents and data collected, including final reports for each state
- Guidance on the state reporting process for the client’s internal resources

### KEY RISK AREAS AND LESSONS LEARNED

State compliance and reporting is extremely complex. Throughout the reporting process, CIS identified and mitigated risks in the areas of data collection, vendor compliance and internal processes. CIS identified specific shortcomings that required an additional manual effort in the state compliance and reporting program. By addressing these shortcomings, the manufacturer was able to create a more efficient and cost-effective state reporting process going forward. Examples of the areas in which the manufacturer required additional manual efforts were:

- The lack of an HCP customer master list identifying:
  - State licenses associated with an HCP
  - A standardized format for capturing HCP activities and expenses
- Inconsistency in employee use of the expense reporting system, including significant gaps in data retention, data entry and categorizing expenses
- Lack of monitoring and auditing of vendor compliance



*“CIS’ multi-level work to identify non-compliance issues, eliminate existing gaps, and implement specific controls strengthened the client’s reporting process — allowing them to meet state reporting deadlines with efficiency and accuracy.”*

- An insufficient training program regarding state requirements and corporate policies both internally and with third-party vendors
  - Specifically, a lack of training about the nuances of state requirements and the impact outside of the individual states
- A lack of clearly defined roles and responsibilities for state requirements within individual departments
- The lack of a communication protocol within the organization

### BENEFITS

CIS’ multi-level work to identify non-compliance issues, eliminate existing gaps, and implement specific controls strengthened the client’s reporting process — allowing them to meet state reporting deadlines with efficiency and accuracy. Our experts educated key stakeholders about the nuances of various state reporting requirements, identified activities that would benefit from process changes, and assisted the client’s legal and compliance departments in revising internal state reporting policies and procedures. Overall, CIS’ collaboration with the client on this project provided them with a clear path forward and a process that was more efficient, economical and compliant.