

State Level Reporting Compliance Services

As new state level reporting requirements pose increasing challenges for pharmaceutical companies, their compliance teams are discovering that any solution must be able to react quickly to the expanding variability in requirements from state to state. While regulators' emphasis to date has been on reporting of sales and marketing activities, proposed legislation contemplates a much broader array of business functions and related expenditures that pharmaceutical companies must track and/or report, including:

- Sampling
- Clinical trials spend
- Direct-to-consumer expenditures
- Speaker compensation
- Advisory board payments
- Charitable contributions
- Medically relevant items
- Non-medical items

How can pharmaceutical and life sciences companies create a sustainable state-specific reporting framework to effectively track expenditures and activities?

Pharmaceutical companies currently face countless federal laws, regulations and industry guidelines governing sales and marketing, including the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, the Office of Inspector General's (OIG) Guidance to Pharmaceutical Manufacturers and FDA regulation. In addition, an increasing number of states require US pharmaceutical companies to report their sales and marketing expenses. Seven states – California, Minnesota, Vermont, Maine, West Virginia, Georgia, Colorado – and the District of Columbia already require some level of reporting. We anticipate that, over the next five years, the majority of states will require pharmaceutical companies to provide detailed sales, marketing and other functional categories of expenditure/activity information.

Individual state requirements, such as which activities must be reported, how activities are defined and how companies must submit these reports, often differ. To address these rapidly moving requirements, many pharmaceutical companies are mounting large scale manual efforts that are often inefficient, cost-intensive and complex.

How Can PwC help your organisation?

To develop a sustainable approach to state-level reporting, pharmaceutical companies must properly automate the way they source, maintain and compile vast amounts of accurate and consistent sales and marketing data at both a state level and a prescriber or customer level. As the reporting landscape grows more complex, companies must seek to leverage their existing financial reporting and data-management capabilities, taking into account new process, data and systems considerations as needed.

To address these challenges, we help our clients take a practical approach to the development of sustainable, state-level reporting programmes that enable organisations to:

Evaluate the current compliance requirements and systems/data capabilities to pinpoint existing strengths and gaps

Design the building blocks of a new compliance reporting platform, from blueprint to business rules to actual reporting

Implement the overall programme and supporting processes

Monitor to ensure the reporting solution keeps up with changes in the compliance environment

Leverage this information and functionality across the enterprise, as appropriate, particularly in the area of compliance monitoring and compliance key performance indicator development

Contacts

Tony Farino

Partner
anthony.farino@us.pwc.com
312-298-2631

Brian Riewerts

Principal
brian.riewerts@us.pwc.com
410-659-3390

David Wysocky

Director
david.j.wysocky@us.pwc.com
973-236-5179

Benefits you can realise

PwC is a long-standing market leader in providing governance, risk and compliance (GRC) advisory services, with an enhanced focus on designing and implementing cost-effective processes to address federal and state sales and marketing compliance requirements and related reporting.

Your PwC team will develop and implement a sustainable state-specific reporting framework that provides:

Increased business monitoring and reporting efficiency for less manual or repetitive work

Reduced time and effort analysing large quantities of data to identify high priority issues

Greater ability to implement automated controls and performance metrics that can proactively identify various business compliance performance issues

More flexibility to quickly adapt monitoring activities and related reporting to new legislation or changes to internal policies and procedures

Refined use of monitoring and reporting key performance indicators and other metrics (i.e., 'compliance intelligence')

Greater proactive alerting to avoid missed deadlines or exceeded specified thresholds

Successfully implementing a sustainable state-specific reporting framework also establishes enhanced tools and processes to benefit other operational areas of your organisation. With the framework's architectural building blocks integrated, you can leverage the underlying data and process components throughout the organisation to increase the productivity, quality and consistency of key processes to realize even greater returns on this investment.

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Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.