

State Transparency Laws — Beyond Sunshine: Insights from Porzio, Bromberg & Newman's Annual Life Sciences Symposium

June 2, 2025

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Navigating the evolving landscape of life sciences compliance requires staying ahead of complex state laws and deadlines. On May 20, 2025, Porzio, Bromberg & Newman held its annual Life Sciences Symposium (the Symposium), when we explored State Transparency Laws and Compliance, the Intersection of Innovation and Compliance in the Data Privacy Matrix, Best Practices for Investigations, and concluded with a moderated Compliance Officer Panel with industry representatives.

The first session, "State of the States: State Transparency and Compliance Considerations," explored what many in the industry refer to as "reporting season" due to the myriad reporting deadlines that are continuously thrust upon manufacturers between March and July. This is the first of the Life Sciences Client Alerts where we will summarize the discussion around this session and highlight some of the potential challenges and pitfalls that come with such a varied and dynamic area of the law.

The Symposium highlighted five distinct categories of state transparency laws – each of which we will explore in more detail below.

Drug Price Transparency

There are close to 20 states with some type of drug price transparency reporting law. The majority of these state laws require price increase justification reports, with nine states also mandating a price justification report upon launching a "high cost" drug, defined in all states but one (Washington) as an introductory wholesale acquisition cost (WAC) that exceeds the Medicare Specialty Drug Threshold. Washington's law requires the submission of a new drug report upon the launch of a drug with an introductory WAC of \$10,000 or more. Triggers vary from 10% to 50%, and deadlines differ among states as well. If a report is triggered, companies must determine the relevant deadlines, process, and obtain required report information. Four states – Connecticut, Maine, Nevada, and Vermont – will identify and request a drug report (either via portal or in a public posting) from manufacturers on an annual basis. Many of the report elements involve sensitive, proprietary information, so there are trade secret concerns and internal strategies involved in preparing these reports that manufacturers should be aware of when submitting such reports.

State Compliance/Limitations

There are laws in eight states that (i) require Compliance Program certification and/or (ii) have limitations or gift prohibitions. This includes, for example, Vermont's gift ban, Minnesota's \$50 allowance, and New Jersey's meal limitations. In addition, Nevada and Massachusetts require annual audits and submission of Compliance Program certifications.

Healthcare Professional (HCP) Spend Reporting

Beyond federal transparency obligations mandated by the Federal Sunshine Act (Sunshine Act), several states also have their own “mini” Sunshine reporting obligations. These reports are due annually, with deadlines between March 1 and July 1, and are typically related to HCP spend by registered sales representatives, but not always. For example, in Massachusetts, together with the annual Compliance Program certification, manufacturers must disclose all “sales and marketing” activities of more than \$50. All of these reporting requirements are preempted by the Sunshine Act, so if a payment or transfer of value was reported to CMS, it need not be reported again to a state. If, however, a state defines “HCP” more broadly and certain payments were not reportable under the Sunshine Act, they should be reported by the applicable state deadline.

Rep Registration

Several jurisdictions require rep registration before such individuals begin to market to HCPs. Chicago (Illinois), Nevada, Oregon, and Washington D.C. have minimum time frames before registration is required; if there is rep activity over a certain number of days as set forth in the law, registration will be required. In at least two jurisdictions, Nevada and Oregon, virtual interactions are “counted” toward such minimums. Finally, there is some question as to whether medical science liaison (MSL) activity triggers registration, with at least one state indicating that MSL activities could also necessitate registration.

State Marketing Disclosure Requirements

Finally, three states have (HCP) Marketing Disclosure requirements. While the concept among these laws is similar, the details vary greatly. For example, Colorado and Connecticut require the disclosure of the “list” price, or WAC, while Vermont requires that the average wholesale price be provided, and Vermont and Colorado both require some degree of comparison between the marketed drug and other drugs from the same therapeutic class, whereas Connecticut requires manufacturers to disclose any “variation efficacy data” in different racial and ethnic groups. In addition, while Colorado and Vermont have specific statutory exceptions to the disclosure requirement, Connecticut does not.

Manufacturers should be aware of, understand, and prepare for upcoming deadlines, as the required compliance obligations are constantly changing. Porzio's team of Life Sciences attorneys can provide legal and compliance counsel to assist life sciences companies to analyze these laws and structure a company's compliance program to take into account all of the various triggers, deadlines, and obligations to remain compliant while “reporting season” is upon us.