Summer is the Season: New Price Transparency Reporting Requirements and Updates

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The month of June saw the drug transparency landscape continue to evolve with the enactment of a New York law and the release of long-awaited guidance in Connecticut regarding its new pharmaceutical representative reporting requirements, due no later than July 1.

New York

Adding to the growing list of states with price transparency obligations, a New York law, passed in in December 2023, requiring manufacturers to notify the state Superintendent of Insurance ("Superintendent") about qualifying price increases, became effective June 19, 2024.

Prescription drug manufacturers of drugs purchased or reimbursed in New York by insurance companies and pharmacy benefit managers, with a WAC of more than $40 for a course of therapy must notify the Superintendent if there is a WAC increase of more than 16%, including the proposed increase and any cumulative increases that occurred within the previous 24 months. The notification must occur at least 60 days before the effective date of the qualifying price increase.

In addition to the date of the planned increase, the notice must include the drug's current WAC and the dollar amount of the planned WAC increase. Notably, the notice must also include a statement regarding whether a change or improvement necessitates the WAC increase and a description of the change or improvement. This law also requires the Superintendent to publish the notice within five days of receipt, thus informing the public of the upcoming price change.

The state has updated its website, providing FAQs for manufacturers, and we will continue to monitor whether any implementing regulations and/or additional guidance is released. For the time being, manufacturers should add NY's new requirements to their state price transparency analysis so the requisite notice is sent within the required 60-day time period as any planned qualifying price increases that take place 60 days after June 19, 2024 will trigger this obligation. According to the law, the Superintendent may impose penalties of up to $5,000 per day for each day that information is not submitted after the required reporting period.

Connecticut

At long last, the Connecticut Division of Consumer Protection (DCF) has released its pharmaceutical representative report FAQs clarifying the reporting requirements for pharmaceutical representatives ("FAQs"). In August, we released a client alert describing the new requirements for drug manufacturers, which include annual registration of companies as a "pharmaceutical marketing firm" as well as all individuals employed or compensated by the company as pharmaceutical sales representatives, annual submission of a report that includes details of interactions with prescribing practitioners in CT for the previous calendar year, and the provision of a price disclosure to HCPs with whom registered representatives interact about a drug at each "contact." The last portion of the law to go into effect was the "pharmaceutical marketing

firm reporting form," which, according to the law, must include: (i) the aggregate number of contacts a pharmaceutical sales representative had with a prescribing practitioner; (ii) the specialty of each prescribing practitioner and pharmacist with whom such pharmaceutical sales representative made contact; (iii) whether product samples, materials or gifts of any value were provided to a prescribing practitioner or such practitioner's staff in a prescribing practitioner's office or to a pharmacist; and (iv) the aggregate report of all free samples, by drug name and strength. As implemented, all registered pharmaceutical manufacturing firms must also report the value of any gift provided to prescribing practitioners. The FAQs define a "gift" as "anything that has monetary value [obtained] for less than 'market value.'" The FAQs further explain that a gift may be "tangible or intangible" and includes "meals and services, including transportation, travel and lodging." All submitted information will be compiled by DCF and posted publicly by December 1 annually.

Non-compliance with Connecticut's new requirements could result in the DCF Commissioner's refusal to approve a manufacturer's registration (or renewal) to operate as a pharmaceutical marketing firm in Connecticut, the revocation, limitation, or suspension of a manufacturer's registration to operate, as well as a penalty of up to $1,000 for each violation.

Porzio's team of Life Sciences attorneys can help you navigate your company's legal obligations under these new requirements, or other state law transparency obligations.