KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

February 8, 2018

2017 Year in Review: State Laws Target Pharma Manufacturers

States Sharpen Their Focus on Prescription Drug Costs and Industry Relationships with Health Care Providers

In the past year, we have seen a nearly unprecedented focus by state legislatures on prescription drug manufacturers. The ongoing scrutiny of prescription drug prices and the public health crisis surrounding the opioid epidemic have served as a catalyst for legislative action intended to address those issues. The result is a growing patchwork of new state laws focused on prescription drug pricing decisions and pricing transparency, sales representative registration and licensing, and new laws and regulations that pile on to the myriad existing state restrictions and related requirements that govern industry interactions with health care providers. We provide below a brief overview of key state and local laws and regulations passed or promulgated in 2017 and early 2018.

Early indications from 2018 show no signs that the trend is waning. Prescription drug manufacturers should closely monitor the rapidly evolving landscape, and be ready to take steps to comply with the growing number of state and local regulatory requirements.

Drug Price Transparency Laws

California – Under California's drug cost transparency law (SB 17), which took effect January 1, 2018, manufacturers of prescription drugs with a wholesale acquisition cost ("WAC") of more than $40 for a course of therapy must provide written notice to certain purchasers at least 60 days in advance of an increase in WAC that is more than 16%, including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year. Manufacturers that take WAC increases that exceed the 16% threshold will be required to report certain information to the state regarding the price increases, including, but not limited to, a description of the factors (both financial and nonfinancial) used to make the decision to increase the WAC and a description of the change/improvement in the drug, if any, that necessitates the price increase.

Louisiana – On June 14, 2017, Louisiana enacted two drug price transparency laws, HB 436 and SB 59. Louisiana HB 436 requires each

For more information, contact:

Nikki Reeves
+1 202 661 7850
nreeves@kslaw.com

Brian A. Bohnenkamp
+1 202 626 5413
bbohnenkamp@kslaw.com

Seth H. Lundy
+1 202 626 2924
slundy@kslaw.com

John Shakow
+1 202 626 5523
jshakow@kslaw.com

Caitlyn J. Ozier
+1 404 572 4654
cozier@kslaw.com

Terrence B. Burek
+1 202 626 2992
tburek@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

drug manufacturer or pharmaceutical marketer who engages in prescription drug marketing in Louisiana to provide the Louisiana Board of Pharmacy with the current WAC of drugs marketed in Louisiana on a quarterly basis. Manufacturers were required to submit their first quarterly reports to the Louisiana Board of Pharmacy by October 1, 2017. LA SB 59 requires the Louisiana Board of Pharmacy to maintain a website relating to prescription drug prices and provides that pharmaceutical marketers "may" inform prescribers and their staff of the website.

Maryland – In May 2017, Maryland enacted HB 631, which prohibits manufacturers and wholesale distributors from engaging in "price gouging" of "essential off-patent or generic drugs." This law empowers the Maryland Attorney General to investigate certain price increases and, as part of such an investigation, may request that a manufacturer file a report containing certain requested information (e.g., the cost to produce the drug).

New York – In April 2017, New York enacted SB 2007, a law that allows New York's Department of Health ("DoH") to (a) set an annual projected spending target for drugs, and (b) demand additional rebates of drug manufacturers to meet that target. If, based on quarterly projections for individual drug expenditures or all drugs covered under New York's Medicaid program, the DoH determines that Medicaid drug spending is projected to exceed the target, DoH officials are empowered to negotiate additional supplemental Medicaid rebates for specific drugs. If a manufacturer does not agree to an additional rebate, then its drugs may be subject to prior authorization or other restrictions, and the DoH may require that manufacturers submit extensive business and pricing information to the state.

Nevada – On June 15, 2017, Nevada enacted a law (SB 539) that imposes a variety of requirements on prescription drug manufacturers. Under this new law, manufacturers of diabetes drugs identified by the Nevada Department of Health and Human Services as essential for treating diabetes must file: (1) annual cost/price transparency reports containing specified information (e.g., cost of producing the diabetes drug, total administrative expenditures relating to the diabetes drug, including marketing and advertising costs); and (2) if an essential diabetes drug has experienced an increase in WAC above certain thresholds, a second report regarding the price increase.

Bans and Prohibitions

California – California's coupon ban (AB 265), which took effect January 1, 2018, prohibits manufacturers from providing discounts, product vouchers, or other reductions in an individual's out-of-pocket expenses associated with his/her insurance (e.g., copayment, deductible) for a prescription drug in certain circumstances. The ban applies if a lower cost generic drug is available on a lower cost-sharing tier that is designated by FDA as therapeutically equivalent to the prescription drug. There are limited exceptions to the ban, including in cases where the patient has completed any applicable step therapy or prior authorization requirement for the branded drug, as mandated by the individual's insurer.

Maine – On November 1, 2017, Maine's Gift Ban (LD 911) became law. LD 911 prohibits licensed manufacturers and wholesalers from offering or giving to a Maine practitioner: (1) "a cash gift in any amount"; or (2) "a gift for which reciprocity is expected or implied." There are five exceptions to the gift ban, including: (1) prescription drug samples; (2) educational materials; (3) modest meals and refreshments provided at an educational presentation or meeting; (4) academic institution, residency, and fellowship funding support; and (5) reasonable honoraria and expenses for practitioners at conferences or meetings.

New Jersey – On January 16, 2018, the New Jersey Attorney General published final rules that prohibit New Jersey prescribers from accepting certain items of value from pharmaceutical manufacturers (e.g., meals cannot exceed $15), as well as impose an annual aggregate $10,000 cap on compensation that New Jersey prescribers may

receive from pharmaceutical manufacturers for certain types of services (e.g., consulting, advisory board participation). The rules took effect upon publication.

Pharmaceutical Representative Licensing, Registration, and Reporting

Chicago, Illinois – In November 2016, the Chicago City Council passed an ordinance that established licensing requirements for pharmaceutical representatives. On June 1, 2017, the Chicago Department of Public Health issued final rules to implement the licensing provisions, and beginning July 1, 2017, pharmaceutical representatives who conduct business in Chicago are required to obtain a license prior to doing business in the city on 15 or more days in a calendar year. Licensed representatives are required to adhere to a city-authored set of ethical standards and complete continuing education requirements. In addition, representatives who market and promote Schedule II controlled substances are required to track their interactions with health care professionals and, upon request, provide certain information to the Department of Public Health regarding those interactions.

Nevada – Under Nevada SB 539, in addition to the drug price transparency requirements described above, manufacturers are required to submit a list of pharmaceutical sales representatives who market prescription drugs (any prescription drugs, not just diabetes medications) to health care providers and others in Nevada. Registered individuals are required to annually report a list of health care providers and others to whom they provided "compensation" exceeding certain thresholds, as well as a list of recipients to whom they provided prescription drug samples. Manufacturers were required to list their representatives with the Nevada Department of Health and Human Services by October 1, 2017. Representatives' disclosure reports are first due by March 1, 2018, covering the period October 1 through December 31, 2017.

* * *

These new laws add to the roster of existing transparency requirements, gift bans, compliance program requirements, and pharmaceutical representative licensing requirements in California, Connecticut, the District of Columbia, Massachusetts, Minnesota, Nevada, and Vermont.

The King & Spalding Ad Hoc Sunshine and State Law Compliance Group

The King & Spalding Ad Hoc Sunshine and State Law Compliance Group, established in 2004, is a coalition of pharmaceutical, medical device, and biotechnology manufacturers with a focus on federal and state laws that directly regulate industry interactions with health care professionals, including the federal Physician Payments Sunshine Act, and state code of conduct laws, gift ban laws, sales/marketing representative licensing requirements, and transparency laws. We closely monitor state and local pending legislation, enacted state laws, regulations, and implementation guidance relevant to pharmaceutical and medical device manufacturers' interactions with health care providers.

If you would like more information about joining the King & Spalding Ad Hoc Sunshine and State Law Compliance Group, please contact Nikki Reeves (nreeves@kslaw.com), Brian Bohnenkamp (bbohnenkamp@kslaw.com), or Seth Lundy (slundy@kslaw.com).