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New Jersey Joins Wave of States Proposing New Rules for Drug Marketing and HCP Interactions

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Drug manufacturers are once again facing new state limits on marketing and interactions with healthcare providers. After several years without major changes or additions to the set of state laws and regulations governing these activities, a handful of states and one major city are pushing forward with a range of new restrictions and transparency laws. And while many of the new laws are billed as efforts to fight the opioid abuse epidemic, most of the rules reach far beyond opioid manufacturers and would impose new requirements across the drug industry. Manufacturers should review the new laws and regulations carefully, consider how they might engage with the agencies interpreting the new limits, and begin preparing their own compliance efforts.

New Jersey Joins the Fray

On August 31, New Jersey became the latest state to propose new restrictions on drug manufacturer interactions with prescribers in the state. The office of Governor Chris Christie announced in a press release that the state soon will propose a rule that, among other things, would impose new limits on certain gifts and fair market value payments from pharmaceutical manufacturers to licensed prescribers in New Jersey. Although the state frames the new rule as a response to the opioid crisis, the rule as described in the press release appears to cover all drug manufacturers, not just manufacturers of opioids. Notably, the release states that New Jersey physicians received US$69 million from drug and device manufacturers last year (a figure presumably based on data reported by companies under the federal Open Payments program), and suggests that the new rule is also based on "growing concerns [that doctors] allow drug company money to influence their prescribing habits."

Although the text of the proposed rule has not yet been made available, the press release suggests the rule would go beyond the voluntary industry guidelines laid out in the PhRMA Code on Interactions with Healthcare Professionals in certain respects. In particular, the rule would:

- Limit meals offered to prescribers "for learning" to a value of US$15 per provider and 4 times per year for each provider;

- Cap payments at US$10,000 per prescriber per calendar year for "bona fide services", including consulting, advisory boards, and promotional speaking, but excluding speaking at continuing education events; and

- Prohibit payments supporting non-faculty attendance at promotional events and continuing education events.

The New Jersey rule also appears to take an unusual approach to regulating manufacturer-HCP interactions in that it would impose limits on prescribers, with enforcement by the professional boards governing those prescribers, rather than imposing limits on manufacturers. This may be because state officials believe they have inherent authority to regulate licensed professionals, whereas the imposition of similar restrictions directly on manufacturers seemingly would require legislation.

The proposed rule is scheduled to be published on October 2, 2017 in the New Jersey Register, and is expected to provide additional detail on the proposed limitations. A hearing on the rule will be held on October 19, 2017 to receive public comment on the proposed rule from stakeholders, including regulated entities, industry representatives, and the public.

Part of a New Wave

New Jersey's proposed rule follows recent enactments by two states and one local jurisdiction imposing new restrictions and reporting requirements on pharmaceutical manufacturers.[1]

- **Nevada** – Listing of Drug Representatives (effective Oct. 1, 2017)
    - Among other provisions, the Nevada law requires drug manufacturers to provide the state with a list of its sales representatives who market drugs to providers and insurers in Nevada, and will prohibit marketing by any person not included on the list. The law also requires each listed sales representative to submit a report to the state by March 1 of each year disclosing information about free drug samples and payments above US$10 (or above US$100 total each year) that the representative gave on behalf of the manufacturer to Nevada providers in the preceding calendar year.
- **Chicago** – Licensing of Drug Representatives (effective July 1, 2017) and Reporting for Marketing of Schedule II Medications (effective October 1, 2017)
    - The City of Chicago's ordinance and implementing regulations require any person who markets or promotes drugs to healthcare professionals in Chicago for at least 15 calendar days per year to obtain a license as a pharmaceutical representative. Drug company representatives cannot conduct business in the city without a license and must comply with specified ethical standards. The new law does not apply to Medical Science Liaisons (MSLs) or similar individuals.
    - The ordinance, as implemented by the city, also requires licensed representatives to disclose information about their marketing and promotion of Schedule II medications to healthcare professionals in Chicago, including the names of all professionals contacted; duration and location of each interaction; and any compensation, samples, or other items of value provided.
- **Maine** – Gift Restrictions (effective November 1, 2017)

[1] In California, the legislature is currently considering a bill (SB 790), modeled on the Vermont gift ban law, which would prohibit manufacturers of prescription drugs from providing gifts or other things of value to California healthcare providers, subject to certain enumerated exceptions. The bill passed the California Senate in May 2017 and is currently awaiting third reading on the floor of the California Assembly.

- The new Maine law prohibits manufacturers and wholesalers of prescription drugs (and their agents) from offering or giving to licensed prescribers any cash gift or any gift "for which reciprocity is expected or implied.
- The law specifies that it does not apply to non-cash items of minimal value that directly benefit the practitioner's patients (including drug samples, educational materials, and modest meals or refreshments provided in connection with informational meetings or presentations); certain funding for participation of practitioners in training in professional meetings; and reasonable payment and expenses for practitioners at professional or educational conferences or meetings. In addition to these explicit exceptions, the law also may permit other transfers of value that are common in the drug industry and permitted under the PhRMA Code, depending on how broadly the state reads the term "for which reciprocity is expected or implied."

While it is too early to tell how these new laws will be interpreted or enforced, some of these new requirements may fundamentally alter existing practices, including the ways in which healthcare professionals interact with manufacturers to learn about new therapies. We encourage all drug manufacturers to review the new laws and regulations carefully and consider whether and how to engage with the government agencies interpreting and implementing these laws. Drug manufacturers also should begin to put appropriate policies, procedures, and training are in place to promote compliance with the new requirements.

If you have any questions about any of the new laws or regulations, please feel free to reach out to any of the Hogan Lovells lawyers listed as contacts here.

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