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New Jersey issues rules to chill drug manufacturer payments to prescribers

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The New Jersey Attorney General plans to finalize new limits on payments and other benefits that New Jersey licensed prescribers may accept from pharmaceutical manufacturers, although the expected final rule is less restrictive than the proposed rule published by the state in October 2017. This alert highlights key provisions of the final rule: (1) a US$10,000 annual aggregate cap on each prescriber's payments for services from all drug manufacturers, but with new exceptions; (2) a US$15 per-meal limit on promotional meals, but no limit on the frequency of the meals as proposed; and (3) a new exception for recruitment expenses.

The new limits take effect on January 16, 2018. The new rules do not apply to contracts entered into before that date. Although the rule has not yet been released in official form, it is not expected to change from the unofficial version released by the state.

Who will feel the chill?

- The new restrictions apply only to individuals licensed to prescribe drugs and biologics in New Jersey, and will be enforceable by the state's medical and other professional boards against those prescribers.
- The rule will not be enforceable directly against drug manufacturers. However, the rule may create legal, reputational, and business-related obstacles and risks for manufacturers. It also may discourage New Jersey prescribers from at least some interactions with pharmaceutical manufacturers.
- The rule applies to any New Jersey licensed physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist, excluding employees of a pharmaceutical manufacturer who do not provide patient care.
    - The Attorney General rejected a request to revise the rule to apply only to licensed prescribers who regularly practice in New Jersey.
    - The rule also applies to immediate family members of New Jersey licensed prescribers, which the final rule narrows to include only the prescriber's spouse or domestic partner, children, and other close relatives who reside in the same household as the prescriber.

- The Attorney General notes that it does not intend for the rule to apply to prescribers or family members in their capacity as patients (e.g., when receiving financial assistance for medications from pharmaceutical manufacturers), and will revise the rule in future rulemaking to address this issue.

- The rule limits certain payments from "pharmaceutical manufacturers."
  - Pharmaceutical manufacturers include any entity engaged in the production, preparation, propagation, compounding, conversion, processing, packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or biologics, but exclude health care facilities licensed by the Department of Health and licensed pharmacies.
  - The rule also applies to any manufacturer's agent, which includes employees or contractors engaged in detailing, promotional activities, or other marketing of prescription drugs or biologics to licensed prescribers.

- The rule does not apply to medical device companies.
  - If a company manufactures both drugs and medical devices, the new rule apply only to the company's drug business, meaning that corporate subsidiaries engaged solely in the device business would not be subject to the new rule.
  - The Attorney General notes that it will continue to assess the "impact of undue influence to determine if future rulemaking is necessary."

Loosening the US$10,000 cap on services: Research, "education events", and royalties exempt

- The rule prohibits each individual prescriber from accepting more than US$10,000 per calendar year in total from all pharmaceutical manufacturers for "bona fide services," which are defined to include presentations as speakers at promotional activities, education events, participation on advisory boards, and consulting arrangements.

- **Research**: The final rule clarifies that payments for research are excluded from this US$10,000 cap.
  - "Research" is defined broadly to include "any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies, or any systemic investigation, including scientific advising on the development, testing and evaluation, that is designed to develop or contribute to general knowledge, or reasonably can be considered to be of significant interest or value to scientists or prescribers working in a particular field." The definition includes both pre- and post-market research activities.

- **Educational Events**: The final rule expands the exception for educational events so that the US$10,000 cap does not apply to payments for "education events," which will be excluded from the cap even if they are not accredited and even if they are sponsored by a manufacturer, as long as they are held in a venue conducive to informational communication, the gathering is dedicated to promoting objective scientific and educational activities, and the main purpose for bringing the attendees together is to further their knowledge on the topics presented.

  - Payments to speakers at "promotional events" are still subject to the cap, so manufacturers should be cautious in applying the exemption for "education events" to company-sponsored speaker programs. However, if a company-sponsored event is genuinely dedicated to objective scientific or educational activity, payments to speakers may be exempt from the cap. Further guidance from the state may be necessary to definitively address how this exemption applies to company-sponsored speaker programs.
  - The final rule is broader than the proposed rule, which exempted only "continuing education events" consistent with standards for accredited CE events.
  - The final rule states clearly that payments for participation on advisory boards and other consulting arrangements will be subject to the US$10,000 cap.

- **Royalties and Licensing Fees**: The final rule also states that royalties and licensing fees are excluded from the US$10,000 cap.
  - The Attorney General notes that these fees "are clearly distinct from the promotional activities the Attorney General is addressing through this rulemaking."

- The rule finalizes requirements for any services arrangement, which are largely consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code and industry standards for such arrangements (e.g., written agreement specifying compensation, services, qualifications, documentation that services were provided). However, the final rule also requires an attestation that the prescriber's decision to render the services is not "unduly influenced" by a pharmaceutical manufacturer's agent.

Meals: US$15 cap stays, but no limit on frequency

- The rule finalizes that meals provided to prescribers may not exceed a value of US**$15 per meal**, whether in or out of office, including meals provided to attendees at speaker programs.
- However, the rule does not finalize the proposal to limit the number of such meals that a prescriber may accept to four meals per year, per manufacturer.
- The US$15 limit does not apply to meals or other expenses reimbursed as part of a fair market value services agreement. The final rule also suggests that such expenses do not count toward the US$10,000 cap on payments for services described above.

Recruitment expenses permitted

- The final rule adds a provision that explicitly permits reasonable payment or remuneration to job candidates for travel, lodging, and other personal expenses associated with recruitment.

Restrictions on other gifts and benefits

- The final rule prohibits prescribers from accepting "any financial benefit or benefit-in-kind" unless specifically permitted under the rules above.
  - The rule explicitly prohibits certain specific items, consistent with the PhRMA Code (e.g., no items with company logo, no items for the personal benefit of the prescriber or staff, no cash or cash equivalents, no payments directly to prescribers to attend events).

    - Other items are specifically permitted, including educational items (consistent with the PhRMA Code), subsidized registration fees at continuing education events (if available to all participants), modest meals as defined above, and fair market value compensation for services (subject to the cap described above).

- Samples are specifically excluded from these restrictions if they are intended to be used exclusively for the benefit of patients and the prescriber does not charge for the samples, and all dispensing standards set forth by the applicable licensing board are satisfied.

Practical implications

- Although the requirements technically apply to prescribers, drug manufacturers likely will need to establish policies and systems to ensure that they do not provide payments, meals, or other benefits to a New Jersey prescriber that the prescriber would be prohibited from accepting.

    - Drug manufacturers may wish to establish policies and training for employees similar to those they have established for state-specific limits in states like Vermont and Massachusetts.

    - It is also possible that some prescribers or institutions in New Jersey will respond to the new rules by imposing their own limits on what they or their employees may accept from drug manufacturers.

- The US$10,000 cap remains an aggregate cap, meaning that New Jersey prescribers will be prohibited from accepting more than US$10,000 from all drug manufacturers over the course of a year. The final rule puts the burden of tracking progress toward the aggregate limit on the prescriber. This may discourage some New Jersey prescribers from engaging in consulting arrangements that are subject to the cap.

- However, the final rule's exemption of research, education events, and royalty payments from the US$10,000 cap means that prescribers may be able to continue to enter into those exempted arrangements.

If you have any questions about the New Jersey rules, please contact one of the Hogan Lovells lawyers listed in this alert or with whom you usually work.

Contacts

Helen Trilling
Partner, Washington, D.C.
T +1 202 637 8653
helen.trilling@hoganlovells.com

Meredith Manning
Partner, Washington, D.C., Denver
T +1 202 637 6585 (Washington, D.C.)
T +1 303 899 7385 (Denver)
meredith.manning@hoganlovells.com

Ron Wisor
Partner, Washington, D.C.
T +1 202 637 5658
ron.wisor@hoganlovells.com

Thomas Beimers
Partner, Minneapolis, Washington, D.C.
T +1 612 402 3025 (Minneapolis)
T +1 202 637 5600 (Washington, D.C)
thomas.beimers@hoganlovells.com

Eliza Andonova
Counsel, Washington, D.C.
T +1 202 637 6153
eliza.andonova@hoganlovells.com

Andrew Furlow
Senior Associate, New York
T +1 202 637 6843
andrew.furlow@hoganlovells.com

Laura McDonald
Associate, Washington, D.C.
T +1 202 637 7723
laura.mcdonald@hoganlovells.com

www.hoganlovells.com