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PHARMA MANUFACTURERS IMPACTED BY NEW LIMITS ON PAYMENTS AND GIFTS TO NJ PRESCRIBERS

A recently passed NJ rule imposes restrictions on gifts and new limits on the amount of compensation NJ prescribers may accept from pharma manufacturers. The new rule is effective for all agreements entered into after January 16, 2018.

Although the new rule applies directly only to NJ prescribers, pharma manufacturers and manufacturer agents will want to ensure that their contracts with NJ prescribers for any bona fide services (speaking, consulting, advisory board) and any policies or practices that apply to NJ prescribers related to gifts or payments for meals, entertainment or participation at educational or promotional events all comply with the requirements of the new rule described below.

NJ Prescribers Subject to Rule

- The rule applies to NJ licensed physicians, podiatrists, PAs, APNs, dentists and optometrists (and their immediate family members)
- There is an exception for NJ prescribers who are employees of a pharma manufacturer and do not provide patient care

Pharmaceutical Manufacturer

- Pharmaceutical manufacturer includes an entity engaged in the production, preparation, propagation, compounding conversion or processing of prescription drugs or biologics including packagers, labelers and distributors
- Manufacturer's agent includes a person employed by or under contract with a pharma manufacturer who engages in detailing, promotional activities or other marketing of prescription drugs or biologics

\$10,000 Aggregate Cap on Payments for Services

- The rule provides that a NJ prescriber shall not accept more than \$10,000 in the aggregate from **ALL** pharma manufacturers in any calendar year for bona fide services
- Bona fide services include speaking at promotional events, serving on advisory boards and consulting arrangements
- Exceptions to the cap for:
 - ◇ speaking at educational events – but compensation must still be fair market value and be set forth in a written agreement
 - ◇ research activities
 - ◇ royalties and licensing fees

Written Agreement Required

- A written agreement between the NJ prescriber and pharma manufacturer is required for all bona fide services must specify:
 - ◇ the services to be provided
 - ◇ the compensation to be paid based on fair market value of the services



- ◇ that meetings held in association with the bona fide services occur in venues and under circumstances conducive to the services (that must be the primary focus of the meeting)
- ◇ the legitimate need for the services
- ◇ the connection between the expertise of the NJ prescriber and the purpose of the arrangement
- ◇ how NJ prescriber's role achieves the identified purpose
- ◇ how NJ prescriber will maintain records concerning the arrangement and the services provided
- ◇ an attestation that the NJ prescriber's decision to render the services is not unduly influenced by a pharma manufacturer's agent

Prohibited Gifts/Payments

- The rule prohibits a NJ prescriber from accepting any of the following gifts or benefits from a pharma manufacturer or manufacturer's agent:
 - ◇ entertainment or recreational items (tickets to sporting or theatre events or leisure trips)
 - ◇ any item of value that does not advance disease or treatment education (pens, notepads, mugs or items with a company logo)
 - ◇ items for the personal benefit of the NJ prescriber or staff (flowers, sports equipment, artwork or electronic devices that have nonprofessional utility)
 - ◇ cash or gift certificates
 - ◇ payment or subsidy to non-faculty NJ prescriber to attend an educational event or promotional activity (including cost of travel, lodging or personal expenses) unless the NJ prescriber is a speaker at such educational or promotional event
 - ◇ meals costing more than \$15

Permitted Gifts/Payments

- The rule permits a NJ prescriber to accept the following gifts or benefits from a pharma manufacturer or manufacturer's agent:
 - ◇ items designed primarily for patient or prescriber educational purposes with minimal value outside the prescriber's professional responsibilities (anatomical models, information directly related to patient care or prescriber education)
 - ◇ subsidized registration fees at educational events if available to all participants
 - ◇ meals costing less than \$15 at educational events or promotional activities
 - ◇ reasonable payment for travel, lodging and personal expenses in connection with research activities or employment recruitment
 - ◇ sample medications used exclusively for the NJ prescriber's patients (provided the NJ prescriber does not charge for such samples)


Enforcement of Rule

- Rule applies directly only to NJ prescribers and not to pharma manufacturers or manufacturers agents



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- Enforced by the NJ Attorney General and NJ professional licensing boards
 - Penalties to NJ prescribers who violate the rule include disciplinary action (including loss of license) or civil money penalties up to \$10,000 for the initial and \$20,000 for each subsequent violation
 - Sunshine Act reporting requirements will provide NJ authorities an easy way to monitor NJ prescribers' compliance with the new rule
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Please contact Sandra Jarva Weiss at sjarvaweiss@nmmlaw.com with any questions concerning the new rule.

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