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The Latest State Law Addressing the Opioid Crisis: New Regulations Prohibit New Jersey Prescribers Accepting Payments from Drug Manufacturers

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In a prior blog post from September 8, 2017, we wrote about the many ways in which states are addressing the opioid crisis through legislation. One of the states we discussed was New Jersey who at the time had proposed a new rule to regulate the relationship between manufacturers and prescribers. This month that New Jersey rule became final.

On January 16, 2018 the New Jersey Attorney General issued final regulations entitled **Limitations On and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers** ("the Rule"). The stated intent of the Rule is to minimize the potential for conflicts of interest and reduce incentives for treatment decisions to be influenced by payments from drug manufacturers, thereby encouraging healthcare practitioners who prescribe to focus on the patient's best interests.[1] The Rule became effective on January 16, 2018. The Rule does not apply to contracts entered into on or before January 15, 2018.[2]

Second, the Rule only prohibits "prescribers" (defined as physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists licensed in New Jersey) from accepting certain compensation from pharmaceutical manufacturers; the Rule does not prohibit the offering or payment of any compensation.[3] In other words, the Rule does not authorize any penalties or other enforcement action against any pharmaceutical manufacturer; rather the various New Jersey professional licensing boards have authority to take enforcement action against prescribers for accepting prohibited compensation.

Prohibited Gifts and Payments

A New Jersey prescriber may not accept, directly or indirectly, any of the following from a pharmaceutical manufacturer or a manufacturer's agent:

- Any financial benefit or benefit-in-kind, including, but not limited to, gifts, payments,

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stock, stock options, grants, scholarships, subsidies, and charitable contributions, except as specifically permitted by the Rule.

- Any entertainment or recreational items (e.g., tickets to theater or sporting events, or leisure or vacation trips).
- Items of value that do not advance disease or treatment education, including, but not limited to:
  - Pens, note pads, clipboards, mugs, or other items with a company or product logo;
  - Items intended for the personal benefit of the prescriber or staff, such as floral arrangements, sporting equipment, or artwork;
  - Any payment in cash or a cash equivalent; or
  - Any payment or direct subsidy to a non-faculty prescriber to support attendance at, as remuneration for time spent attending, or for the costs of travel, lodging, or other personal expenses associated with attending, any education event or a promotional activity.

- Any meals unless permitted as described below under Permitted Gifts and Payments. [4]

“Pharmaceutical manufacturer" means any entity:

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    - engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs or biologics, by extraction from substances of natural origin, or independently by means of chemical synthesis; or
    - directly engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or prescription biologics.

“Pharmaceutical manufacturer's agent" or "manufacturer's agent" means a person who, while employed by, or under contract with, a pharmaceutical manufacturer, engages in detailing, promotional activities, or other marketing of prescription drugs or biologics to any prescriber authorized to prescribe, dispense, or purchase prescription drugs, biologics, healthcare facility, or pharmacist, but shall not include a prescriber or pharmacist when acting within the ordinary scope of the practice for which he or she is licensed.[5]

Permitted Gifts

The following permitted gifts and payments from pharmaceutical manufacturers or manufacturer’s agents are permitted:

- Items designed primarily for educational purposes for patients or the prescriber that have minimal or no value to the prescriber outside of his/her professional responsibilities (e.g., anatomical models).
- A subsidized registration fee at an education event, if that fee is available to all participants.
- Modest meals, worth no more than $15 per prescriber[6], provided by an event organizer at an education event, but only if the meals facilitate the educational program to maximize prescriber learning.

- Modest meals, worth no more than $15 per prescriber, provided by a manufacturer to non-faculty prescribers at a promotional activity.
- Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for an education event which may also include reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services, and continuing education credit if applicable.
- Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for a promotional activity, or for participation on advisory bodies or under consulting arrangements. A prescriber may also accept reasonable payment for travel, lodging, and other expenses associated with such services, but may not accept continuing education credit.
- Compensation, based on fair market value, for participation on advisory bodies or under consulting arrangements.
- Reasonable payment or remuneration for travel, lodging, and other expenses in connection with research activities.
- Reasonable payment to prospective applicants for travel, lodging, and other expenses in connection with employment recruitment.
- Royalties, licensing fees, or other arrangements regarding the purchase of intellectual property rights from a prescriber.[7]
- Sample medications intended to be used exclusively for the benefit of the prescriber's patients, so long as the prescriber does not charge for these samples.[8]

Bona Fide Services Payment Cap

Prescribers are limited to a total of $10,000 in the aggregate per calendar year from all pharmaceutical manufacturers for speaking at promotional activities, participation on advisory boards, and consulting arrangements.[9]

Permitted payments for speaking at education events (in contrast to payments for speaking at promotional activity) are not subject to the $10,000 cap but must be fair market value and set forth in a written agreement.

Payments for research activities and payments for royalties and licensing fees are also not subject to this cap.[10] Research is defined to include pre- and post-market activities **assessing the safety or efficacy of prescribed products** as well as scientific advising on the development, testing, and evaluation of prescribed products.[11]

"Bona fide services" means those services provided by a prescriber pursuant to an arrangement formalized in a written agreement including, but not limited to, presentations as speakers at promotional activities and education events, participation on advisory boards, and consulting arrangements. The written agreement shall specify the services to be provided, the dollar value of the consideration to be received by the prescriber, based on the fair market value of the services, specify that the meetings held in association with bona fide services occur in venues and under circumstances conducive to the services provided and that the activities related to the services are the primary focus of the meeting, and identify the following:

1. The legitimate need for services in advance;
2. The connection between the competence, knowledge, and expertise of the prescriber and the purpose of the arrangement;
3. How participation of the prescriber is reasonably related to achieving the identified purpose;
4. The manner by which the prescriber will maintain records concerning the arrangement and the services provided by the prescriber; and
5. An attestation that the prescriber's decision to render the services is not unduly influenced by a pharmaceutical manufacturer's agent.[12]

"Bona fide services" does not include services provided by a prescriber in connection with research activities.

Required Disclosures

Prescribers speaking at an education event or for a promotional activity must directly disclose to attendees, either orally or in writing, at the beginning of the presentation that they have accepted payment from the sponsoring manufacturer within the preceding 5 years.[13]

A prescriber who is **an employee of** a pharmaceutical manufacturer and who also provides patient care must disclose this to patients, but those employees are exempt from the compensation prohibitions of the Rule.[14]

Conclusions

The final Rule will certainly impact the interaction between manufacturers and prescribers licensed in New Jersey. A key difference between the New Jersey Rule and other state laws and voluntary ethics codes addressing relationships between pharmaceutical manufacturers and prescribers is that the New Jersey Rule is directed at prohibiting New Jersey licensed prescribers from accepting prohibited compensation. Until now, much of the federal and state law (other than anti-kickback statutes) regulating this area has focused on prohibiting manufacturers from paying prescribers certain types or levels of compensation (or mandating disclosure of such payments). In contrast, the Rule places at risk the professional licensure of a New Jersey prescriber if they accept a prohibited payment.

This New Jersey rule regulating the relationship of manufacturers and prescribers is one of several approaches to curb the opioid crisis and increase transparency and may become a model as other states evaluate how to stem the tide of this growing epidemic.

[1] *See* Attorney General Response to Comment 1, 50 N.J.R. 578(a).

[2] N.J.A.C. § 13:45J-1.1A.

[3] N.J.A.C. § 13:45J-1.2.

[4] N.J.A.C. § 13:45J-1.3.

[5] N.J.A.C. § 13:45J-1.2.

[6] N.J.A.C. § 13:45J-1.2 (defining “Modest Meal”).

[7] N.J.A.C. § 13:45J-1.4.

[8] N.J.A.C. § 13:45J-1.5.

[9] N.J.A.C. § 13:45J-1.6.

[10] N.J.A.C. § 13:45J-1.6.

[11] N.J.A.C. § 13:45J-1.2 (defining “Research” as “ 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. "Research" shall include both pre-market and post-market activities that satisfy the requirements of this definition.”).

[12] N.J.A.C. § 13:45J-1.2 (defining “Bona Fide Services”).

[13] N.J.A.C. § 13:45J-1.7.

[14] N.J.A.C. § 13:45J-1.8.