ASSEMBLY, No. 2789

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED FEBRUARY 13, 2020

Sponsored by:
Assemblywoman NANCY J. PINKIN
District 18 (Middlesex)

SYNOPSIS

Establishes limitations on and conditions associated with prescribers' acceptance of compensation from pharmaceutical manufacturers.

CURRENT VERSION OF TEXT

As introduced.

AN ACT concerning prescriber compensation by pharmaceutical manufacturers and supplementing Title 45 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Bona fide services" means those services provided by a prescriber pursuant to a written agreement including, but not limited to, presenting as a speaker at promotional activities and continuing educational events, participation on advisory boards, and consulting arrangements. The written agreement shall specify the services to be provided, specify the dollar value of the consideration to be received by the prescriber based on the fair market value of the services, 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; (5) the venue and circumstances of any meeting in which the prescriber participates and how the venue and circumstances are conducive to the services provided and advance the primary focus of the meeting; and (6) an attestation that the prescriber's decision to render the services is not unduly influenced by a pharmaceutical manufacturer's agent.

"Continuing education event" means a continuing education event, third-party scientific or educational conference, professional meeting, education and training required by the United States Food and Drug Administration, or any other gathering where responsibility for, and control over, the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizers in accordance with the standards of a nationally recognized accrediting entity, held in a venue that is appropriate and conducive to informational communication and training about healthcare information, where: (1) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse, in which one or more educational presentations is the highlight of the gathering; and (2) the main purpose for bringing attendees together is to further their knowledge on the topics being presented.

"Non-faculty" means a prescriber who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for a continuing education event or for a promotional activity.

"Modest meals" means food or refreshment, the fair market value of which does not exceed $15 for each prescriber, or such

other amount as established by regulation of the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Pharmaceutical manufacturer" or "manufacturer" means any entity that: (1) is 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 (2) is directly engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or biologics. "Pharmaceutical manufacturer" or "manufacturer" does not include a health care facility licensed by the Department of Health or a pharmacy holding a permit issued by the New Jersey State Board of Pharmacy.

"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: (1) a prescriber authorized to prescribe, dispense, or purchase prescription drugs or biologics; (2) a health care facility; or (3) a pharmacist. "Pharmaceutical manufacturer's agent" or "manufacturer's agent" does not include a prescriber or pharmacist when acting within the ordinary scope of the practice for which the prescriber or pharmacist is licensed.

"Prescriber" means a physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist licensed pursuant to Title 45 of the Revised Statutes. "Prescriber" does not include a licensee who is an employee of a pharmaceutical manufacturer and who does not provide patient care.

"Promotional activity" means any unaccredited activity, meeting, or program organized or sponsored by a pharmaceutical manufacturer or the manufacturer's agent that is directed at prescribers to promote the prescription, recommendation, supply, administration, use, or consumption of the manufacturer's products through any medium.

2. a. A prescriber shall not accept, directly or indirectly, any financial benefit or benefit-in-kind, including but not limited to gifts, payments, stock, stock options, grants, scholarships, subsidies, or charitable contributions, from any manufacturer or manufacturer's agent, except as permitted by section 3 of this act.

b. A prescriber shall not accept, directly or indirectly, any entertainment or recreational items, such as tickets to theatrical or sporting events, or leisure or vacation trips, from any manufacturer or manufacturer's agent.

c. Except as permitted by section 3 of this act, a prescriber shall not accept from any manufacturer or manufacturer's agent any

item of value that does not advance disease or treatment education, including:

(1) pens, note pads, clipboards, mugs, or other items with a company or product logo;

(2) items intended for the personal benefit of the prescriber or staff, such as floral arrangements, sporting equipment, artwork, or items that may have utility in both the professional and non-professional setting, such as electronic devices;

(3) any payment in cash or cash equivalent, such as a gift card or gift certificate; or

(4) any payment or direct subsidy to a non-faculty prescriber to support attendance at, or as remuneration for time spent attending, or for the costs of travel, lodging, or other personal expenses associated with attending, any continuing education event or a promotional activity.

d. A prescriber shall not accept meals from any manufacturer or manufacturer's agent, except as provided in section 3 of this act.

e. Unless an immediate family member is employed by a manufacturer and receives, as part of the usual and customary employment relationship, compensation, financial benefit, or other item of value, the prohibitions listed in this act shall also apply to the prescriber's immediate family. For purposes of this subsection, "immediate family" means an individual's spouse, civil union partner, or domestic partner, or the individual's or spouse's, civil union partner's, or domestic partner's parent, child, brother, sister, aunt, uncle, niece, nephew, grandparent, grandchild, son-in-law, daughter-in-law, stepparent, stepchild, stepbrother, stepsister, half-brother, or half-sister, whether the relative is related to the individual or the individual's spouse, civil union partner, or domestic partner by blood, marriage, or adoption.

3. Consistent with the requirements of this section, a prescriber may accept the following from a manufacturer or manufacturer's agent:

a. Items designed primarily for educational purposes for the prescriber or patients that have minimal or no value to the prescriber outside of the prescriber's professional responsibilities. Examples of educational items include anatomical models for use in an examination room or other information and materials in any form directly related to patient care or prescriber education. Items that may have an independent value to the prescriber outside of the prescriber's professional responsibilities, such as electronic devices, may only be accepted if they are used by patients and remain in a common area of the prescriber's office.

b. A manufacturer-subsidized registration fee at a continuing education event if that fee is available to all event participants.

c. Modest meals provided through the event organizer at a continuing education event, provided that the meals facilitate the educational program to maximize prescriber learning.

d. Modest meals provided to non-faculty prescribers through promotional activities no more than four times in a calendar year from the same manufacturer.

e. Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for a continuing education event. A prescriber serving in this capacity may also accept reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may be granted continuing education credit for participation in such activities if the continuing education requirements of the prescriber's professional licensing board are satisfied.

f. 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, consistent with the limits set forth in section 5 of this act. A prescriber serving in this capacity may also accept reasonable payment or remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may not claim continuing education credit for participation in such activities.

g. Compensation, based on fair market value, for participation on advisory bodies or under consulting arrangements, consistent with the limits set forth in section 5 of this act.

4. A prescriber may accept sample medications or devices that are intended to be used exclusively for the benefit of the prescriber's patients, provided that the prescriber does not charge patients for such samples, and all applicable dispensing standards set forth in the licensing board rules applicable to the prescriber are satisfied.

5. A prescriber shall not accept more than $10,000, or such other amount as established by regulation by the Director of the Division of Consumer Affairs in the Department of Law and Public Safety, in the aggregate from all manufacturers in any calendar year for the bona fide services of presenting as a speaker or faculty organizer or academic program consultant at promotional activities, participation on advisory boards, and consulting arrangements. Payments for speaking at continuing education events are not subject to this limit, but shall be based on fair market value and set forth in a written agreement.

6. A prescriber serving as a speaker at a continuing education event or for a promotional activity shall directly disclose to

attendees either orally or in writing at the beginning of the presentation whether the prescriber has accepted payment for bona fide services from the sponsoring manufacturer within the preceding five years.

7. A prescriber who is employed by a manufacturer and who also provides patient care shall comply with the disclosure requirements of section 6 of this act, but is exempt from the compensation prohibitions of this act.

8. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety shall, in accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt any rules and regulations as the director deems necessary to carry out the provisions of this act.

9. This act shall take effect on the first day of the seventh month next following the date of enactment, except that the Director of the Division of Consumer Affairs in the Department of Law and Public Safety may take any anticipatory administrative action in advance as shall be necessary for the implementation of this act.

STATEMENT

This bill establishes limitations on, and conditions associated with, prescribers' acceptance of compensation from pharmaceutical manufacturers.

Licensed physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists are all authorized to prescribe pharmaceutical products within the scope of their professional practice. These professionals are also permitted to enter into financial relationships with drug manufacturers, which are limited in varying ways by the different licensing boards, but which may raise concerns that these relationships might influence prescriber's treatment decisions to the detriment of their patients.

The bill generally prohibits prescribers and members of their immediate families from accepting, from a pharmaceutical manufacturer or a manufacturer's agent, any financial benefits or benefits-in-kind, entertainment or recreational items, things of value that do not advance disease or treatment education, or meals. A prescriber would be permitted to accept gifts or payments that meet certain conditions: items that are used primarily for educational purposes for the prescriber or patients that have minimal value outside of the prescriber's professional responsibilities; subsidized registration fees at continuing education events if that subsidized fee is available to all participants; modest meals provided at a

continuing education event, modest meals at promotional activities up to four times per year; compensation based on fair market value for bona fide services as a speaker or organizer or consultant at a continuing education event.

The bill permits prescribers to accept sample medications or devices exclusively for the benefit of the prescriber's patients, provided that the prescriber does not charge patients for such samples and all requirements of the prescriber's licensing board are met.

The bill also permits a prescriber to receive compensation for bona fide services as a speaker or faculty organizer or academic program consultant at promotional events, participation on advisory boards, and other consulting arrangements, subject to a cap of $10,000 per year in aggregate. The $10,000 cap could be altered by the Director of the Division of Consumer Affairs by regulation, such as to reflect inflationary changes.

Under the bill, a prescriber who serves as a speaker at a continuing education or promotional event would be required to disclose whether the prescriber has accepted payment for bona fide services from the sponsoring manufacturer in the preceding five years.

A prescriber employed by a manufacturer and who also provides patient care would be subject to the disclosure requirements of the bill, but exempt from the compensation provisions.