

SENATE, No. 3527

STATE OF NEW JERSEY 217th LEGISLATURE

INTRODUCED NOVEMBER 30, 2017

Sponsored by:

Senator JOSEPH F. VITALE

District 19 (Middlesex)

SYNOPSIS

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

CURRENT VERSION OF TEXT

As introduced.



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

4
5 **BE IT ENACTED** *by the Senate and General Assembly of the State*
6 *of New Jersey:*

7
8 1. As used in this act:

9 “Bona fide services” means those services provided by a
10 prescriber pursuant to an arrangement formalized in a written
11 agreement including, but not limited to, presentations as speakers at
12 promotional activities and continuing educational events,
13 participation on advisory boards, and consulting arrangements. The
14 written agreement shall specify the services to be provided, specify
15 the dollar value of the consideration to be received by the prescriber
16 based on the fair market value of the services, and identify the
17 following: (1) the legitimate need for services in advance; (2) the
18 connection between the competence, knowledge, and expertise of
19 the prescriber and the purpose of the arrangement; (3) how
20 participation of the prescriber is reasonably related to achieving the
21 identified purpose; (4) the manner by which the prescriber will
22 maintain records concerning the arrangement and the services
23 provided by the prescriber; (5) the venue and circumstances of any
24 meeting in which the prescriber participates and how the venue and
25 circumstances are conducive to the services provided and advance
26 the primary focus of the meeting; and (6) an attestation that the
27 prescriber’s decision to render the services is not unduly influenced
28 by a pharmaceutical manufacturer’s agent.

29 “Continuing education event” means a continuing education
30 event, third-party scientific or educational conference, professional
31 meeting, U.S. Food and Drug Administration required education
32 and training, or any other gathering where responsibility for and
33 control over the selection of content, faculty, educational methods,
34 materials, and venue belongs to the event’s organizers in
35 accordance with the standards of a nationally recognized
36 accrediting entity, held in a venue that is appropriate and conducive
37 to informational communication and training about healthcare
38 information, where: (1) the gathering is primarily dedicated, in
39 both time and effort, to promoting objective scientific and
40 educational activities and discourse, in which one or more
41 educational presentations is the highlight of the gathering; and (2)
42 the main purpose for bringing attendees together is to further their
43 knowledge on the topics being presented.

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

1 “Modest meals” means food or refreshment, where its fair
2 market value does not exceed \$15 for each prescriber, or such other
3 amount as established by the Director of the Division of Consumer
4 Affairs by regulation.

5 “Pharmaceutical manufacturer” or “manufacturer” means any
6 entity that: (1) is engaged in the production, preparation,
7 propagation, compounding, conversion, or processing of
8 prescription drugs or biologics, by extraction from substances of
9 natural origin or independently by means of chemical synthesis; or
10 (2) is directly engaged in the packaging, repackaging, labeling,
11 relabeling, or distribution of prescription drugs or biologics.
12 “Pharmaceutical manufacturer” or “manufacturer” does not include
13 a health care facility licensed by the Department of Health or a
14 pharmacy holding a permit issued by the New Jersey State Board of
15 Pharmacy.

16 “Pharmaceutical manufacturer’s agent” or “manufacturer’s
17 agent” means a person who, while employed by or under contract
18 with a pharmaceutical manufacturer, engages in detailing,
19 promotional activities, or other marketing of prescription drugs or
20 biologics to: (1) a prescriber authorized to prescribe, dispense, or
21 purchase prescription drugs or biologics; (2) a health care facility;
22 or (3) a pharmacist. “Pharmaceutical manufacturer’s agent” or
23 “manufacturer’s agent” does not include a prescriber or pharmacist
24 when acting within the ordinary scope of the practice for which the
25 prescriber or pharmacist is licensed.

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

31 “Promotional activity” means any unaccredited activity, meeting,
32 or program organized or sponsored by a pharmaceutical
33 manufacturer or the manufacturer’s agent that is directed at
34 prescribers to promote the prescription, recommendation, supply,
35 administration, use, or consumption of the manufacturer’s products
36 through any medium.

37
38 2. a. A prescriber shall not accept, directly or indirectly, any
39 financial benefit or benefit-in-kind, including but not limited to
40 gifts, payments, stock, stock options, grants, scholarships,
41 subsidies, or charitable contributions, except as permitted under
42 section 3 of this act, from any manufacturer or manufacturer’s
43 agent.

44 b. A prescriber shall not accept, directly or indirectly, any
45 entertainment or recreational items, such as tickets to theater or
46 sporting events, or leisure or vacation trips, from any manufacturer
47 or manufacturer’s agent.

1 c. Except as permitted under section 3 of this act, a prescriber
2 shall not accept from any manufacturer or manufacturer's agent any
3 item of value that does not advance disease or treatment education,
4 including:

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

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

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

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

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

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

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

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

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

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

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

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

16 f. Compensation, based on fair market value, for providing bona
17 fide services as a speaker or faculty organizer or academic program
18 consultant for a promotional activity, consistent with such limits as set
19 forth in section 5 of this act. A prescriber serving in this capacity also
20 may accept reasonable payment or remuneration for travel, lodging,
21 and other personal expenses associated with such services. A
22 prescriber may not claim continuing education credit for participation
23 in such activities.

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

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

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

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44 6. A prescriber serving as a speaker at a continuing education
45 event or for a promotional activity shall directly disclose to
46 attendees either orally or in writing at the beginning of the
47 presentation whether the prescriber has accepted payment for bona
48 fide services from the sponsoring manufacturer within the preceding
49 five years.

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

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

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

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