

SENATE, No. 1119

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

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

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

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.

33

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.

- 1 b. A manufacturer-subsidized registration fee at a continuing
2 education event if that fee is available to all event participants.
- 3 c. Modest meals provided through the event organizer at a
4 continuing education event, provided the meals facilitate the
5 educational program to maximize prescriber learning.
- 6 d. Modest meals provided to non-faculty prescribers through
7 promotional activities no more than four times in a calendar year from
8 the same manufacturer.
- 9 e. Compensation, based on fair market value, for providing bona
10 fide services as a speaker or faculty organizer or academic program
11 consultant for a continuing education event. A prescriber serving in
12 this capacity also may accept reasonable payment and remuneration
13 for travel, lodging, and other personal expenses associated with such
14 services. A prescriber may be granted continuing education credit for
15 participation in such activities if the continuing education
16 requirements of the prescriber's professional licensing board are
17 satisfied.
- 18 f. Compensation, based on fair market value, for providing bona
19 fide services as a speaker or faculty organizer or academic program
20 consultant for a promotional activity, consistent with such limits as set
21 forth in section 5 of this act. A prescriber serving in this capacity also
22 may accept reasonable payment or remuneration for travel, lodging,
23 and other personal expenses associated with such services. A
24 prescriber may not claim continuing education credit for participation
25 in such activities.
- 26 g. Compensation, based on fair market value, for participation on
27 advisory bodies or under consulting arrangements, consistent with
28 such limits as set forth in section 5 of this act.
- 29
- 30 4. A prescriber may accept sample medications or devices that
31 are intended to be used exclusively for the benefit of the
32 prescriber's patients, provided the prescriber does not charge
33 patients for such samples, and all applicable dispensing standards
34 set forth in the prescriber's licensing board rules are satisfied.
- 35
- 36 5. A prescriber shall not accept more than \$10,000, or such
37 other amount as established by the Director of the Division of
38 Consumer Affairs by regulation, in the aggregate from all
39 manufacturers in any calendar year for the bona fide services of
40 presentations as a speaker or faculty organizer or academic program
41 consultant at promotional activities, participation on advisory
42 boards, and consulting arrangements. Payments for speaking at
43 continuing education events are not subject to this limit, but must be
44 for fair market value and set forth in a written agreement.
- 45
- 46 6. A prescriber serving as a speaker at a continuing education
47 event or for a promotional activity shall directly disclose to

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

5
6 7. A prescriber who is employed by a manufacturer and who
7 also provides patient care shall comply with the disclosure
8 requirements of section 6 of this act, but is exempt from the
9 compensation prohibitions of this act.

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

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

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25 STATEMENT

26
27 This bill establishes limitations on, and conditions associated
28 with, prescribers’ acceptance of compensation from pharmaceutical
29 manufacturers.

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

38 The bill generally prohibits prescribers and members of their
39 immediate families from accepting, from a pharmaceutical
40 manufacturer or a manufacturer’s agent, any financial benefits or
41 benefits-in-kind, entertainment or recreational items, things of value
42 that do not advance disease or treatment education, or meals. A
43 prescriber would be permitted to accept gifts or payments that meet
44 certain conditions: items that are used primarily for educational
45 purposes for the prescriber or patients that have minimal value
46 outside of the prescriber’s professional responsibilities; subsidized

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1 registration fees at continuing education events if that subsidized
2 fee is available to all participants; modest meals provided at a
3 continuing education event, modest meals at promotional activities
4 up to four times per year; compensation based on fair market value
5 for bona fide services as a speaker or organizer or consultant at a
6 continuing education event.

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

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

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

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