

CHAPTER 45J
LIMITATIONS ON AND OBLIGATIONS ASSOCIATED WITH PRESCRIBER
ACCEPTANCE OF COMPENSATION FROM PHARMACEUTICAL
MANUFACTURERS

SUBCHAPTER 1. LIMITATIONS ON AND OBLIGATIONS ASSOCIATED WITH
PRESCRIBER ACCEPTANCE OF COMPENSATION FROM PHARMACEUTICAL
MANUFACTURERS

13:45J-1.1 Purpose

The rules in this chapter regulate the receipt and acceptance by prescribers of anything of value from pharmaceutical manufacturers to ensure that such relationships do not interfere with prescribers' independent professional judgment.

13:45J-1.1A Pre-existing contracts

The provisions of this chapter shall not apply to contracts entered into on or before January 15, 2018.

13:45J-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

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

"Education event" means an education event, third-party scientific or educational conference, professional meeting or workshop, seminar, U.S. Food and Drug Administration required education and training, or any other gathering 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 (one or more educational presentation(s) should be the highlight of the gathering); and
2. The main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

"Modest meals" means a food and/or refreshment, where its fair market value does not exceed \$15.00 for each prescriber.

"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 an education event or for a promotional activity.

"Pharmaceutical 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 prescription biologics, provided, however, that "pharmaceutical manufacturer" or "manufacturer" shall not include a healthcare facility licensed by the Department of Health, or a pharmacy holding a permit issued by the 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 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.

"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, as defined in N.J.A.C. 18:35-7.1, of a pharmaceutical manufacturer 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 media or medium. "Promotional activity" does not include an education event or services provided in connection with research activities.

"Research" means 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.

13:45J-1.3 Prohibited gifts and payments

(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, and charitable contributions, except as permitted under N.J.A.C. 13:45J-1.4, from any pharmaceutical manufacturer or manufacturer's agent.

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

(c) Except as permitted under N.J.A.C. 13:45J-1.4, a prescriber shall not accept from any pharmaceutical 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 certificate;
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 education event or a promotional activity.

(d) A prescriber shall not accept meals from any pharmaceutical manufacturer or manufacturer's agent, except as provided in N.J.A.C. 13:45J-1.4.

(e) Unless an immediate family member is employed by a pharmaceutical 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 section shall also apply to the prescriber's immediate family.

1. For purposes of this rule, "immediate family" means an individual's spouse, civil union partner, or domestic partner, or the individual's child or when residing in the same household of the individual, that individual's or his or her spouse's, civil union partner's, or domestic partner's parent, brother, sister, aunt, uncle, niece, nephew, grandparent, grandchild, son-in-law, daughter-in-law, stepparent, stepchild, stepbrother, stepsister, half-brother, or half-sister, whether their relative is related to the individual or the individual's spouse, civil union partner, or domestic partner by blood, marriage, or adoption.

13:45J-1.4 Permitted gifts and payments

(a) Consistent with the requirements of this chapter, a prescriber may accept the following from a pharmaceutical manufacturer or manufacturer's agent:

1. Items designed primarily for educational purposes for the patients or the prescriber that have minimal or no value to the prescriber outside of his or her 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 his or her 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.

2. A pharmaceutical manufacturer subsidized registration fee at an education event, if that fee is available to all event participants.

3. Modest meals provided through the event organizer at an education event, provided the meals facilitate the educational program to maximize prescriber learning.

4. Modest meals provided by a manufacturer to non-faculty prescribers through promotional activities.

5. 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. 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.

6. 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 such caps as set forth at N.J.A.C. 13:45J-1.6. A prescriber serving in this capacity also may 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.

7. Compensation, based on fair market value, for participation on advisory bodies or under consulting arrangements, consistent with such cap as set forth at N.J.A.C. 13:45J-1.6. A prescriber serving in this capacity also may accept reasonable payment or remuneration for travel, lodging, and other personal expenses associated with such services.

8. Reasonable payment or remuneration for travel, lodging, and other personal expenses in connection with research activities.

9. Reasonable payment or remuneration to prospective applicants for travel, lodging, and other personal expenses associated with employment recruitment.

10. Royalties and licensing fees paid in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the prescriber holds an ownership right.

13:45J-1.5 Sample medications

A prescriber may accept sample medications that are intended to be used exclusively for the

benefit of the prescriber's patients, provided the prescriber does not charge patients for such samples, and provided all dispensing standards, as applicable, set forth in the prescriber's licensing board rules are satisfied.

13:45J-1.6 Bona fide services cap

A prescriber shall not accept more than \$ 10,000 in the aggregate from all pharmaceutical manufacturers in any calendar year for the bona fide services of presentations as speakers at promotional activities, participation on advisory boards, and consulting arrangements. Payments for speaking at education events are not subject to this cap, but must be for fair market value and set forth in a written agreement. Payments for research activities and, consistent with N.J.A.C. 13:45J-1.4(a)10, payments for royalties and licensing fees are not subject to this cap.

13:45J-1.7 Disclosure requirements

A prescriber serving as a speaker at an education event or for a promotional activity shall directly disclose to attendees either orally or in writing at the beginning of the presentation that the prescriber has accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years.

13:45J-1.8 Prescribers employed by pharmaceutical manufacturer

A prescriber who is an employee of a pharmaceutical manufacturer and who also provides patient care shall disclose to patients either orally or in writing his or her employment by the pharmaceutical manufacturer, but is exempt from the compensation prohibitions of this chapter.