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LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

Limitations on and Obligations Associated with Acceptance of Compensation from Pharmaceutical Manufacturers by Prescribers

Adopted New Rules: N.J.A.C. 13:45J

Proposed: October 2, 2017, at 49 N.J.R. 3330(a).

Adopted: December 20, 2017, by Christopher S. Porrino, Attorney General of New Jersey.

Filed: December 20, 2017, as R.2018 d.054, with **non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-17.b.

Effective Date: January 16, 2018.

Expiration Date: January 16, 2025.

The notice of proposed new rules was published in the New Jersey Register on October 2, 2017 at 49 N.J.R. 3330(a), which included a public hearing held on October 19, 2017. Notice of the proposal was posted on the Division of Consumer Affair website, was sent to the Statehouse Press, and was emailed to interested parties and attorneys as listed with the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, and New Jersey State Board of Optometrists under N.J.A.C. 1:30-5.2(a)3. Notice of the public hearing also appeared in newspapers around the State. Written comments were accepted through December 1, 2017.

Summary of Hearing Officer's Recommendation and Agency's Response:

The public hearing was held on October 19, 2017, at the Offices of the Division of Consumer Affairs in Newark, New Jersey. The following persons or entities offered testimony at the public hearing: Dr. Andy Kaufman, New Jersey Society of Interventional Pain Physicians; Kristina M. Moorhead, MPAff, Senior Director, State Advocacy, Pharmaceutical Research and Manufacturers of America (PhRMA); Andrew N. de Torre MD, FACS, Liver, Pancreas and Biliary Surgery, St. Joseph's Medical Center; Dr. Otto Sabando, New Jersey Association of Osteopathic Physicians and Surgeons; Dean Paranicas, President and CEO, HealthCare Institute of New Jersey (HINJ); Patrick Plues, Vice President, State Government Affairs, the Biotechnology Innovation Organization (BIO); Howard Fienberg, Director of Government Affairs, The Insights Association; Debbie Hart, President and CEO, BioNJ; Larry Downs, Esq., Chief Executive Officer, Medical Society of New Jersey; John Kamp, Executive Director, Coalition for Healthcare Communication; Steven Andreassen, Esq., Chief of Staff, Rutgers Biomedical & Health Sciences; Douglas Peddicord, Ph.D., Executive Director, Association of Clinical Research Organizations (ACRO); and Beverly Wong, MD Candidate, Class of 2018, Rutgers Robert Wood Johnson Medical School. Maryann Sheehan, Director, Legislative and Regulatory Affairs, Division of Consumer Affairs presided at the hearing. A record of the public hearing and hearing report are available for inspection in accordance with applicable law by contacting:

Division of Consumer Affairs

Office of the Director

Legislative & Regulatory Affairs

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nonetheless take reasonable steps to help ensure compliance with the final rules. The commenters believe that, to allow sufficient time to permit prescribers and manufacturers to implement reasonable measures to help ensure compliance with the new rules, the Attorney General should afford at least a 180-day implementation period between when the final rules are published in the New Jersey Register and when they go into effect.

RESPONSE: The Attorney General declines to delay the effective date of the rules as the commenters suggested. However, the Attorney General recognizes that some contractual relationships have already been entered into that will impact the upcoming calendar year. Accordingly, the rules will apply only to those contracts that are entered into, and any conduct that occurs on or after the effective date of the rules. The Attorney General, upon adoption, will add N.J.A.C. 13:45J-1.1A to clearly articulate that N.J.A.C. 13:45J shall not apply to contracts entered into on or before January 15, 2018. In addition, the rules will apply only to conduct that occurs on or after January 16, 2018, the effective date of these rules.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rules are governed by N.J.S.A. 45:1-17.b and are not subject to any Federal standards or requirements.

Full text of the adopted new rules follows (additions to the proposal indicated in boldface with asterisks ***thus***; deletions from the proposal indicated in brackets with asterisks *[thus]*):

***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 *[continuing educational]* ***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 *[their]* ***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.-3. (No change from proposal.)

4. The manner by which the prescriber will maintain records concerning the arrangement and the services provided by the prescriber; ***and***

[5. The venue and circumstances of any meeting in which the prescriber participates, if applicable, addressing how it is conducive to the services provided and advances the primary focus of the meeting; and]

[6.] ***5.*** (No change in text from proposal.)

"*[Continuing education]* ***Education*** event" means *[a continuing]* ***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 *[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.-2. (No change from proposal.)

...

"Pharmaceutical manufacturer" means any entity that:

1. (No change from proposal.)

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.

...

"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.***

...

"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]* ***an*** education event or for a promotional activity.

...

"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)-(b) (No change from proposal.)

(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.-3. (No change from proposal.)

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) (No change from proposal.)

(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, *[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 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. (No change from proposal.)

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

3. Modest meals provided through the event organizer at *[a continuing]* ***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 *[no more than four times in a calendar year from the same manufacturer]*.

5. Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for *[a continuing]* ***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. (No change from proposal.)

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 *[or devices]* 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 *[continuing]* 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 *[a continuing]* ***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 *[employed by]* ***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.