



*State of New Jersey*  
OFFICE OF THE ATTORNEY GENERAL  
DEPARTMENT OF LAW AND PUBLIC SAFETY  
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May 14, 2018

Members, State Board of Medical Examiners  
c/o William V. Roeder, Executive Director  
140 East Front Street  
Trenton, NJ 08625

Dear Board Members,

On January 16, 2018, former Attorney General Christopher Porrino adopted N.J.A.C. 13:45J-1.1 et seq. in an effort to establish uniform standards to minimize the conflicts of interest between health care prescribers and pharmaceutical manufacturers to ensure that patient care is guided by the unbiased, best judgment of treating prescribers. In the intervening months we have heard that the rule, by operation of the definition of "modest meal" -- a sum expressly limited to \$15.00, is unrealistic in many parts of New Jersey. Moreover, its broad applicability to all manner of presentations has served to stifle valuable educational gatherings at which prescribers obtain scientific, evidence-based data and important information about developments concerning treatment options to address a variety of disease states. It is these types of educational events that the regulatory framework should facilitate.

Accordingly, pursuant to the authority set forth at N.J.S.A. 45:1-17(b), I am proposing to amend N.J.A.C. 13:45J-1.1, 1.2 and 1.4. The rule amendments I am proposing would:

1. Modify the current "modest meal" definition to allow \$15.00 for breakfast and lunch and \$30.00 for dinner, in calendar year 2018. This sum will be tied to a consumer price index, allowing for dollar increases in subsequent years if the index reflects increases of 50 cents or more. In addition, the rule will expressly reflect that the standard charges for delivery, service or a facility rental fees or for taxes need not be included in the fair market value of a modest meal associated with promotional activities, and
2. Remove these limits as to meals associated with educational events, even if supported by a pharmaceutical manufacturer, these limits are not applicable, so long as the presentations are conducive to the educational purpose and include information concerning disease states and treatment approaches.

Because questions have arisen concerning the scope of some of the original provisions of the rule, we are making clear that the rule applies to active licensees practicing in New Jersey or treating New Jersey



patients and that the sums paid by pharmaceutical manufacturers for meals consistent with the amendments are not subject to or included in the bona fide services cap set forth in N.J.A.C. 13:45J-1.6.

These amendments are not intended to reduce the resolve, shared by my predecessor to assure that medical judgments are guided by the best interest of patients. The changes are designed to elevate the content of educational discourse to assure that it is of true educational value, enhancing the ability of prescribers to understand treatment options available so as to better serve patients.

I am forwarding this notice to the four boards regulating prescribers, as required by N.J.S.A. 45:1-17(b). To resolve the concerns of the regulated community as quickly as possible, I plan on forwarding the rule proposal to the Office of Administrative Law on July 6, 2018. Given that we are pursuing this regulatory change, I would forbear from prosecuting matters during the rule-making process, if a prescriber's conduct would be in compliance with the proposal.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gurbir S. Grewal', with a stylized flourish at the end.

Gurbir S. Grewal  
Attorney General

**LAW AND PUBLIC SAFETY**

**DIVISION OF CONSUMER AFFAIRS**

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

**Proposed Amendments: N.J.A.C. 13:45J-1.1, 1.2, and 1.4.**

Authorized By: Gurbir S. Grewal, Attorney General of New Jersey.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2018- .

Submit written comments by 2018, to:

Maryann Sheehan, Director, Legislative and Regulatory Affairs

Division of Consumer Affairs

124 Halsey Street, 7th Floor

PO Box 45027

Newark, New Jersey 07101

or electronically at: [www.njconsumeraffairs.gov/Proposals/Pages/default.aspx](http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx)

The agency proposal follows:

## Summary

The Attorney General is proposing amendments to N.J.A.C. 13:45J, concerning limitations on and obligations associated with the acceptance of compensation from pharmaceutical manufacturers. On January 16, 2018, the former Attorney General adopted new rules at N.J.A.C. 13:45J to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber (See 50 N.J.R. 578). The rules imposed a limitation of \$15 on the amount of a modest meal that could be provided at an education event or promotional activity. Since the adoption of these rules, many have expressed concern about the impact of the modest meals limitation on the availability of venues conducive to a learning environment. In response to these comments, the Attorney General proposes to amend the modest meal limitation to distinguish between the amount allowable for breakfast and lunch, and that for dinner; provide a mechanism for adjusting these amounts; specify that the limitation does not include the cost of standard delivery, service, or facility rental fee charges, or of tax; and to specify that meals associated with education events are not subject to the modest meal limitation. The Attorney General recognizes the educational value of learning about disease states and treatment options and believes that the proposed amendments will enhance the rules to further the educational exchange between practitioners and pharmaceutical manufacturers for the benefit of patient care.

The proposed amendments at N.J.A.C. 13:45J-1.1 specify that the rules at N.J.A.C. 13:45J apply to a prescriber (physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist) who holds an active New Jersey license and who either practices in New Jersey or has New Jersey patients regardless of the prescriber's practice site. The title of this rule is also proposed for amendment to reflect that the rule encompasses the scope of the rules.

In addition, the Attorney General proposes to amend the definitions at N.J.A.C 13:45J-

1.2 of the terms “modest meals” and “prescriber,” and to include a definition for “Consumer Price Index.” The proposed new term “Consumer Price Index” is defined as the annual average, rounded to the nearest dollar, of the Consumer Price Index for Food Away From Home – Northeast Urban, as posted in January for the preceding year by the U.S. Department of Labor Bureau of Labor Statistics at <https://www.bls.gov/>, or a successor index. To round, amounts under 50 cents shall be disregarded, and amounts of 50 cents or more shall be increased to the next dollar. The proposed amendments to “modest meals” specify that the fair market value limitation in the calendar year 2018 is \$15.00 for breakfast or lunch, and \$30.00 for dinner. In addition, the Attorney General is proposing to include a mechanism to adjust these dollar amounts based upon changes in the Consumer Price Index. If the Consumer Price Index increases by 50 cents or more, the specified amounts allowed for modest meals will be increased to the next dollar. The proposed amendments also make it clear that the fair market value does not include the cost of standard delivery, service, or facility rental fee charges, or of tax.

The proposed amendment to the term “prescriber” specifies that the rules apply to only those physicians, podiatrists, physician assistants, advanced practice nurses, dentists, or optometrists who have an active New Jersey license. This amendment is consistent with the proposed clarification that the rules at N.J.A.C. 13:45J apply to those prescribers who practice in New Jersey or who have patients in New Jersey.

As noted above, the Attorney General recognizes the value of education and believes that prescribers may benefit from educational programs that are offered by pharmaceutical manufacturers and that the information enhances patient care. Accordingly, the proposed amendments to N.J.A.C. 13:45J-1.4 remove any limitation on the value of meals provided through the event organizer at an education event, even if supported by a manufacturer, as long

as the meals facilitate the educational program to maximize prescriber learning, including information about disease states and treatment approaches. Meals provided by a pharmaceutical manufacturer to non-faculty prescribers through promotional activities will remain subject to the modest meal limitations.

The Attorney General also proposes to amend N.J.A.C. 13:45J-1.4(a)3 and 4 to specify that meals provided through the event organizer at an education event and the modest meals provided by a pharmaceutical manufacturer to non-faculty prescribers through promotional activities are not subject to the bona fide services cap set forth at N.J.A.C. 13:45J-1.6.

The Attorney General has determined that the comment period for this notice of proposal shall be 60 days; therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

#### **Social Impact**

The proposed amendments will have a positive social impact on prescribers and patients. The proposed amendments will permit the types of venues that are conducive to a learning environment to be used for education events, which will ensure that prescribers can participate in learning opportunities to enhance patient care.

#### **Economic Impact**

The proposed amendments will not have an economic impact on prescribers or patients. The proposed amendments may have a positive economic impact on the restaurant industry, its suppliers, and employees.

#### **Federal Standards Statement**

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

### **Jobs Impact**

The proposed amendments will not result in an increase or decrease in the number of jobs in the State.

### **Agriculture Industry Impact**

The proposed amendments will have no impact on the agriculture industry in the State.

### **Regulatory Flexibility Analysis**

Currently, the Division of Consumer Affairs licenses 62,500 prescribers. If these are considered “small businesses” within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., then the following analysis applies.

The proposed amendments do not impose any recordkeeping, compliance or reporting requirements upon licensees, and no additional professional services will be needed to comply with the proposed amendments. The costs of compliance with the proposed amendments are discussed in the Economic Impact statement above. The Attorney General believes that the proposed amendments should be uniformly applied to all licensees in order to ensure the welfare of the general public in the provision of healthcare services. Therefore, no differing compliance requirements for any licensees are provided based on the size of the business.

### **Housing Affordability Impact Analysis**

The proposed amendments will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the amendments would evoke a change in the average costs associated with housing because the proposed amendments concern limitations on and obligations of prescribers associated with the acceptance of compensation

from pharmaceutical manufacturers.

### **Smart Growth Development Impact Analysis**

The proposed amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the amendments would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendments concern limitations on and obligations of prescribers associated with the acceptance of compensation from pharmaceutical manufacturers.

**Full text** of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

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

##### 13:45J-1.1 Purpose **and scope**

(a) 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.

**(b) The rules in this chapter shall apply to a prescriber who holds an active New Jersey license and who:**

##### **1. Practices in New Jersey; or**



**2. Has New Jersey patients regardless of the prescriber's practice site.**

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:

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**“Consumer Price Index” means the annual average, rounded to the nearest dollar, of the Consumer Price Index for Food Away From Home – Northeast Urban, as posted in January for the preceding year by the U.S. Department of Labor Bureau of Labor Statistics at <https://www.bls.gov/>, or a successor index. To round, amounts under 50 cents shall be disregarded, and amounts of 50 cents or more shall be increased to the next dollar.**

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**“Modest meals” means a food and/or refreshment, where its fair market value does not exceed \$15.00 (for breakfast or lunch) or \$30.00 (for dinner), in 2018, for each prescriber. In each succeeding calendar year after 2018, these amounts shall be adjusted if the Consumer Price Index reflects a sum, which, if rounded, would raise it by one dollar increments. To round, amounts under 50 cents shall be disregarded, and amounts of 50 cents or more shall be increased to the next dollar. The fair market value shall not include the cost of standard delivery, service, or facility rental fee charges, or of tax.**

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**“Prescriber” means a physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist [licensed] who has an active license 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.

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#### 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. – 2. (No change.)

3. [Modest meals] **Meals** provided through the event organizer at an education event, **even if supported by a manufacturer**, provided the meals facilitate the educational program to maximize prescriber learning, **including information about disease states and treatment approaches. Meals in this context are not subject to the limitations set forth in the definition of "modest meals," nor are they subject to the bona fide services cap set forth at N.J.A.C. 13:45J-1.6.**

4. Modest meals provided by a manufacturer to non-faculty prescribers through promotional activities. **Modest meals in this context are not subject to the bona fide services cap set forth at N.J.A.C. 13:45J-1.6.**

5. – 10. (No change.)