11. A practitioner who is prescribing no more than a five-day supply of a controlled dangerous substance to a patient immediately, but no more than 24 hours, after the patient has undergone an operation or treatment for acute trauma, in a general hospital or a licensed ambulatory care facility, so long as that operation or treatment was not part of the care or treatment in the emergency department of a general hospital as provided in (a) above.

(d) (No change.)

13:45A-35.11 Professional misconduct

(a) Noncompliance with the rules in this subchapter may be deemed professional misconduct and may subject the pharmacy permit holder, an out-of-State pharmacy that is subject to this subchapter, pharmacist, practitioner, licensed health care professional, registered dental assistant, mental health practitioner, or licensed athletic trainer to disciplinary action pursuant to the provisions of N.J.S.A. 45:1-21 and to the penalties set forth in N.J.S.A. 45:1-49.

(b)-(c) (No change.)

(d) Noncompliance with the rules in this subchapter may provide a basis for the withdrawal of the authorization to a certified medical assistant or medical scribe to access the PMP. Upon receipt of the notice of proposed withdrawal, the certified medical assistant or medical scribe shall have an opportunity to provide a written explanation for the noncompliance.

(e)-(g) (No change.)

13:45A-35.12 Patient requests to correct inaccurate information

(a) A patient, or the parent or legal guardian of an unemancipated minor who is a patient, may request a pharmacy permit holder that submitted prescription monitoring information concerning a prescription for controlled dangerous substances for that patient or unemancipated minor to correct information that the person believes to have been inaccurately entered into that patient's or unemancipated child's prescription profile. The request shall be in writing using the process established by the pharmacy permit holder.

(b) A pharmacy permit holder shall have written policies and procedures for processing, evaluating, reviewing, and handling patient requests to correct information submitted to the prescription monitoring program. The policies and procedures shall include, at a minimum:

1. A statement explaining in detail the basis for the requested correction;

2. The precise change requested;

3. Documentation of the error and of the correct information; and

4. The requester's name, address, telephone number, and original signature.

(c) Upon receiving notice from a patient, or the parent or legal guardian of an unemancipated minor who is a patient, that the prescription monitoring data specific to that patient's prescription history is incorrect, the pharmacy permit holder shall:

1. Verify that the information is incorrect and, if so, correct the information in both the patient profile and the PMP within 14 days of the patient notification.

i. The pharmacy permit holder shall notify the patient when the information has been corrected in the PMP.

2. If the pharmacy permit holder determines that a correction is not appropriate or justified, within 14 days of the patient request, the pharmacy permit holder shall notify the patient, and advise the patient of the process for requesting the Board of Pharmacy to review the disputed request for correction.

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# (a)

## DIVISION OF CONSUMER AFFAIRS

## Limitations on and Obligations Associated with Prescriber Acceptance of Compensation from Pharmaceutical Manufacturers

## Adopted Amendments: N.J.A.C. 13:45J-1.1, 1.2, and 1.4

Proposed: August 6, 2018, at 50 N.J.R. 1704(a).
Adopted: February 8, 2019, by Gurbir S. Grewal, Attorney General.
Filed: April 9, 2019, as R.2019 d.037, 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: May 6, 2019.
Expiration Date: January 16, 2025.

**Summary** of Public Comments and Agency Reponses:

The official comment period ended October 5, 2018. The Attorney General received comments from the following:

1. Steve Borrus, MD, Lawrence Medical Associates;

2. Gregory J. Barone, DO, FACOI, Section Head, Endocrinology Division, Medical Director, Jefferson Nutrition Center, Jefferson Health;

3. Andrew M. Rosenberg, J.D., Senior Advisor, CME Coalition;

4. David Mullins;

5. John Juchniewicz, MCIS CHCP, MCIS, CHCP;

6. Kristen Dascoli;

7. Kristin Gusack;

8. Sara Brykalski;

9. Leslie Wood, Deputy Vice President, State Advocacy, and Joanne Chan, Assistant General Counsel, Law, Pharmaceutical Research and Manufacturers of America (PhRMA);

10. Maria Deutsch;

11. Shea McCarthy;

12. Amanda Kaczerski, MS, CHCP;

13. Patrick Plues, Vice President, State Government Affairs, The Biotechnology Innovation Organization (BIO);

14. Thomas Sullivan;

15. Sharyn S. Lee, RN, MS, FACEHP;

16. Susan H. Yarbrough, CHCP;

17. Paul G. Cook, CME Professional;

18. June Halper;

19. June Ikeda;

20. Andrea Funk;

21. Chris Prifte;

22. Dina Kouveliotes;

23. Faith Bantivoglio;

24. Rene Manzo;

25. Emily Scully;

26. Lynda Lyons;

27. Arielle Garbarino;

28. Betti Bandura;

29. Wayne McCourt;

30. Megan Lewis

31. Christy Marsh;

32. Shawna Graves;

33. Terry Ann Glauser, MD, MPH;

34. Jennifer Moore;

35. Katie Robinson;

36. Debra Toulson;

37. Cheryl Coco Capri;

38. Bridget OBrien;

39. Darla Thompson;

40. Renee Gay;

41. Zafar Ahmed;

42. Mira Valkova;

43. Kathy Merlo;

44. Megan Boone;

45. Leanne Berger;

46. Paula Talbott;

47. Marc I. Sandberg, MD, FACP, CDE, Medical Director, Diabetes Health Center, Diabetes and Endocrine Associates of Hunterdon, Clinical Assistant Professor, Department of Medicine, Temple University School of Medicine;

48. Marilou Halvorsen, President, New Jersey Restaurant & Hospitality Association;

49. Debbie Hart, President & CEO, BioNJ;

50. Kathy Whyte;

51. Jenna Gentile;
52. Ben Carson;
53. George Saunders, CFO, Matossian Eye Associates;
54. Kenneth T. Moore;
55. Dean J. Paranicas, President and Chief Executive Officer, Health Care Institute of New Jersey (HINJ);
56. Andrew G. Kaufman, M.D.;
57. Kelly Jordan;
58. Leigh Anne Leas, Vice President and US Country Head, Public Policy, Novartis Services, Inc.;
59. Christine Colella, Associate General Counsel, Eisai, Inc.;
60. Carolyn M. Bruguera, Vice President & General Counsel, Medical Device Manufacturers Association (MDMA);
61. Andrew L. Pecora, M.D., FACP, CPE, President Physician Enterprise, Chief Innovation Officer, Hackensack Meridian Health, Rosemarie J. Sorce Endowed Chair in Innovation, Professor of Medicine and Oncology at Georgetown University;
62. Neil Eicher, Vice President, Government Relations & Policy, New Jersey Hospital Association (NJHA);
63. Ronald L. Wisor, Jr., Partner, Hogan Lovells US LLP, on behalf of a global manufacturer of pharmaceuticals and other innovative health care products;
64. Daniel P. Ferrante, D.O., FACOG, Lifeline Medical Associates;
65. Melinda R. Martinson, General Counsel, Medical Society of New Jersey (MSNJ);
66. Jeff Gudin, MD, Director, Pain Management and Palliative Care, Board Certified: Pain Management, Addiction Medicine, Anesthesiology, Palliative Care; Englewood Hospital and Medical Center;
67. Laurie A. Clark, Legislative Counsel, on behalf of the New Jersey Association of Osteopathic Physicians and Surgeons, the New Jersey Society of Interventional Pain Physicians, the Neurological Association of New Jersey, and the New Jersey Podiatric Medical Society;
68. Alan Matarasso, MD, FACS, President, American Society of Plastic Surgeons; and
69. Tony Bawidamann, Vice President, Government Affairs, New Jersey Business & Industry Association (NJBIA).

1. COMMENT: One commenter expressed support for the proposed amendments because, while the commenter did not believe it was ever the intention of the former Attorney General to negatively impact physician education, the enforcement of a "modest meals" provision would have unnecessarily complicated event planning for those hoping to educate New Jersey physicians and would have placed an unrealistic burden on health professionals hoping to benefit from continuing medical education (CME). The commenter believes that the Attorney General's proposed amendments reverse what had amounted to a prohibition against providing meals and refreshments at continuing medical education conferences and programs. The commenter applauded this revision of the rule, which will encourage, rather than discourage, New Jersey physicians to participate in accredited CME activities. The commenter also stated that eliminating the strict limitation on the provision of refreshments from accredited CME activities will have a positive impact on physician participation in CME, without creating the sort of conflicts of interest the Attorney General rightly seeks to eliminate from any relationships between industry and physicians.

RESPONSE: The Attorney General thanks the commenter for its support.

2. COMMENT: Forty-seven commenters expressed support for the Attorney General's proposed amendments to relax New Jersey's strict limitations regarding the provision of meals during accredited CME conferences and activities. The commenters were particularly pleased that 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" and that patient outcomes will improve if we encourage, rather than stigmatize and limit, physician participation in accredited CME. The commenters also noted that, as having participated in numerous CME conferences, they feel strongly that any possibility of these meals serving as an inducement to encourage inappropriate physician prescribing practices is non-existent, while the benefits of participation in CME education are immense.

RESPONSE: The Attorney General thanks the commenters for their support.

3. COMMENT: Five commenters expressed support for the Attorney General's proposed amendments with respect to the clarification of the meal limits, the calculation of the limits, and definition of "consumer price index." In addition, the commenters appreciated the Attorney General's clarification that meals that are provided by an event organizer, even if supported by a manufacturer, are exempt from the limitations set forth in the definition of "modest meals" and from the bona fide services cap, and that modest meals provided to non-faculty prescribers through promotional activities are not subject to the bona fide services cap. One of these commenters noted that the proposed amendments will benefit the restaurant and hospitality business in the State. Another commenter stated that it believes that removing the cap on meals associated with educational events allows for greater facilitation of instructive activity for providers on the scientific advancements and clinical trial information on emerging and cutting-edge treatment options, which ultimately helps providers bring these treatments to patients in the most appropriate manner.

RESPONSE: The Attorney General thanks the commenters for their support.

4. COMMENT: One commenter expressed support of the proposed amendments to N.J.A.C. 13:45J. The commenter stated that lifting the limitations on modest meals to more reasonable amounts and providing additional exemptions from the capitation on bona fide services are welcome changes that will enable providers to continue to collaborate with pharmaceutical manufacturers in a way that encourages scientific innovation and discovery. The commenter further stated that, as home to some of the country's leading physicians and the North American headquarters of numerous pharmaceutical companies, it is imperative that New Jersey supports the collaboration between these two entities for the benefit of patients nationwide.

RESPONSE: The Attorney General thanks the commenter for its support.

5. COMMENT: One commenter expressed support for the proposed amendments, such that meals provided through the event organizer at an education event are not subject to the modest meals limitation. In addition, the commenter noted that, although a $30.00 cap for dinner is still lower than needed in many parts of the State, it appreciated the Attorney General reviewing this provision and increasing the maximum dollar amount allowed for dinner.

RESPONSE: The Attorney General thanks the commenter for its support.

6. COMMENT: One commenter expressed its support of the intent of the regulations to prohibit inappropriate payments from pharmaceutical manufacturers intended to influence or inflate prescribing. The commenter stated that overprescribing, particularly of opioids, can be dangerous to patients and wasteful of increasingly scarce healthcare dollars. The commenter further stated that allowing for the "modest meals" cap to increase with inflation and raising the cap for dinner meals to $30.00 are positive steps. In addition, the commenter stated that clarifying that the term "prescriber" only applies to those referenced professionals with an active New Jersey license will remove potential confusion. The commenter also stated that enhancing the educational exchange of researchers and prescribers by removing limitations for meals associated with education events is a welcome measure.

RESPONSE: The Attorney General thanks the commenter for its support.

7. COMMENT: One commenter recommended further amending the rules to clarify the nature of an educational event. The commenter suggested that the rules specify that a dinner meeting meets the definition of an educational event if the speaker is a physician or specialist who is an expert in the particular subject that is to be presented. The commenter believes that the company's product could be discussed as one of a number of treatments per Food and Drug Administration (FDA) regulations, in-depth discussions with time for questions could then occur, and that continuing medical education credits would not be necessary for the event to be considered educational. The commenter also believes that because these meetings have to be held after office hours, during dinnertime, providing meals is entirely reasonable.

The commenter stated that a promotional event should be regarded as one in which only the company representative is present to provide information about a drug, which generally occurs at breakfast or lunch meetings at the physician's office and believes that the $15.00 per person amount excluding costs such as taxes, tips, and delivery charges is reasonable. The commenter noted that, if a dinner meeting is held at the doctor's office for those with evening hours, then the $30.00 per person consideration would work, but dinner meetings at restaurants at $30.00 per doctor would not be practical at today's costs. The commenter also noted that these types of meetings in which the doctors join only the representatives for dinner were eliminated years ago.

The commenter believes that restoring these drug company-sponsored conferences would also have a positive economic effect on restaurants and audio-visual companies that participate. The commenter, moreover, believes that the opportunity to learn about new products, research involving drug efficacy in disease, and the dissemination of new information about medications would be paramount. According to the commenter, the knowledge would benefit not only the doctors, but would be of utmost importance to enhance the care of their patients.

8. COMMENT: One commenter sought confirmation that the educational events addressed through the amendment at N.J.A.C. 13:45J-1.4(a)3 include the variety of educational programs that pharmaceutical companies offer to prescribers. The commenter stated that, as drafted, the amendment to N.J.A.C. 13:45J-1.4(a)3 provides that meal limitations do not apply to meals provided at an educational event, "provided the meals facilitate the educational program to maximize prescriber learning, including information about disease states and treatment approaches." The commenter noted that, while pharmaceutical companies certainly provide many educational events offering information about disease states and treatment approaches, pharmaceutical companies also support a variety of other educational events for prescribers, such as speaker programs that address end-of-life issues for patients with certain disease states. The commenter sought confirmation that these and other speaker programs with an educational focus would not be subject to the meal limits identified in the regulations. The commenter suggested that the exemption for meals be revised to apply to meals intended to facilitate educational programs that "maximize prescriber learning, including information about disease states, treatment approaches, and other similar programming."

9. COMMENT: One commenter requested clarification that pharmaceutical manufacturers' "bona fide educational programs" are considered "education events" in accordance with the rules at N.J.A.C. 13:45J.

The commenter stated that bona fide educational programs, which are referred to as speaker programs, are designed to educate health care professionals about the appropriate uses and indications of medications and/or about related disease states. The commenter stated that such programs present information about pharmaceutical products supported by on-label information (and/or information that is consistent with a products label). The commenter also stated that the programs and their content are strictly governed by statutes and regulations administered and enforced by the FDA that require information presented be consistent with product labeling, truthful, and not misleading, supported by substantial evidence, and appropriately balance the benefits of the product with its risks. The commenter noted that manufacturers may utilize trained speakers who are compensated consistent with fair market value to present the information, that the programs are conducted in modest locations that are conducive to educational/informational communication, such as private rooms at restaurants that can accommodate a professional educational presentation, and entertainment and recreational venues are strictly prohibited per industry standard. The commenter stated that the sole purpose of conducting these bona fide educational programs is to further health care professionals' knowledge about the products and disease states presented.

The commenter believes that, consistent with the above description, a bona fide educational program conducted by a manufacturer would be an "education event" as defined under N.J.A.C. 13:45J-1.2. The commenter stated its understanding that the Attorney General's proposed revisions to N.J.A.C. 13:40A-1.4 to help ensure that the types of bona fide educational programs described above would not be unduly hindered by meal limits. The commenter stated that bona fide educational programs conducted by manufacturers are a critical resource for many health care professionals to receive the latest, most accurate information available regarding the benefits, risks, and appropriate uses of prescription medicines. The commenter, therefore, supports the proposed revisions and believes that they will enhance the ability of New Jersey prescribers to receive important scientific and educational information from pharmaceutical manufacturers to understand treatment options available to better serve their patients. The commenter, however, also believes that New Jersey prescribers and manufacturers would benefit from additional confirmation and clarity from the Attorney General concerning this issue to avoid confusion and ambiguity with respect to the proposed exception, to help ensure that New Jersey prescribers can be confident that attending such bona fide educational programs would not contravene the rules. The commenter requested that the Attorney General confirm and clarify in his commentary accompanying the final revisions to N.J.A.C. 13:45J and/or in sub-regulatory guidance regarding N.J.A.C. 13:45J that the types of bona fide manufacturer-conducted educational programs described here would not be subject to the meal limits.

10. COMMENT: One commenter expressed concerns with the rules at N.J.A.C. 13:45J because the difference between education and promotion is unclear, which creates an unnecessary barrier to pharmaceutical-sponsored educational events and has led pharmaceutical companies to cancel educational events. The commenter believes that activity that complies with FDA guidance and the pharmaceutical industry's guidelines should be a safe harbor.

11. COMMENT: One commenter recommended further amending the definition of "education event" to include speaking activities, whether through a bureau or other agency. The commenter believes that speaking activities and other training (for example, surgery, etc.) events that are compliant with industry guidelines should not be subject to the bona fide services cap. The commenter believes that these activities are necessary for educational purposes, including proper prescribing practices, and should be exempted from the annual compensation cap. The commenter noted that, as improper prescribing practices have been a contributing factor in opioid prescription abuse, properly educating prescribers in this area is critical to continuing the State's work to address the crisis.

12. COMMENT: One commenter suggested further amending N.J.A.C. 13:45J-1.4(a)3 to clarify that the modest meal limitation does not apply to meals provided at educational events even if they are "offered or supported by" the manufacturer. The commenter noted that pharmaceutical companies support two types of educational programming: (1) speaker programs, which are organized by and conducted on behalf of a company and (2) continuing medical education (CME) programs, which are provided by independent third parties but are funded by one or more companies. The commenter believes that that some prescribers may not understand the scope of the exemption for educational events and may incorrectly view it as limited to continuing medical education programs.

RESPONSE TO COMMENTS 7 THROUGH 12: The Attorney General believes that the existing definition of "educational event" at N.J.A.C. 13:45J-1.2 sufficiently encompasses a broad range of educational programs and activities, including those that may be offered by pharmaceutical manufacturers. The Attorney General, however, has learned that there may be a misunderstanding amongst prescribers and the pharmaceutical industry because of the FDA's classification of certain education programs as promotional. To the extent that this is the source of confusion that is impacting educational activities in New Jersey, upon adoption, the Attorney General changes the definition of "education event" to specify that notwithstanding the FDA's classification of a program as promotional, programs that meet the definition of "education event" are deemed "education events" for purposes of N.J.A.C. 13:45J.

Moreover, the Attorney General supports key thought leaders having the ability to be engaged by the pharmaceutical manufacturers to provide scientific information to prescribers to enhance patient care. The rules at N.J.A.C. 13:45J are intended to elevate the content and quality of the experience at the education event by requiring that it is held in a venue that is appropriate and conductive to informational communication and training about healthcare information, that 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 the main purpose for bringing attendees together is to further their knowledge on the topic(s) being presented.

As set forth in the notice of proposal, 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. To emphasize that healthcare information includes information about disease states and treatment approaches, upon adoption, the Attorney General changes the definition of "education event."

Additional public notice of these changes to the definition of "education event" is not required because they are clarifications that do not change the effect of the intent of the rule, so as to destroy the value of the original notice.

13. COMMENT: One commenter expressed concerns that the prescriber compensation cap of $10,000 was not increased. The commenter believes that this limit is arbitrary and will likely end up prohibiting the companies from providing the educational programs that this rulemaking acknowledges have value. The commenter stated that, if speakers are limited to a handful of engagements, there will not be a sufficient number of speakers to provide the programs. The commenter believes that, as a result, restaurants will continue to see a decline in business and providers throughout the State will continue to be limited in the ability to obtain important clinical information.

The commenter acknowledged the State's intent to ensure that providers are on "the up-and-up" when it comes to behaviors and influence from pharmaceutical companies but notes that the pharmaceutical industry is already heavily regulated. The commenter noted that all speakers who contract to provide promotional talks have to go through specific training, which includes compliance issues; the presented material is pre-approved by the FDA; speakers are not permitted to alter or adjust the slides presented; and there is legal recourse available for speakers who deviate from the contracted expectation. The commenter further stated that many individual pharmaceutical companies impose limitations on the amount an individual speaker can earn over the course of the year. The commenter believes that, for those cases where an individual provider's judgement or actions are inconsistent with best practices and favorable for a pharmaceutical company, a concern can be raised with the State medical board. The commenter questioned how limiting the amount of compensation to a provider protects the patients of New Jersey and expressed concerns about a state dictating to physicians how they can earn money.

14. COMMENT: Two commenters requested that the $10,000 bona fide services cap be removed. The commenters believe that the arbitrary cap set forth in N.J.A.C. 13:45J-1.6 could place New Jersey experts at a disadvantage with respect to other clinical experts in the tri-State area and could limit their ability to lend expertise to foster clinical excellence in New Jersey by ensuring that prescribers have the best information for making treatment decisions. The commenters stated that health care professionals should be able to offer their expertise without arbitrary limits when providing services currently subject to N.J.A.C. 13:45J-1.6, as long as the services meet the requirements of the federal Anti-Kickback Statute personal services and management contracts safe harbor at 42 CFR 1001.952(d).

15. COMMENT: One commenter noted that, although it is supportive of the proposed amendments to the increase in the modest meals cap for dinner and the exemption for activities that are educational, the commenter expressed concern that the prescriber compensation rules could have a deleterious impact on efforts to attract and maintain quality physician researchers to the State of New Jersey. The commenter noted that New Jersey has long been a critical cog in the life sciences industry, with more than 3,000 life sciences companies operating in New Jersey and an enhanced focus on research within institutions. The commenter believes that the implementation of limitations on prescriber compensation could further the "brain drain" in the health sciences fields, which New Jersey has experienced in recent years and could put New Jersey at a competitive disadvantage when compared to other states in the region with significant life sciences and research clusters. The commenter noted that New Jersey has typically ranked in the middle of all states in retaining physicians graduating from New Jersey-based graduate medical education programs, and ranks in the lowest quartile in both physicians nearing retirement and physicians under age 40. The commenter believes that additional regulatory barriers could further the exodus of physicians from the State in clinical, research, or academic settings. The commenter also believes that, as the health sector grapples with the possibility of physician shortages in all settings, the limitations on physician compensation could add to the State's issues in physician workforce development and retention, and negatively impact research and patient care alike.

RESPONSE TO COMMENTS 13, 14, AND 15: The Attorney General declines to change the bona fide services cap because he believes it is necessary to minimize the potential for conflicts of interest to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. In addition, the Attorney General notes that, in accordance with N.J.A.C. 13:45J-1.6, payments for research activities and payments to prescribers for speaking at education events are not subject to the bona fide services cap.

The Attorney General believes that a safe harbor provision is unnecessary and declines to change the rules to include one. The Attorney General believes that the rules at N.J.A.C. 13:45J are broader with respect to the permissible activities (for example, educational event) than allowed under FDA guidance. In addition, the Attorney General believes that the proposed amendments are consistent with the Federal Anti-Kickback Statutes and provide New Jersey prescribers necessary guidance, so as to ensure that their interactions with pharmaceutical companies are free from conflicts of interest.

16. COMMENT: Three commenters expressed concern that, even with the consumer price index amendment, the modest meal limitation is unrealistic, in light of the high cost of living in New Jersey due to it being part of the New York City and Philadelphia metropolitan areas. One of these commenters contended that this hampers the ability of pharmaceutical representatives to educate doctors on current inline products or new products coming to market and restricts the ability of physicians to learn more about the medicine in both promotional and non-promotional settings. The commenter stated that these breakfasts, lunches, and dinners provide a forum where physicians can discuss and ask questions about the medicines that they prescribe, either peer-to-peer or with a company's medical staff. The commenter further stated that these programs help better educate the physician on the medicine but are often times labeled internally [as promotional] by pharmaceutical companies and as a result are canceled because of the rule.

In addition, one of the commenters contended that, as pharmaceutical companies cancel these breakfast, lunch, and dinner programs, it has had a damaging effect on the State's restaurant and hospitality industry. The commenter stated that in a survey conducted by the New Jersey Business & Industry Association (NJBIA), its members forecasted a loss of over $8 million in revenue within the first year and that this lost revenue hurts businesses, their employees, and has a dramatic impact to the State's economy. The commenter, therefore, requested that the modest meal limitation be amended to allow pharmaceutical companies to offer meals to physicians that are modest in price by local standards.

17. COMMENT: One commenter noted that the rules at N.J.A.C. 13:45J have been challenging for both the pharmaceutical industry and the hospitality industry. The commenter stated that because the rules required meals given to prescribers be "modest" at no more than $15.00 per person, including tip, there was little room for employees in the restaurant and hospitality world to be appropriately compensated. The commenter also stated that because these meals between pharmaceutical representatives and prescribers act as the meeting during which a representative has the opportunity to educate prescribers on the medicine in questions, which is limited to opioids, the unintended consequences have caused confusion from the pharmaceutical industry as they attempted to find new ways to meet with and educate prescribers. The commenter noted that as a result of a survey of just over 100 restaurants, participants reported a forecasted loss of more than $8 million in revenue within the first year. The commenter also stated that employees will see a reduction in tips and a loss of hours due to a decrease in shifts.

RESPONSE TO COMMENTS 16 AND 17: The Attorney General recognizes the educational value of learning about disease states and treatment options, including when there are limited options, and believes that the amendments in this rulemaking will enhance the rules to further the educational exchange between practitioners and pharmaceutical manufacturers for the benefit of patient care. As discussed in the Response to Comments 7 through 12 above, upon adoption the Attorney General will change the definition of "education event" to clarify that it includes information about disease states and treatment options and that programs that meet the definition of "education event" at N.J.A.C. 13:45J-1.2 are deemed "education events" irrespective of the FDA's classification.

With respect to the concerns about the cap for modest meals, the Attorney General believes that the cap is reasonable.

18. COMMENT: One commenter expressed concern about the increased regulatory burden the rules at N.J.A.C. 13:45J place on manufacturers and providers. The commenter stated that its member companies already have extensive programs in place to ensure compliance with the Federal Anti-Kickback statute, Federal Sunshine Act, and the "Federal Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the U.S. Department of Health and Human Services Office of Inspector General (OIG). The commenter stated that OIG guidance also pertains to communications with healthcare providers and "gifts" that the proposed rule intends to regulate. The commenter further stated that, according to the OIG, compliance with the PhRMA Code of Conduct "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements." The commenter noted that the preamble to the originally proposed rules at N.J.A.C. 13:45J stated that these proposed prohibitions "closely mirror those set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code of Ethics for its member companies with respect to gifts to prescribers." The commenter further noted that the PhRMA Code was developed as a workable and reasonable approach to manufacturer interactions with healthcare providers and that, while many of its members are compliant with the PhRMA Code, there are some members that do not have resources for large scale marketing efforts, yet act within the guidance issued by the OIG. The commenter, moreover, noted that the Department of Justice may prosecute any company in violation of those guidelines.

RESPONSE: The Attorney General disagrees that current regulatory and/or voluntary compliance requirements are sufficient and believes that the proposed rules are necessary to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. In addition, the Attorney General notes that the rules at N.J.A.C. 13:45J place obligations upon prescribers.

19. COMMENT: One commenter expressed concern that the proposed amendments do not address the impact this rule may have on vital public health activities, including grants to hospitals and community health centers to support infectious disease screening and testing. The commenter is concerned that, unlike measures seen in other states, this rulemaking covers both direct and indirect compensation, including grants, scholarships, and charitable contributions, from pharmaceutical companies to providers, which will negatively impact critical public health efforts in New Jersey, while doing nothing to address opioid or other prescribing practices in the State. The commenter suggested that the regulation be amended to exclude public health initiatives from the prohibited or capped compensation definitions.

RESPONSE: The Attorney General did not intend, and does not believe, that the language at N.J.A.C. 13:45J-1.3(a) impacts public health initiatives or financial assistance, scholarships, or charitable contributions that are made to, and controlled by, an educational institution. In addition, to the extent that financial assistance or scholarships are offered to students, residents, or fellows who are not licensed pursuant to Title 45 of the Revised Statutes or practices, the Attorney General notes that the rules at N.J.A.C. 13:45J do not apply.

20. COMMENT: One commenter expressed concern with the overly broad definition of "immediate family member" in the rule and requested that the Division refine the definition. The commenter believes that it is impractical to expect that an immediate family member should automatically be known to manufacturers. The commenter stated, for example, that an individual interviewing for employment with a manufacturer may not reveal to the manufacturer that he or she is related to a physician, particularly if that individual happens to be a grandparent or other relative that is included in N.J.A.C. 13:45J-1.3. The commenter also stated that the same may be true in situations at conferences or other non-product specific educational programming events. The commenter noted that many manufacturers, through their philanthropic endeavors, provide non-product specific educational forums intended to provide general information on disease-states, such as cancer or HIV/AIDS and that these sessions often include refreshments, dinners or receptions for participants. The commenter believes that it would be impossible for the company to know who is an "immediate family member" under the definition contained in the rule, and, as a result, this could have a chilling effect on non-product related endeavors.

RESPONSE: The Attorney General disagrees that the definition of "immediate family" is overly broad and notes that the definition is consistent with the State's conflict of interest law at N.J.S.A. 52:13D-13.i. The relationships that are subject to the rule reflect the types of relationships with the potential to result in undue influence and are limited to spouse or equivalent, children, and only those other relatives who reside in the same household as the prescriber. In addition, the Attorney General notes that N.J.A.C. 13:45J-1.3(e) specifically states that the rules do not apply to an immediate family member who 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.

21. COMMENT: One commenter noted its support for the State's efforts aimed at addressing the ongoing opioid crisis and supports efforts to ensure prescribers and patients alike are educated on the dangers of opioid abuse. The commenter, however, believes that the rules at N.J.A.C. 13:45J concerning compensation from biopharmaceutical manufacturers would have a negligible impact on opioid use and abuse. The commenter further believes that the rules could serve as a disincentive for physicians, researchers, and others to maintain their New Jersey professional licenses. The commenter recommended repealing the rules at N.J.A.C. 13:45J.

22. COMMENT: One commenter objected to the existing $10,000 per year bona fide services cap on the amount paid by pharmaceutical companies to doctors who write prescriptions. The commenter stated that when the rule was first proposed, the overwhelming preponderance of comments opposed it but it was still adopted despite any evidence that there was an issue that the rule addressed. The commenter averred that if the rule was intended to curtail opioid abuse, it is not the impact that it will have. The commenter believes that this rule limits what doctors can legitimately do in advising pharmaceutical companies without any evidence that such income is connected in any way to the prescriptions that doctors write. The commenter noted that doctors are highly-trained professionals and experts in their areas of specialty, who are often hired as consultants to pharmaceutical companies to advise them on how doctors use their medications in practice, how to introduce new medications in a market, or how to best educate doctors on the correct usage of their products. The commenter stated that this is a longstanding practice and there is no evidence that the payments for such services influence doctors in the prescriptions they write. The commenter believes that limits on payments from pharmaceutical companies to doctors for expert consulting services is using a "sledgehammer to pound a small finishing nail," unfairly limits the ability of doctors who have spent years developing their technical expertise from earning income based on that expertise, and is a restraint on trade. The commenter stated that is not uncommon for doctors to earn far more than $10,000 from such services, so the limit of $10,000 annually is out of line with actual practice. The commenter further noted that no other state has passed such a rule, so the rule places New Jersey doctors at a disadvantage.

The commenter stated that, if the intent of the rule is to limit the abuse of dangerous drugs, that would be relatively easy to do with readily available data because all payments from pharmaceutical companies to prescribers is listed by Medicare in a national database and the amount of prescriptions doctors write is also available in a State database. The commenter believes that if there is evidence that payments for expert services leads to increased writing of prescriptions of dangerous substances, then it should be relatively easy to address with specific providers. The commenter does not believe that all doctors should be

punished on the chance that some doctors may behave improperly. The commenter also noted that, as the largest single payor for medical services, Medicare has chosen to address the possibility of corrupt intent related to doctor/pharmaceutical company relationships by using transparency in posting payments on a national database, so that all can see what doctors get paid for their expertise, and has not opted to limit such payments because there is no evidence that there is any correlation between payments to doctors and the prescriptions they write in the normal course of their practice.

The commenter urged the Attorney General to repeal the entire rule because it serves no purpose other than to penalize New Jersey physicians.

RESPONSE TO COMMENTS 21 AND 22: The Attorney General declines to repeal the rules at N.J.A.C. 13:45J, which are intended to strengthen enforcement efforts to address prescriber acceptance of items of value from drug manufacturers. The Attorney General notes that studies show that gifts, no matter their size, can influence prescriber decision making. Although the Attorney General agrees that the rules are an additional step to stem New Jersey's opioid epidemic, the new rules are designed to reduce incentives for treatment decisions to be influenced by payments from drug manufacturers, which will encourage healthcare practitioners who prescribe to focus on the patient's best interests, and to minimize the potential for conflicts of interest to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. In addition, the proposed amendments elevate the educational quality of the interactions at between prescribers and pharmaceutical manufacturers that occur at education events.

23. COMMENT: One commenter raised concerns about the applicability of the rules at N.J.A.C. 13:45J to State licensed practitioners whose primary practice site is in other states. The commenter believes that these dually licensed practitioners may decline to attend necessary training and other educational activities outside of New Jersey as a result of the underlying compensation limitations. The commenter recommended amending the rules to apply to only activities held within the State or to practitioners who spend the majority of their practice time within New Jersey. The commenter also stated that, while the proposed amendments are important to clarifying to whom the rules will apply, the proposed amendments may cause unintended confusion among certain prescribers. The commenter encouraged the Attorney General's office to work with the Board of Medical Examiners and others to ensure a communications plan is in place to provide adequate notification of this clarification to all holders of New Jersey licenses without regard to practice site. The commenter believes that the communications effort could help to prevent unintended rule violations by a prescriber serving a small number of New Jersey patients while practicing in a non-New Jersey clinical setting.

24. COMMENT: One commenter raised concerns about the proposed amendments to N.J.A.C. 13:45J-1.1, which clarifies the scope of prescribers subject to the regulations to include any "prescriber who holds an active New Jersey license" and either "practices in New Jersey" or "has New Jersey patients regardless of the prescriber's practice site." The commenter understands that the purpose of the proposed amendments is to ensure that the obligations imposed by the regulation are placed only on those prescribers who treat a significant number of New Jersey patients, rather than create a nationwide requirement for all New Jersey-licensed prescribers. The commenter, however, believes that rather than simplify matters, the addition of the new limitation inadvertently creates more confusion about which prescribers are subject to the regulation.

The commenter agreed with the proposed amendment to make the rules applicable to prescribers with an active New Jersey license who practice within the State and noted that whether a prescriber meets this criteria is clear and easily determined.

The commenter, however, stated that the category of prescribers who would be subject to these regulations who have an active New Jersey license who have "New Jersey patients regardless of the prescriber's practice site," is not as well defined. The commenter stated that this language could apply to any prescriber with a New Jersey license in any state who treats even a single New Jersey patient. The commenter understands that many New Jersey residents travel to bordering states for medical treatment and agree that regional prescribers who treat these patients should be subject to the regulation, but expressed concern that this amendment would mean that the regulations are also applicable to many distant prescribers who do not regularly see New Jersey residents. The commenter stated, for example, a physician located in California who treats an occasional New Jersey patient visiting the state may be subject to these regulations even if the vast majority of the physician's patients are located in California, or, similarly, a Chicago-based physician who treats a college student with New Jersey residency may also have to comply with these regulations. The commenter contended that, in many cases, the treating physician may be unaware of the patient's state of residence and that requiring out-of-State prescribers to screen all patients for New Jersey residency would place an enormous burden on prescribers.

The commenter also believes that making all New Jersey-licensed prescribers who treat any New Jersey patient subject to the new regulations could also have unintended consequences. The commenter stated, for example, that a New Jersey prescriber located in a different state may unwittingly violate the regulation by accepting meals in excess of the limits because the prescriber does not anticipate seeing any New Jersey patients, only to later treat a patient from the State, or an actively licensed New Jersey prescriber located outside the New Jersey region may refuse to treat the occasional New Jersey patient altogether to prevent violating the regulations. The commenter contended, therefore, that compliance with the regulation could create significant challenges for patients and prescribers and could render the additional limitations, which were meant to narrow the scope of the regulation, meaningless.

The commenter suggested that New Jersey consider removing the portion of the amendment applying the new regulations to any New Jersey-licensed prescriber who "has New Jersey patients regardless of the prescriber's practice site." The commenter believes that this change would render the requirements applicable only to any New Jersey prescriber with an active medical license who practices in New Jersey. Alternatively, the commenter suggested that the regulation could be amended to apply to New Jersey-licensed prescribers who practice in New Jersey or "regularly and routinely treat a significant number of New Jersey patients every year." The commenter believes that limiting application of these requirements to prescribers who practice in the State or regularly treat New Jersey patients would not only be more practical from an implementation standpoint, it would also be consistent with the Attorney General's clarifications limiting the reach of these regulations.

RESPONSE TO COMMENTS 23 AND 24: The Attorney General believes that the rules should apply equally to all prescribers licensed by the State and that no distinction should be made for where the prescribers regularly practice.

25. COMMENT: One commenter recommended that the State delay implementation of the prescriber compensation limitations to ensure adequate compliance processes are established for prescribers impacted by the limitations. The commenter believes that the Division should work with the Board of Medical Examiners to work proactively with professional societies, manufacturers, research institutions, and other stakeholders to ensure significant prescriber awareness of the new rules and regulations. The commenter believes that the delay will allow the health care continuum adequate time to prepare for new rules and regulations.

RESPONSE: The Attorney General declines to delay implementation of the proposed amendments to N.J.A.C. 13:45J. In addition, the Attorney General notes that the rules at N.J.A.C. 13:45J, including the bona fide services cap, have been in effect since January 16, 2018.

26. COMMENT: One commenter expressed concern with the applicability of the rules at N.J.A.C. 13:45J to those manufacturers who manufacture biologics or pharmaceuticals and medical devices. The commenter noted that in connection with the original rulemaking, the former Attorney General made clear that the rules were not intended to apply to medical devices. The commenter believes that the existing rules unintentionally impact prescribers who interact with a hybrid company regarding only that company's medical devices because the company is also a pharmaceutical manufacturer. The commenter, therefore, suggested amending N.J.A.C. 13:45J-1.1 as follows (addition in bold):

"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. **The rules in**

**this chapter do not apply to prescribers' interactions with pharmaceutical manufacturers to the extent that (i) such pharmaceutical manufacturers also manufacture medical devices and (ii) such interactions are directed solely to medical devices.**"

The commenter urged this clarification to avoid the unintended consequence of the rules regulating prescribers' interactions with the industry relating to medical devices.

27. COMMENT: One commenter requested that the Attorney General resolve an ambiguity in the current wording of the rules at N.J.A.C. 13:45J and in its application to companies that manufacture both pharmaceuticals and other health care products, such as medical devices. The commenter noted that some manufacturers of pharmaceuticals or biologics also manufacture medical devices/and or other health care products that are not regulated by the FDA as drugs or biologics. The commenter stated that, under a strict textual reading of the rules, such a hybrid entity would seem to fall within the definition of a "pharmaceutical manufacturer" because it does, in fact manufacture pharmaceuticals. The commenter believes that this ambiguity creates the unintended consequence of potentially regulating medical devices, that is, even if a prescriber's interactions with a hybrid manufacturer relate only to a company's medical devices, that prescriber seemingly is subject to the rules' limitations if the company also is a pharmaceutical manufacturer. The commenter further stated that the rules also place on prescribers the potentially difficult task of determining whether medical device company representatives with whom they interact are part of a larger organization that also manufactures drugs or biologics. The commenter requested the following clarification at N.J.A.C. 13:45J-1.1 (addition in bold):

"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. **The rules in this chapter do not apply to prescribers' interactions with pharmaceutical manufacturers to the extent that (i) such pharmaceutical manufacturers also manufacture other products that are not regulated by the FDA as drugs or biologics, and (ii) such interactions are related solely to such other products.**"

The commenter urged this clarification to avoid the unintended consequence of the rules regulating prescribers' interactions with industry relating to medical devices and other health care products that the Attorney General did not intend to bring within the scope of the regulation. The commenter believes that its suggested clarification also will prevent hybrid manufacturers, from being unfairly disadvantaged in their interactions with health care professionals when those interactions relate solely to medical devices, given that other device manufacturers with which they compete are plainly not subject to the rules. The commenter stated that, because this modification to the rules would not change its intended effect, and because the Attorney General's response to comments on the original rule provided adequate notice of the Attorney General's intent not to apply the rule to medical devices, we believe the Attorney General may, and should, adopt the proposed modification without requiring additional public notice.

RESPONSE TO COMMENTS 26 AND 27: As noted in the original rulemaking, the Attorney General never sought for the rules at N.J.A.C. 13:45J to apply to manufacturers of medical devices (see 50 N.J.R. 578(a)). The Attorney General agrees with the commenters that clarification is needed with respect to those manufacturers that manufacture biologics or pharmaceuticals and medical devices. Accordingly, upon adoption, the Attorney General will change N.J.A.C. 13:45J-1.1 to clarify that the rules in the chapter do not apply to prescribers' interactions with pharmaceutical manufacturers to the extent that such pharmaceutical manufacturers also manufacture medical devices and that such interactions are directed solely to medical devices. Additional public notice of this change is not required because it provides clarification as to the applicability of the rules and does not change the effect of the intent of the rule so as to destroy the value of the original notice.

28. COMMENT: One commenter raised concerns about the bona fide services cap and believes that if participation on advisory boards is for scientific purposes, then compensation for this important work should not be capped. The commenter stated that the work of the vast majority of physicians participating in similar educational venues has nothing to do with narcotics or other pain medications, of which the "original Physician Gift [Ban]" was designed to curtail. The commenter stated that the Gift Ban has severely curtailed the critical need for physician education in a wide spectrum of medical disorders, thus, limiting the knowledge of New Jersey physicians to understand the benefits and risks of the latest technology to help patients. The commenter requested that the rules be limited to opiate educational and promotional activities, otherwise, the rules will have the unintended consequence of limiting the important information exchange between pharmaceutical companies and physicians on new medications and treatment protocols to improve quality of life for those suffering from chronic diseases.

29. COMMENT: One commenter expressed concerns with the rules at N.J.A.C. 13:45J because the rules have had an unintended "chilling effect" on the ability to recruit researchers to the State, as well as have fostered a perception that the State is hostile to those closely affiliated to pharmaceutical research. The commenter believes that, as written, the current rule would limit licensed clinicians to no more than $10,000 per year, in total, from all pharmaceutical manufacturers, to participate on advisory boards or consult with life science companies. The commenter stated that researchers from across the country view this approach as a negative, a barrier to their desire to work in a field that may result in a therapy via pharmaceutical intervention. The commenter also stated that it recognizes the role incentives play in the field, and guidelines currently exist that require researchers to be transparent in their relationships with pharmaceutical companies. The commenter contended that the mere existence of the cap has fostered distrust and concern among prescribers.

In addition, the commenter stated that recruiting from other states has been rendered far more difficult as a result of this perception. The commenter stated that it has heard that physicians that live in New Jersey but practice in New York have considered giving up their New Jersey licenses to avoid these restrictions. The commenter contended that its own recruitment hit rate (the percentage of physicians who interview and take the job, divided by all those who interview) for new physicians has dropped 30 percent in the past six months due to the regulation. The commenter stated that the increase to $30.00 for dinner does not solve this problem. The commenter believes that the cap of $10,000 should not apply to those who serve on pharmaceutical company scientific advisory boards, or serve as consultants, certainly for those companies that do not manufacture opioids.

The commenter also recommended amending N.J.A.C. 13:45J-1.4(a)5 to exclude faculty organizers or academic program consultants from the bona fide services cap.

The commenter stated that prohibiting grants and scholarships also cause potential issues for the recruitment of young physicians. The commenter urged the Attorney General to consider permitting pharmaceutical companies to support grants and scholarships to advance the careers of those physicians who seek to pursue research as a core component of their education. The commenter believes that such support will not lead to inappropriate prescribing but rather help address workforce concerns.

The commenter believes that limiting branded talks or non-educational or non-scientific endeavor activities while removing all cap restrictions and limits on life science supported activities (including advisory boards and consulting) would address the fundamental problem. The commenter suggested that perhaps a different approach might be taken that would require transparency but without the burden of caps. The commenter stated, for example, prescribers might be required to reveal their income from pharmaceutical manufacturers on an annual basis to their respective licensing boards if they serve as a consultant or participate on an advisory board for a pharmaceutical manufacturer.

30. COMMENT: One commenter suggested exempting participation on advisory boards and consulting arrangements for education or research from the $10,000 limit on payments for bona fide services. The commenter stated that these arrangements may have value for research and education. The commenter expressed concern that the rules impede the progress of clinical trials and medical research in New Jersey. The commenter stated that recruiting and retaining the highest quality medical

faculty and researchers remains a top priority for many New Jersey hospitals. The commenter noted that confusion and hesitation surrounding the restrictions on advisory boards and consulting arrangements have been cited as making the task of recruitment more difficult.

The commenter also stated that it has heard concerns regarding the limitation of grants and scholarships, which inhibits the recruitment of young physicians. The commenter urged the Attorney General to consider permitting pharmaceutical companies to support grants and scholarships to advance the careers of those physicians who seek to pursue research as a core component of their education.

RESPONSE TO COMMENTS 28, 29, AND 30: As stated in the Response to Comment 19, the Attorney General did not intend, and does not believe, that the language at N.J.A.C. 13:45J-1.3(a) impacts financial assistance, scholarships, or charitable contributions that are made to, and controlled by, an educational institution. In addition, to the extent that financial assistance or scholarships are offered to students, residents, or fellows who are not licensed pursuant to Title 45 of the Revised Statutes or practices, the Attorney General notes that the rules at N.J.A.C. 13:45J do not apply.

The Attorney General agrees that research activities and clinical trials are in the overall best interest of the patients and should not be curtailed. The Attorney General believes that the existing definition of "research" at N.J.A.C. 13:45J-1.2 sufficiently encompasses a broad range of activities, including participation on advisory boards and consulting in connection with research.

As defined at N.J.A.C. 13:45J-1.2, "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.

Accordingly, payments for participation on advisory boards or consulting, which meet the definition of "research," are not subject to the bona fide services cap. Similarly, payments for speaking at education events are not subject to the cap, but must be for fair market value and set forth in a written agreement.

The Attorney General believes the cap should include participation on advisory boards and consulting arrangements, other than those related to research or for payments to speakers at education events, to minimize the potential for conflicts of interest to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. Accordingly, the Attorney General declines to otherwise exempt consultants or advisory roles from the bona fide services cap.

The recruitment and retention of physicians in the States is a complex issue that entails many decision-making factors. The Attorney General does not believe that the enhanced rules at N.J.A.C. 13:45J are the motivating factor for physicians to determine whether to remain in New Jersey.

31. COMMENT: One commenter appreciated the work of this Administration, and, in particular, the Division, to craft amendments to the rule limiting compensation from pharmaceutical companies to physicians in a way that will advance research, science, and education in New Jersey. The commenter is heartened that the important peer-to-peer education about medications will be accommodated by the proposed amendments, as understood by the commenter. The commenter, however, expressed concern that the proposed amendments are not well understood by the physician and pharmaceutical industry. The commenter stated that this concern is based upon: dinner meetings being cancelled; contracts not being renewed for speakers' bureau programs; speakers' bureau participants not being scheduled; and physicians being asked not to eat meals at educational functions, including CME. The commenter noted that all want to comply, so it is important that the rule is clarified to ensure that important educational activities will recommence.

The commenter requested the Division to clarify, in the adoption preamble or through the responsive comments, that certain educational events (commonly understood to be speakers' bureau programs) that comply with the amendments are not subject to the $10,000 cap in terms of the meal cost and in terms of the speaker's fee. In addition, the commenter believes that education, that complies with the FDA guidance document on marketing [Guidance for Industry, Industry-Supported Scientific & Educational Activities, 62 FR 232 (Dec. 3, 1997)] and that conforms to the industry guidelines [Code on Interactions with Healthcare Professionals, Pharmaceutical Research & Manufacturers of America (January 2009)], should be considered to be in a safe harbor. The commenter stated that FDA and pharmaceutical industry guidelines are extensive and taken seriously by both the companies and physicians; speakers are trained and compliance programs are in place; and physicians expect to follow the rules and the companies monitor their compliance. The commenter contended that a safe harbor would go a long way toward assuring the medical community that this important peer-to-peer education is exempt from the cap.

The commenter noted that many of its members are relieved to be able to attend speakers' bureau programs to learn about new and emerging treatments from the speakers, as well as their peers, and many have expressed grave reservations that rare diseases, for which there are effective treatments, will not be diagnosed and that this will result in sub-par medical treatment, pain and suffering, and unnecessary cost. The commenter also noted that, especially in the area of rare diseases, physicians rely upon their expert peers to become educated, in order to accurately diagnose and provide better care to patients. The commenter expressed hope that these educational activities will be reinvigorated in the State (both in terms of program offerings for participants and for physician speakers) to facilitate better medical treatment. The commenter stated that for physicians who research and treat serious illness, such as Hereditary Angioedema (HAE), it has been frustrating to stand on the side lines as new medications are being released that could save and change lives.

The commenter expressed concern that the original rule was overbroad in scope and will have unintended consequences. The commenter stated that the rule was well-intended to address the serious opioid public health crisis and believes that all in the medical community must do their part to prevent opioid addiction.

The commenter noted that part of its objection to the original rules was based on a granular analysis of the data that the prior administration relied upon to conclude that compensation from the pharmaceutical industry to physicians is always suspect and will always result in bias. The commenter stated that analysis of the payments reveals that the very object of the rule (preventing opioid addiction) will be thwarted by the application of the cap on compensation to physicians, who are working with the pharmaceutical industry and the FDA to develop opioid alternatives, opioids that cannot be abused, and opioid antidotes. The commenter stated that this research and development work is imperative to address the public health issue of opioid addiction. The commenter also believes that this work (research and development) was meant to be exempt from the rule but, because this work is often performed under a consulting arrangement or by serving on an advisory board it may be suspect.

The commenter provided as an example a physician who was listed among those receiving compensation from the pharmaceutical industry, and allegedly part of the problem, is an expert in analgesics, and is a leader in the State on efforts to avoid the use of opioids by working with pharmaceutical companies and the FDA to develop less addictive pain medications. The commenter believes that this is exactly the kind of endeavor that the rule should embrace and advance but, instead, it is suspect. The commenter stated that compensation related to the solution to the opioid problem should be exempt from the cap on compensation. The commenter, moreover, believes that New Jersey can only lead on solutions to the opioid crisis if this Administration allows this important work to continue. The commenter also provided as an example physicians, who specialize in headaches and wish to educate their peers on how to bring new medications to their patients to prevent pain, suffering, and debilitation that could result in the use of opioids.

The commenter noted that participation on advisory boards is almost always for research and development purposes. The commenter stated that physicians are sought to give advice on the clinical response and side

effects to medications and to further refine medications. The commenter also stated that, generally, advisory board meetings last a couple of hours, follow strict agendas, and are professional in nature. In addition, the commenter stated that the discussions are focused and include industry representatives, as well as physicians who are leaders in their field. The commenter believes that it is an important means for manufacturers to obtain input from practicing physicians on product effectiveness in real life scenarios.

The commenter expressed concern that there is a misimpression that advisory board participation is essentially promotional and subject to the cap. The commenter believes that the intent of both the original rule and the proposed amendments is to advance research, development, and education, as evidenced by the expansion of the rule to include pre- and post-market activity (See 50 N.J.R. 578(a)). The commenter noted that physicians who serve on these boards ordinarily meet several times a year and spend considerable time preparing for the meetings, which may include review of their own clinical data, as well as that of others. The commenter contended that it is unreasonable to expect that physicians would be able to commit extensive time and expertise on a charity basis and that it is only fair that physicians be compensated for this important work. The commenter also contended that this collaboration is important so that pharmaceutical companies learn about patient response to improve their products. The commenter believes that a cap on this kind of work may force the leading physicians in New Jersey to discontinue the work or to leave the State. The commenter stated its belief that, so long as the advisory board activity is for research and development and not marketing, it is not subject to the cap. The commenter, asked that compensation for advisory board participation and consulting that is for research and development purposes not be capped and believes that this is a fair interpretation of the rule.

The commenter stated that, while the rule limiting compensation from pharmaceutical companies to physicians was clearly well intentioned, it is concerned about unintended consequences. The commenter believes that the rule will have a negative impact on public health because the rule applies to all medications, not just opioids. The commenter urged the Division to make clear that advancing a drug without mention of a competitive product is not in and of itself promotional if the drug is one of a kind. The commenter noted that the FDA guidance specifically addresses the issue, when it indicates that competing products should be reviewed, "except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies." 62 CFR at 64097. The commenter also expressed concern about the impact on an innovative public/private partnership in which profits from the commercial sale of a specific product are used to defray the cost to low-income women and requested that, given the important public health initiative, the promotion of the specific product through the public/private initiative, not be swept into the cap on compensation to those physicians who have made this initiative possible. The commenter contended that, while the abuse of opioids is a compelling public health issue, worthy of efforts to solve from all in the healthcare system, other public health issues may inadvertently be damaged by the rule.

The commenter also expressed concern with the impact on recruiting and retaining physicians in the State. The commenter stated that it is well documented that the majority of physicians trained in New Jersey leave the State to practice elsewhere (See Wallet Hub Survey available at https://wallethub.com/edu/best-and-worst-states-for-doctors/11376/). According to the commenter, the conventional wisdom is that newly licensed physicians are unlikely to stay in New Jersey unless they have significant family ties in the State. The commenter, moreover, stated that large group practices report that it is difficult to attract physicians to the State and that the high cost of living and negative environment for physician practice are factors. The commenter believes that the rules at N.J.A.C. 13:45J are yet another reason that physicians will not be attracted to the State. In addition, the commenter alleged that physicians from New York City and Philadelphia are no longer willing to maintain a New Jersey license because it will subject them to the rule, and it is expected these dually licensed physicians will drop their New Jersey licenses. In addition, the commenter contended that these physicians are no longer responding to offers to relocate to New Jersey.

In addition, the commenter stated that equally troubling is the loss of capacity to treat strokes because stroke specialists licensed in Pennsylvania and working in greater Philadelphia willing to treat stroke victims in South and Central Jersey through telemedicine will no longer pursue New Jersey licenses to be able to do so because of the breadth of this rule. The commenter further stated that an unmet medical need will remain unfulfilled because licensure in the State coupled with treatment via telemedicine would foreclose the potential to collaborate with pharmaceutical companies and be compensated for doing so.

The commenter contended that physicians approaching the end of their clinical work are particularly hurt by this rule. The commenter stated that some have reached the height of their expertise (usually from research and development) and plan to phase out their clinical practice, while continuing to collaborate on drugs that they may have helped to develop. The commenter also stated that these physicians are no longer prescribing, yet they fear that they can no longer accept any compensation for continued work. The commenter contended that many physicians believe that they have a free speech right to discuss and be compensated for their expertise. See *Sorrell v. IMS Health Inc.*, 564 *U.S.* 552 (2011). The commenter believes that physicians who do not prescribe or treat patients should be exempt from the cap.

The commenter believes that it is in the interest of the residents of New Jersey for the pharmaceutical industry to continue to grow and that patients and physicians benefit from the collaboration between New Jersey physicians and the pharmaceutical industry. The commenter stated that a rule that makes it more difficult for the pharmaceutical industry to use New Jersey medical talent for research and development activity will cause the industry to find the State a less attractive place to do business. The commenter urged the Division to think about the long-term consequences of the rule as it incents the industry to pass over New Jersey physicians for its important research and development needs.

The commenter stated that, for all of the above reasons and to implement the underlying intent of the regulation, it respectfully urged the Division to limit the rule to opioids.

RESPONSE: The Attorney General declines to eliminate the cap for bona fide services and notes that studies show that gifts, no matter their size, can influence prescriber decision making. The intent of the rules at N.J.A.C. 13:45J is to minimize conflicts of interest, so that prescriber treatment decisions are guided by the best interest of patients. In addition, although the Attorney General agrees that the rules are an additional step to stem New Jersey's opioid epidemic, the intent of the rules is to apply to all prescription medications, so as to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber.

The Attorney General agrees with the commenter that payments for participation on advisory boards, which includes both pre- and post-market activities that meet the definition of "research," are not subject to the bona fide services cap. (See Response to Comments 28 through 30).

The Attorney General also notes that in accordance with the definition of "prescriber" at N.J.A.C. 13:45J-1.2, 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, is not subject to the rules at N.J.A.C. 13:45J.

The Attorney General believes that a safe harbor provision is unnecessary and declines to amend the rules to include one. (See Response to Comments 13, 14, and 15).

With respect to the concern raised about speakers' bureau programs, as discussed in Response to Comments 7 through 12, upon adoption, the Attorney General changes the definition of "education event" to specify that notwithstanding the FDA's classification of a program as promotional, programs that meet the definition of "education event" are deemed "education events" for purposes of N.J.A.C. 13:45J. In accordance with the rules, educational programs that meet the definition of "education event" at N.J.A.C. 13:45J are not subject to the modest meals limitations, nor are payments for speaking at such events subject to the bona fide services cap.

The recruitment and retention of physicians in the States is a complex issue that entails many decision-making factors. The Attorney General does not believe that the enhanced rules at N.J.A.C. 13:45J are the motivating factor for physicians to determine whether to remain in New Jersey.

32. COMMENT: One commenter requested that this Administration consider the unintended consequences of a well-intentioned regulation. The commenter believes that the effort to stem the opioid crisis is simply too wide reaching and will result in negative public health impacts. The commenter noted that he writes from his own personal experience as a former principle investigator, a trainer, instructor, and speaker, and expressed his concern about the long-term negative impacts of a rule that should have been limited to the crisis by regulating the promotion of opiates. In addition, the commenter noted his participation at the advisory board level in a first of its kind partnership between a non-profit and for-profit pharmaceutical manufacturer, in which the money generated by sales in the private sector would fund the product for women in underserved communities so that they could purchase it at a reduced price.

The commenter also noted that he is considered a national opinion leader in the fields of reducing unintended pregnancies, reducing preterm deliveries, and cord blood stem cell preservation, and attended advisory boards and spoke around the nation in an attempt to assist in the promotion of NIH-promoted health initiatives. The commenter stated, however, that since the former administration eliminated these activities he has not spoken or been to an advisory board, and that the companies that have used him are now afraid to violate any law, especially ones they do not understand.

The commenter noted that he only took assignments that have major public health implications, yet have been foreclosed from doing so in any meaningful way since this regulation took effect. The commenter contended that it is in the public interest and the health of mothers and infants for physicians like him to educate, and even to promote, the use of a specific novel drug. In addition, the commenter noted that he is actively involved in the research and development of treatment with stem cells, which are successfully being used to treat neurologic conditions, such as cerebral palsy in addition to such common conditions as juvenile onset diabetes, stroke, and myocardial infarction through a new field called regenerative medicine where stem cells can regenerate damaged cells and tissues all over the body.

The commenter further noted that all of the public health issues that he speaks about have benefitted from drugs developed by the pharmaceutical industry. The commenter stated that, of course, the drug manufacturers make money from the sales of the products, the same money that funds the product development in the first place. The commenter further stated that the pendulum has swung so far that this has now become vilified. The commenter noted that the opioid crisis somehow translated into "all drug companies and their promotion as unethical" in New Jersey, but the reality is that this very misguided policy has resulted in New Jersey physicians being unable to benefit from education in legitimate public health and medical issues whether they be promotional or not. The commenter questioned how all pharmaceutical companies became perceived as "evil profit gorging monsters," when there are examples how they clearly are not.

In addition, the commenter contended that medications that serve the public interest should be promoted, and profit from their sale as well, so that the research and development of the next drug--that may change the life of a family member--can be developed. The commenter does not believe that there can be an across-the-board rule like this that ties the hands of physicians like him and denies New Jersey doctors from legitimate education and research opportunities on important drugs with favorable public health impacts because we have an opioid crisis.

The commenter further noted that he will regrettably give up his New Jersey medical license if he is unable to pursue his life's work. The commenter stated that he is so committed to these public health causes that he will give up his license to continue to pursue these public health goals. The commenter also stated that it is a personal loss to him, but he believes also a loss to New Jersey in that he is considered a national thought leader on these initiatives.

RESPONSE: The Attorney General commends the valued work prescribers do in connection with public health initiatives and agrees that educating prescribers is an important service and that prescribers may also benefit from educational programs that may be offered by pharmaceutical manufacturers. Moreover, the Attorney General notes that there is no intent to restrict the ability of key thought leaders to be engaged by the pharmaceutical manufacturers to provide scientific information to prescribers to enhance patient care. The proposed amendments elevate the educational quality of the interactions at between prescribers and pharmaceutical manufacturers that occur at education events.

The Attorney General notes that studies show that gifts, no matter their size, can influence prescriber decision making. Although the Attorney General agrees that the rules are an additional step to stem New Jersey's opioid epidemic, the intent of the rules is to apply to all prescription medications, so as to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber.

In addition, the Attorney General notes that, in accordance with N.J.A.C. 13:45J-1.6, payments for research activities and payments to prescribers for speaking at education events are not subject to the bona fide services cap.

33. COMMENT: One commenter stated that, although the imposed cap of monies earned from pharmaceutical companies had the good intention to restrict physician incentives for prescribing certain branded products, unfortunately, the rule assumes that all money earned by physicians who consult and advise pharmaceutical companies is somehow insincere or devious and penalizes those prescribers who are doing good work. The commenter stated that, as a respected pain and addiction thought leader in New Jersey who makes meaningful contributions to pharmaceutical development, in addition to both promotional and continuing educational activities, much of what he does is assist pharmaceutical companies with development and FDA approval of novel and safer pain medicines and addiction treatments. The commenter believes that the rule should exempt, and not restrict, legitimate activities when performed under a consulting agreement, in an advisory capacity or through an approved speaker's bureau. The commenter contended that the existing rules unfairly limit clinicians who support their practices with this type of work.

In addition, the commenter believes that the Division must consider the following critical points: pharmaceutical companies need New Jersey key-opinion leaders to help design clinical trials, define best practices, and optimize safe use of new medications; physicians are no longer taken by limousine to tropical destinations for consulting or advisory board meetings, which ended with the PhRMA Guidelines initiative; advisory board and consultant meetings involve real work that produces critical advances in pain management and other medical areas; medical education is largely supported by funding from pharmaceutical companies, and clinicians need and deserve to be educated by New Jersey physician leaders, even when fair-balanced programs are promotional in nature; there are no longer promotional programs sponsoring traditional opioid products, which ended with the scandalous activities of products like Subsys; current promotional lectures in pain management are focused on naloxone, abuse deterrent opioids, and opioid alternatives, not legacy "abusable" opioids; and New Jersey should promote and try to retain its recognized medical leaders and not chase them away with unreasonable caps on consulting and lecturing fees.

The commenter contended that it will be a travesty for some New Jersey thought leaders to forfeit their medical license over this issue and leave the State, especially after years of serving New Jersey patients. The commenter does not believe this is in the best interest of patient care or public health and safety. The commenter believes that the State should reverse this rule and the bona fide services cap, or carve out agreements for those prescribers who are involved in valid pharmaceutical programs and the commenter suggested perhaps restricting those clinicians to prescribing exclusively generic versions of products when available. The commenter also believes that New Jersey needs to welcome the critical educational interaction between clinicians and pharmaceutical companies that promotes research for newer and safer therapies and supports education.

RESPONSE: The Attorney General believes the existing rules and proposed amendments to N.J.A.C. 13:45J balance the interests of ensuring that patient care is guided by the unbiased, best judgment of the treating prescriber, while continuing to support the education of prescribers and without restricting the ability of key thought leaders to be engaged by the pharmaceutical manufacturers to provide scientific information to prescribers to enhance patient care. In addition, the rules do not foreclose research activities that advance patient interests including product development to benefit patient treatment.

In addition, as discussed in the Response to Comment 31, upon adoption, the Attorney General is changing the definition of "education event" to specify that notwithstanding the FDA's or other third-party classification of a program as promotional, programs that meet the definition of "education event" at N.J.A.C. 13:45J are not subject to the modest meals limitations, nor are payments for speaking at such events subject to the bona fide services cap.

The Attorney General did not intend the proposed amendments to foreclose activities that advance patient interests including product development to benefit patient treatment. Moreover, the Attorney General agrees that research activities and clinical trials are in the overall best interest of the patients and should not be curtailed. The Attorney General believes that the existing definition of "research" at N.J.A.C. 13:45J-1.2 sufficiently encompasses a broad range of activities, including participation on advisory boards and consulting in connection with research. Payments for participation on advisory boards or consulting, which meet the definition of "research," are not subject to the bona fide services cap. (See the Response to Comments 28, 29, and 30).

34. COMMENT: One commenter expressed its support for the Attorney General's proposed changes regarding the limits on meals provided at educational events. The commenter, however, suggested more clarity with respect to the provisions concerning CME and non-CME programs. The commenter noted that despite the intention of the Attorney General to provide flexibility prior to publication in the New Jersey Register, very few pharmaceutical manufacturers were comfortable enough with the proposed language to start scheduling programs again and that these activities that were formerly robust have been at a standstill since January of 2018.

The commenter stated that, in addition to the economic harm that has resulted for the restaurant industry and related organizations that service these programs, the rules at N.J.A.C. 13:45J have provided another reason why New Jersey remains at the bottom of all surveys regarding the worst states for doctors to practice medicine. (See WalletHub's Rankings for March of 2018: New Jersey is featured prominently in last place (51 of 51 including District of Columbia)). The commenter questioned how New Jersey can attract the best and brightest and retain the highest quality when it is the only state in the region to have these constraints.

Towards ameliorating that end, the commenter requested that the Attorney General eliminate the $10,000 bona fide services cap set forth in N.J.A.C. 13:45J-1.6 concerning physician earnings from pharmaceutical manufacturers because it creates a distinct disadvantage for New Jersey licensed physicians relative to those in surrounding states. The commenter noted that, because the regulation did not affect contracts signed before the effective date of the regulation, the true effects of this rule have not yet been realized. In addition, the commenter stated that, as the end of the year is now several months away, immediate regulatory relief is needed or the State could stand to lose many talented experts in critical need by the patients of New Jersey.

35. COMMENT: One commenter noted its appreciation for the Attorney General's proposed amendments to increase the limitations to the meal cap and additional changes to the definitions of the terms "modest meals," and "prescriber" at N.J.A.C. 13:45J-1.2. The commenter, however, expressed concerns that the rules at N.J.A.C. 13:45J with proposed amendments have unintended consequences that will have a negative impact on patients, jobs, and the State's economy.

The commenter contended that the rules at N.J.A.C. 13:45J changed the business relationship between the physicians and pharmaceutical manufacturers by capping the aggregate amount that pharmaceutical companies can spend on New Jersey licensed physicians. The commenter stated that, as a result of the aggregate cap, New Jersey licensed physicians are not being hired to participate in these programs and, instead, manufacturers are hiring physicians from Delaware, Pennsylvania, and New York to conduct these educational programs. The commenter further stated that, as a result, New Jersey and its medical community are operating at a competitive disadvantage.

The commenter recommended eliminating the $10,000 aggregate cap, which has the unintended consequence of harming the innovation that occurs between the manufacturer and physician. The commenter stated that transparency already exists, as the data outlining what doctors are receiving from manufacturers is currently being captured by the Federal "Sunshine Act."

The commenter believes that its recommended changes will help continue to drive the State's economy and better inform physicians on specific medicines and, as a result, the patient will benefit from the valuable exchange of information between the manufacturer and the physician.

RESPONSE TO COMMENTS 34 AND 35: The Attorney General declines to eliminate the cap for bona fide services because he believes it is necessary to minimize the potential for conflicts of interest to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber and he disagrees that current regulatory and/or voluntary compliance requirements are sufficient.

In addition, the Attorney General notes that, in accordance with N.J.A.C. 13:45J-1.6, payments for the bona fide services cap does not include payments for speaking at education events that are for fair market value and set forth in a written agreement, research activities, or for royalties and licensing fees that are 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.

**Summary** of Agency-Initiated Change:

The Attorney General is making a grammatical correction to the definition of "research" at N.J.A.C. 13:45J-1.2 to change "systemic" to "systematic." In accordance with Garner's Modern English Usage by Bryan Garner, "systematic" should replace "systemic" unless the reference is to systems of the body. "Systematic" means carried out according to an organized plan, whereas "systemic" means affecting an entire system.

**Federal Standards Statement**

A Federal standards analysis is not required because the adopted amendments 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 adoption follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[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. ***The rules in this chapter do not apply to prescribers' interactions with pharmaceutical manufacturers to the extent that such pharmaceutical manufacturers also manufacture medical devices and that such interactions are directed solely to medical devices.***

(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:

. . .

"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.

"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, ***including information about disease states and treatment approaches,*** where:

1.-2. (No change.)

***Notwithstanding the Food and Drug Administration's classification of a program as promotional, programs that meet the definition of "education event" shall be deemed an "education event" for purposes of this chapter.****

"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, consistent with the definition of "Consumer Price Index," would raise it by one dollar increments. The fair market value shall not include the cost of standard delivery, service, or facility rental fee charges, or of tax.

. . .

"Prescriber" means a physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist 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.

. . .

"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]* ***systematic*** 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-1.4 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. 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.)

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# (a)

## DIVISION OF CONSUMER AFFAIRS
## CHARITIES REGISTRATION UNIT
## Financial Reports List of Contributors
## Adopted Amendments: N.J.A.C. 13:48-4.3 and 5.3

Proposed: December 17, 2018, at 50 N.J.R. 2549(a).

Adopted: March 19, 2019, by Paul R. Rodríguez, Acting Director, Division of Consumer Affairs.

Filed: April 1, 2019, as R.2019 d.036, **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. 45:17A-21.b.

Effective Date: May 6, 2019.

Expiration Date: November 21, 2024.

**Summary** of Public Comments and Agency Responses:

The official comment period ended February 15, 2019. The Director of the Division of Consumer Affairs (Division) received comments from Linda M. Czipo, President and CEO, Center for Non-Profits.

1. COMMENT: The commenter states that the amended rules will impose burdens on non-profit organizations. The commenter points out that, under Federal regulations, organizations with gross receipts that are normally $50,000 or less may file a Form 990-N e-Postcard with the Internal Revenue Service as opposed to a Form 990 or 990-EZ. The Form 990-N e-Postcard does not include contributor information. The commenter states that the amendments to N.J.A.C. 13:48-4.3 and 5.3 would require such organizations to submit contributor information that they were not required to file with the Federal government. The commenter states that there are at least 1,800 New Jersey organizations that qualify to submit the Form 990-N e-Postcard. The commenter also contends that organizations with revenues above $50,000 will also incur burdens under the amended rules. Online registration for charitable organizations does not allow organizations to incorporate Form 990 by reference. The commenter is concerned that, without such incorporation, organizations will be required to manually input donor information, which would be time consuming. The commenter recommends that N.J.A.C. 13:48-4.3 and 5.3 be amended so that 501(c)(3) organizations and organizations that file Form 990-N e-Postcard would be exempt from contributor reporting requirements.

RESPONSE: N.J.S.A. 45:17A-31 requires all charitable organizations to maintain complete and accurate records of their activities in this State. Those records, including contributor information, are to be made available upon demand of the Attorney General. Because organizations that filed Internal Revenue Service form 990-N are required to maintain contributor information, the Division does not believe that filing a contributor schedule would present a significant burden to those organizations, which, by definition, can have no more than 10 contributors of $5,000.00 or more.

However, the Summary of the proposed amendments set forth that the intent of the amendments was to require charitable organizations that would have previously been required to report contributor information to the Internal Revenue Service to continue to report this information to the Division. As charitable organizations that file Internal Revenue Service Form 990-N were not previously required to report contributor information to the Internal Revenue Service or the Division, the Division will not require those organizations to report this information now. The Division has changed N.J.A.C. 13:48-4.3 and 5.3 upon adoption to reflect that intent, and thanks the commenter for raising this issue.

The commenter also asserts that contributor information will need to be manually uploaded by larger charitable organizations because the Form 990 cannot be incorporated by reference in online registration. To clarify, charitable organizations are still able to incorporate Form 990 by reference, and are already required to upload the form, including all schedules, as part of their registration process. The online registration does require organizations to input certain financial information, to the extent it is required for the system to determine which form the organization is required to complete and calculate the appropriate fee. The Division does not believe that the input of the required financial information with the upload of relevant documents, imposes a significantly increased burden on charitable organizations, and in any event, such burden would not be attributable to the rule now under consideration.

As to the commenter's recommendation to exempt all 501(c)(3) organizations from the scope of the proposed amendments, the Division does not believe that a change from the notice of proposal is warranted. Charitable organizations exempt from taxation under Section 501(c)(3) of the Internal Revenue Code are not affected by the change in Internal Revenue Service rules that prompted the proposed amendments and remain subject to the same reporting requirements that they were previously. Therefore, the Division does not believe that the proposed amendments require 501(c)(3) charities to report to the Division any donor information that they are not already required to report to the Internal Revenue Service and to the Division under existing rules.