50 NJR 1(2)
January 16, 2018
Filed December 22, 2017

LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

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

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

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

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

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

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

Effective Date: January 16, 2018.

Expiration Date: January 16, 2025.

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

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

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

Division of Consumer Affairs

Office of the Director

Legislative & Regulatory Affairs

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Newark, NJ 07101

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Summary of Public Comments and Agency Reponses:

In addition to the comments received at the public hearing (as noted above), the Attorney General received comments from:

1. Jim Kremidas, Executive Director, Association of Clinical Research Professionals (ACRP);
2. Christine Pierre, President, Society for Clinical Research Sites (SCRS);
3. Jean Publiee;
4. Dawn Handschuh;
5. Jeff Boatman, Sr., SME, Quality & Compliance, QPharma;
6. Andrew M. Rosenberg, Senior Advisor, CME Coalition;
7. Adrian O. Mapp, Mayor, City of Plainfield, New Jersey;
8. Arthur C. Santora II, MD, Ph.D.;
9. Tracy Doyle, Chief Executive Officer, Phoenix Marketing Solutions;
10. Amanda Kaczerski, Director, Educational Strategy & Design, The Academy for Continued Healthcare Learning;
11. Michael V. Kerwin, Somerset County Business Partnership;
12. Mary Kathryn Roberts, Riker Danzig Scherer Hyland Perretti, LLP, on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA);
13. Steve Borrus, MD, Lawrence Medical Associates;

14. Kathleen A. Arntsen, President & CEO, Lupus and Allied Diseases Association, Inc.;
15. Brian Shott, NJ Government Relations Director, American Cancer Society Cancer Action Network;
16. Stephen A. Fegard, JD, MPH;
17. Angelica Davis, MPPA, President, Fight Colorectal Cancer;
18. Ken M. Farber, President and Chief Executive Officer, Lupus Research Alliance;
19. Richard H. Bagger, Executive Vice President, Corporate Affairs & Market Access, Celgene Corporation;
20. Bryan Lowe, Director, State Government Affairs, Healthcare Distribution Alliance;
21. Timothy J. Fournier, Senior Vice President and Chief Enterprise Risk Management, Ethics, and Compliance Officer, Rutgers, The State University of New Jersey;
22. Gail Andlik, Deborah Heart & Lung Center;
23. Thomas A. Leach, Executive Director, New Jersey Association for Biomedical Research;
24. Neil Eicher, Vice President, Government Relations and Policy, New Jersey Hospital Association (NJHA);
25. Dean J. Paranicas, President and Chief Executive Officer, HealthCare Institute of New Jersey (HINJ);
26. Thomas Sullivan, President, Rockpointe Corporation;
27. David Knowlton, Former Deputy Commissioner of Health for the State of New Jersey and Former President and CEO of the NJ Health Care Quality Institute;
28. George Coutros, Director, State Government Relations, Sanofi U.S.;
29. Sean P. Curtis, MD/MPH, Vice President, Scientific Affairs, Global Center for Scientific Affairs, Merck Research Laboratories;

30. Nikki Reeves, Seth H. Lundy, and Brian A. Bohnenkamp, King & Spalding, LLP, on behalf of the Ad Hoc Sunshine and State Law Compliance Group;
31. Tamar Thompson, Executive Director, State and Federal Payment Agencies Value, Access and Payment, Bristol-Meyers Squibb;
32. Andrew Kaufman, MD, Past President, New Jersey Society of Interventional Pain Physicians, submitted by Laurie Clark, Legislative Counsel;
33. Otto Sabando, DO, President, New Jersey Association of Osteopathic Physicians and Surgeons (NJAOPS), submitted by Laurie Clark, Legislative Counsel;
34. Mark Fleischer, CEO, Physicians World;
35. William H. Carson, MD, President and CEO, Otsuka Pharmaceutical Development & Commercialization, Inc., and Kabir Nath, President, Otsuka America Pharmaceutical;
36. Richard M. Lloyd, Executive Director State Government Affairs, Johnson & Johnson;
37. Leigh Anne Leas, Vice President and US Country Head, Health Policy, Novartis, on behalf of Novartis Pharmaceuticals Corporation and Sandoz, Inc.;
38. Debbie Hart, President and CEO, BioNJ;
39. Wendy M. Lazarus, Director, U.S. Government Relations, Pfizer;
40. Mishael Azam, Chief Operating Officer and Senior Manager, Legislative Affairs, Medical Society of New Jersey;
41. Tiffany Westrich-Robertson, Chief Executive Officer, International Foundation for Autoimmune & Autoinflammatory Arthritis;
42. Debra L. Wentz, Ph.D., President and Chief Executive Officer, New Jersey Association of Mental Health and Addiction Agencies, Inc.;
43. Peter Anastasiou, President, Lundbeck North America;

44. Robert D. Boyd, DO;

45. Patrick Plues, Vice President, State Government Affairs, BIO;

46. Brian Nyquist, MPH, Executive Director, National Infusion Center Association;

47. Jonathon Kellerman, Executive Vice President, Global Chief Compliance Officer, and Loredana Cromarty, Associate Vice President, Government Affairs, Allergan;

48. Kelly Witokowski, Executive Director, Susan G. Komen North Jersey;

49. Francine Fitzgerald;

50. Michael Scola, MD, Hematology/Oncology, Summit Medical Group, Morristown, NJ;

51. Mary Ann Picone, MD, Holy Name Physician Network;

52. Amos Katz, MD, CentraState Healthcare System;

53. Mary Beaumont, Vice President, Health & Legal Affairs, New Jersey Business & Industry Association;

54. Stephen Marmaras, Director, Policy and Advocacy, Global Healthy Living Foundation;

55. Suzanna Masartis, Executive Director, Community Liver Alliance; and

56. Paul A. Boudreau, Morris County Chamber of Commerce.

1. COMMENT: Commenters noted and supported the intent of the proposed rules to ameliorate opioid abuse, but expressed concern that the proposed rules would not accomplish this goal. In addition, the commenters believe the proposed rules will have a broader impact beyond that of opioid medications.

RESPONSE: The Attorney General thanks the commenters for their recognition and support in addressing the opioid crisis. The Attorney General notes that, although he 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 also notes that the proposed rules are intended to strengthen enforcement efforts to address prescriber acceptance of items of value from drug manufacturers. As noted in the notice of proposal, because prescribers, including physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists, as part of their scope of practice, may establish financial relationships with pharmaceutical manufacturers, there is concern that these relationships influence prescriber treatment decisions. 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.

2. COMMENT: One commenter expressed support for the proposed rules at N.J.A.C. 13:45J. The commenter stated that pharmaceutical drug companies make it impossible to know whether a physician is prescribing a drug because the doctor truly believes it is the best treatment for the patient or simply because the doctor has a lucrative arrangement with pharmaceutical salespeople who ply doctors with many different kinds of monetary and other gifts.

RESPONSE: The Attorney General thanks the commenter for its support. While the intent of the new rules is to minimize the potential for conflicts of interests between manufacturers and prescribers to ensure that patient care is guided by the unbiased, best judgment of the treating healthcare professional, the Attorney General believes that the vast majority of prescribers are guided by the best interests of their patients.

3. COMMENT: One commenter expressed support for reining in the buying of doctors by big pharmaceutical manufacturers. The commenter, however, believes that the $10,000 figure for presentations is too much and should be reduced to $5,000.

RESPONSE: The Attorney General thanks the commenter for its support. The Attorney General believes that the $10,000 cap is an appropriate level and declines to lower it.

4. COMMENT: One commenter supported the Attorney General's rule proposal and noted that the State's concern that prescriber financial relationships with pharmaceutical manufacturers may be impacting treatment decisions is timely.

The commenter noted that trust is a cornerstone in the physician-patient relationship and, although most physicians believe that they are not personally influenced in their practice by their pharmaceutical marketing/relationships, most physicians believe their counterparts are influenced by these relationships (citing Patwardhan, A.R. (2016), Physicians-Pharmaceutical Sales Representatives Interactions and Conflict of Interest, The Journal of Health Care Organization, Provision, and Financing, 53). The commenter further stated that physicians are just as likely to believe biased information, have self-serving biases, and suffer from a communal sense of entitlement (citing Sah, S., & Fugh-Berman, A. (2013), Physicians Under the Influence: Social Psychology and Industry Marketing Strategies, The Journal of Law, Medicine & Ethics, 41(3), 665-672).

The commenter recommended strengthening the proposed rules to protect patients by requiring mandatory reporting and penalties. The commenter stated that the rules need to integrate a system of mandatory reporting requirements by both pharmaceutical companies, as

well as physicians. The commenter further stated that these reports should be provided to the respective licensing board of the prescriber. The commenter contended that a progressive system of penalties needs to be applied, so that a simple mistake the first time can be given leniency with a simple fine, progressing to severe penalties with repeat offenders. Although the commenter believes that the proposed rule is a good start and will increase awareness/compliance with many practitioners, the commenter believes that the lack of mandatory reporting and lack of enforcement/deterrence means the new rules will not achieve the desired result.

RESPONSE: The Attorney General thanks the commenter for its support. The Attorney General notes that, in accordance with the Uniform Enforcement Act, N.J.S.A. 45:1-1 et seq., the respective licensing boards have the authority to impose disciplinary action and/or civil penalties, as deemed appropriate by the board after consideration of all relevant facts and circumstances, for a violation of a statute or rule. In addition, the Attorney General notes that the database located at www.cms.gov/openpayments provides greater transparency and public awareness of financial relationships between physicians and teaching hospitals and drug and device manufacturers. Although not all prescribers' payments are included in this database, the Attorney General does not believe it is necessary to impose additional reporting requirements upon manufacturers and prescribers.

5. COMMENT: Commenters expressed concerns that the new rules will have unintended consequences on clinical trials and research conducted in the State because the definition of "bona fide services" is too broad and would encompass payments in connection with vital clinical research. The commenters contended that these consequences include restricting the

ability of providers and manufacturers to conduct potentially life-saving research in New Jersey and negatively impacting the advancement of medicine and commercial drug development, which would curtail treatment options available to patients, and would create barriers to recruiting and retaining the highest quality medical faculty and researchers. In addition, the commenters contended that the new rules would adversely affect the New Jersey economy.

The commenters believe that the "bona fide services" limitation of $10,000 per year in the aggregate from all pharmaceutical manufacturers as proposed in N.J.A.C. 13:45J-1.6 would limit the ability of New Jersey prescribers to participate in clinical pharmaceutical research in a meaningful way. The commenters noted that, given the volume and sophistication of the work associated with clinical research (for example, clinical trial protocol, informed consent, laboratory testing, administration of clinical trial drug, data monitoring, etc.), payments to clinical investigators and their respective institutions often exceed $10,000. The commenters noted that a significant portion of the overall cost of research is the cost for clinical care and data collection that occurs in individual practices. The commenters also noted that medical centers and individual physicians agree to administer a company's clinical trial within their practice, recruiting patients, administering a drug, measuring and recording outcomes, and filing necessary paperwork, and the pharmaceutical companies provide reimbursement for this effort, often to individual physicians, and such payment are considered bona fide services, and might be considered to be in the proposed definition in the new rule. The commenters also stated that, because many investigators and institutions receive research funding from multiple companies each year for various studies, the proposed rules would impose serious practical restrictions on using clinical investigators or institutions based in New Jersey.

The commenters also noted that New Jersey has one of the highest representations of new and novel drug therapies in the world, and several medical institutions in the State are world-renown centers for clinical investigations. The commenters believe that it is unrealistic to expect a physician to conduct a clinical trial for $10,000, and to impose such a limit would guarantee that clinical trials are driven out of New Jersey, with severe impact to the professionals and institutions that have contributed to so many cures. In addition, the commenters believe that such a cap would not have the desired effect, since most clinical trials are conducted on drugs that have not yet been approved for commercial distribution and, therefore, the physicians conducting such trials could not possibly be influenced to prescribe them because they are not yet marketed.

One commenter expressed concern that the $10,000 cap is extremely low for effective advisory contracts with the best candidates, particularly if the providers are contracting for different services from different manufacturers. The commenter stated that fair market value for these professionals can far exceed the $10,000 cap. The commenter noted that scientific advisory boards (SABs) are typically comprised of medical providers and are an important means by which biopharmaceutical companies gain valuable information regarding what is working and not working in clinical treatments, what value a drug may bring or not bring to a patient community. The commenter noted that manufacturers often learn key insights about particular drugs or compounds that they may discover, which are important for clinical development of new therapies for patients with unmet needs. SABs are meant to provide a forum for honest discussion with the medical community regarding a product, or potential new products in clinical development, as distinct from the detailing activities of sales representatives that ultimately improve the quality of care and life of patients. The key element of SABs is that they

are set up so that the healthcare providers can provide information to the manufacturer representatives, not the reverse. Many providers often are the elite experts in their field and may participate on multiple SABs from different companies. The commenter stated that the $10,000 cap may hinder an SAB's effectiveness, and ultimately hinder participation in SABs of the highly respected professionals in their field, and this policy could also result in SABs being conducted outside of the State. The commenter expressed concern on the impact of clinical research organizations, which operate within current Federal guidelines permitted under the Open Payments System operated by the Centers for Medicare and Medicaid Services (CMS).

In addition, the commenters stated that, from an economic perspective, the cap on payments to medical providers could have a tremendous impact on medical research, jobs, and patient treatment options. One commenter stated that the Economic Impact and Jobs Impact statements in the notice of proposal do not recognize the contribution that biopharmaceutical companies make to the State's economy and the risk of causing an imbalance that would send jobs to neighboring states. The commenters noted that, in 2013, more than $245 million was invested in more than 1,200 clinical trials in New Jersey. The commenters also believe that this scientific enterprise positively impacted New Jersey local economies, with a total economic impact of more than $617 million. One commenter also believes that New Jersey does not need more regulations and red tape that discourage companies from conducting their business in New Jersey.

The commenters stated that public policy must keep pace with innovation, especially because it is the beginning of an era of personalized medicine. The commenters also stated that the proposed rules threaten to stifle research and development and move us backwards, instead of advancing innovative initiatives. The commenters noted that New Jersey currently has a

reputation for robust research, due in part to the tremendous number of clinical trials taking place. The commenters believe that the rule proposal could significantly jeopardize investment in clinical research, which will negatively impact jobs and the local economies.

The commenters believe that the unintended consequences of the proposed rules will far outweigh any benefit that might result from their implementation and requested the Attorney General to reconsider the new rules to ensure that patients continue to have access to clinical research and prescribers continue to have the most accurate information to treat them. Specifically, the commenters requested that the Attorney General amend the regulations to remove restrictions on payments made to physicians as part of conducting clinical research.

6. COMMENT: One commenter recommended separating "bona fide services" provided by New Jersey prescribers who design, conduct, analyze, and report legitimate clinical research from "bona fide services" provided to pharmaceutical manufacturers for promotional activities. The commenter noted that the CMS currently discloses payments to physicians in three categories: General – payments that are not associated with a research study; Research – payments that are associated with a research study; and Associated Research – funding for a research project or study where the physician is named as a principal investigator. The commenter stated that, when physicians are not self-employed, payments made by pharmaceutical manufacturers for research are generally made to the physician's employer (for example, a university, hospital, or large multi-specialty group), thus, it is very difficult to determine what portion of research payments, if any, are passed on by the physician's employer to the physician. The commenter also stated that there is an additional level of complexity as research payments often include the cost of the physician's staff, laboratory tests, and overhead, such as the cost of office space, in addition to the payment for the services the physician personally provides.

The commenter believes it is reasonable to limit payments for services related to promotional activities that are not associated with a research study, if there is convincing evidence that the limit set is in the best interest of patients. The commenter, however, believes that it is logical and practical to establish the limit based upon annual payments from a single pharmaceutical manufacturer. The commenter questioned how a payment from "Manufacturer A" could provide any incentive to prescribe the products of "Manufacturer B." In addition, the commenter stated that manufacturers will not be aware of the payments made by other manufacturers to the prescribers. The commenter also stated that payments to prescribers for bona fide services associated with research should be based on fair market value of the services and not capped at an arbitrary level. The commenter believes that this approach would also avoid the accounting difficulty of determining the portion of payments for research made to a physician's employer that are passed on to the regulated prescriber physician.

7. COMMENT: One commenter contended that the definition of "bona fide services" is broad and could potentially capture activities beyond marketing, including research and development. The commenter noted that the definition lists "consulting arrangements" and "advisory boards," which have historically been included in research and/or development activities by pharmaceutical companies and healthcare professionals.

8. COMMENT: Commenters opposed the proposed regulations because it believes the new rules will have a negative impact on New Jersey's competitive position. One commenter noted that, as "New Jersey's medicine chest," the impact will fall disproportionately on Somerset County, which pharmaceutical companies throughout the world have chosen as a place to do business. Another commenter noted that Morris County is the home of many biopharmaceutical companies that employ many people and support additional jobs through their supply chains. The

commenters requested that the Attorney General not adopt the proposed rules and to not create new regulatory requirements that force companies to choose other states for drug trials, medical education conferences, and other appropriate interactions between pharmaceutical manufacturers and health care professionals. The commenters suggested that the Attorney General develop a new approach, after going through a process that allows the industry to give input and recommendations.

9. COMMENT: One commenter noted its concern that the proposed rules would pose unnecessary, and in many cases, insurmountable hurdles to conducting clinical research in New Jersey. The commenter stated that the list of prohibited gifts and payments includes a number of financial arrangements that are widely recognized as being beneficial and unlikely to create inappropriate incentives if provided in a manner consisted with the PhRMA Code on Interactions with Health Care Professionals (PhRMA Code). The commenter further stated that many healthcare professionals receive grants to conduct scientific and educational activities or to perform investigator-initiated research and, without exemptions for these arrangements, the proposed regulations will preclude New Jersey healthcare professionals from participating in programs that benefit them, their patients, and the public health. The commenter requested that the proposed regulations be revised.

10. COMMENT: One commenter noted that many manufacturers consider research and development services to be provided pursuant to "consulting arrangements" and the reference in the new rules to these arrangements creates confusion regarding whether the cap would apply to research and development activities. The commenter also noted that proposed N.J.A.C. 13:45J-1.3(a) broadly prohibits a prescriber from "accept[ing], directly or indirectly, any financial benefit or benefit-in-kind, including, but not limited to ... payments ... except as permitted under

N.J.A.C. 13:45J-1.4 ...” The commenter stated that, accordingly, if “consulting arrangements” were construed to not include research and development activities, it would appear that the proposed rules would prohibit a New Jersey prescriber from accepting any payments at all from a manufacturer for such activities because those payments would fall within the broad prohibition of N.J.A.C. 13:45J-1.3(a). In addition, the commenter stated that research and development relationships are critical to the ability to identify and develop new medicines and therapies for patients. The commenter believes that the Attorney General’s proposed rules could significantly impede vital information sharing and collaboration between New Jersey prescribers and manufacturers. In particular, the commenter is concerned that subjecting bona fide research and development arrangements with New Jersey prescribers to an annual aggregate $10,000 cap across all manufacturers could substantially restrict or practically eliminate beneficial collaborations between industry and New Jersey prescribers and the venerable institutions where they practice. The commenter further stated that it presumes that the Attorney General did not intend that the proposed compensation cap should apply to manufacturers’ research and development relationships with New Jersey prescribers. The commenter pointed out that the proposed rules generally do not address research and development activities at all, and it is unclear whether the scope of the rules would even encompass those activities. Moreover, the PhRMA Code, which the Attorney General referenced in developing the draft rules, does not in any way suggest that compensation relating to research and development activities should be capped.

11. COMMENT: Two commenters recommended exempting from the bona fide services cap clinical trials, scientific input engagements that inform clinical research, and medical education. One of the commenters alternatively recommended that the limitation on payments for these

services be limited to payments made at fair market value that are pursuant to a contractual arrangement outlining the services to be performed, and are transparent to the public via Federal reporting.

12. COMMENT: One commenter expressed concerns that the proposed rules would impose significantly more restrictive prohibitions than those contained within the PhRMA Code. The commenter recommended eliminating the proposed $10,000 cap on payment for bona fide services.

The commenter stated that biopharmaceutical innovator companies frequently rely on physicians and healthcare professionals outside of the clinical trial context for advice, for consulting, and for performing other legitimate services that help biopharmaceutical innovator companies in various ways (for example, learning about new diseases or conditions, identifying treatment changes or trends, understanding gaps in clinical care, becoming aware of patient hurdles or challenges, etc.). The commenter also stated that all of these activities are designed to ensure that biopharmaceutical innovator companies focus on the most important areas of clinical research, development, and education to improve patient outcomes and clinical care. The commenter believes that the bona fide services cap could substantially restrict biopharmaceutical innovator companies from engaging in these important and beneficial collaborations.

13. COMMENT: One commenter proposed that services related to the drug discovery process, specifically consulting and advisory board services related to the development, implementation, and conduct of pre-clinical or clinical research, commonly identified under the Phase I, II, III, or IV nomenclature should not be subject to the $10,000 bona fide services cap. The commenter recommended the following amendments to N.J.A.C. 13:45J-1.6 (additions to proposal in bold; deletions from proposal in strikethrough):

A prescriber shall not accept more than $10,000 in the aggregate from all pharmaceutical manufacturers in any calendar year for the bona fide services of presentations as speakers at promotional activities, participation on **certain** advisory boards, and **certain** consulting arrangements. Payments **not subject to the $10,000 cap are those bona fide services for**:

1. ~~for speaking~~ **Speaking** at continuing education events;

2. ~~are not subject to this cap, but must be for fair market value and set forth in a written agreement.~~ **Consulting or scientific advisory board services related to the development, implementation and conduct of pre-clinical research or clinical research (Phases I-IV) into FDA regulated products.**

14. COMMENT: One commenter suggested amending the definition of "bona fide services" as follows (additions to proposal in bold; deletions from proposal in strikethrough):

"Bona fide services" means those services provided by a prescriber pursuant to an arrangement formalized in a written agreement ~~including, but not limited to,~~ **for** presentations as speakers at promotional activities and continuing educational events, participation on **certain** advisory boards, and **certain** consulting arrangements. The written agreement shall specify the services to be provided, the dollar value of the consideration to be received by the prescriber, based on their fair market value of the services, and identify the following:

1. – 6. (No change.)

The commenter believes the proposed revisions would limit the range of services to the activities listed in the definition and also further limit the types of advisory boards and consulting arrangements acceptable as "bona fide services" under the rule. The commenter believes that

participation in the kinds of advisory boards and consulting arrangements that contribute to the drug discovery process provide useful benefits to the citizens of New Jersey and are also subject to additional public and institutional scrutiny under other regulations.

15. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:45J-1.4 as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> ~~9~~**11**. **Direct or indirect compensation for research activities, including but not limited to, the systematic collection, analysis, and interpretation of data in accordance with a defined investigational protocol designed to develop or contribute to scientific knowledge.**

The commenter suggested exempting indirect compensation for research activities to preserve defined investigational protocol activities.

RESPONSES TO COMMENTS 5 THROUGH 15: The Attorney General did not intend for the proposed rules at N.J.A.C. 13:45J to include research activities and clinical trials. Clinical trials and research activities were not specifically identified in the definition of bona fide services and were not referenced in the notice of proposal. As noted in the notice of proposal Summary, the intent of the rules is to establish principled standards to minimize the potential for conflicts of interest between prescribers and pharmaceutical manufacturers to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. Research activities are clearly distinct from the promotional activities the Attorney General is addressing through this rulemaking. The Attorney General did not intend the proposed rules 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, therefore, upon adoption, is changing N.J.A.C. 13:45J-1.6 to specifically exclude from the bona fide services cap compensation for research activities. In addition, the Attorney General is changing N.J.A.C. 13:45J-1.2 to define "research" as 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. The definition of research will also specify that it includes both pre- and post-market activities that satisfy the definition's requirements. These activities directly benefit patient health and safety and should be encouraged, and compensation for the provision of services in connection with such activities should not be capped. The Attorney General is also changing the definitions of "bona fide services" and "promotional activity" at N.J.A.C. 13:45J-1.2 to specifically exclude research activities from the definition of each of these terms.

Additional public notice of these changes is not required because they do not change the effect of the intent of the rule, to minimize potential for conflicts of interest and to promote patient care, so as to destroy the value of the original notice. The Attorney General does not believe that allowing activities associated with research will increase the potential for conflicts of interest and he believes it is consistent with promoting patient care. In addition, the proposed changes do not add any burden to the regulated community and make clear that activities associated with research, as defined, including clinical trials, are not included in the bona fide

services cap.

16. COMMENT: Four commenters contended that the bona fide services cap is unnecessary because research, consulting, or other arrangements with physicians and healthcare professionals already must generally meet the requirements of the personal services and management contracts safe harbor of the Federal Anti-Kickback Statute (AKS). The commenters contended that the written agreement requirements set forth as part of the definition of "bona fide services" at N.J.A.C. 13:45J-1.2 are already part of the criteria to meet the safe harbor for personal services and management contracts permitted under the Federal AKS.

The commenters stated that the safe harbor requires, among other things, that biopharmaceutical innovator companies ensure that contracted services "do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services," all fee-for-service arrangements must be documented in a written agreement, payment for such services are fair market value, and not based on the value or volume of business generated by the arrangement. The commenter believes that the AKS and the requirements of the safe harbor adequately protect against any concerns about abuse of bona fide service arrangements.

One of these commenters stated that it has bona fide service agreements with physicians for a multitude of clinically oriented, scientifically based services and participation on adjudication and data monitoring committees, and it funds independent investigator-sponsored research through research grants. This commenter noted that committee members are independent of trial conduct and without any conflict of interest per internal policies. The commenter also noted that outcomes research allows it to study the end results of the structure

and processes of the healthcare system on the health and well-being of patients and populations. The commenter, therefore, recommended that additional exclusions to the $10,000 aggregate cap should include all clinically driven bona-fide services agreements and participation in interventional and non-interventional research. For example, clinically driven bona-fide services agreements include: investigator meetings; pre- and post-market research related to outcomes; clinical advisory boards; adjudication, endpoint, and independent review committees; FDA advisory committee; and data monitoring committee.

RESPONSE: As discussed in the Response to Comments 5 through 15, the Attorney General, upon adoption is excluding activities that further "research" from the bona fide services cap. In addition, the Attorney General believes that the new rules 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.

17. COMMENT: Commenters expressed concern that the proposed rules would impact prescribers who have an ownership right from receiving compensation for their patent or other legally recognized discovery. One of these commenters noted that many innovative practitioners and researchers spend many years developing new technologies that transform the way diseases are treated. The commenter further noted that, while these individuals are not motivated exclusively by financial compensation, limiting the value of their innovations and inventions would result in the best and brightest researchers going to other states, and this "brain drain" would be detrimental to medical staffs, medication education, and patients. The commenters requested that the Attorney General exempt payments for royalties, patents, or intellectual property revenues.

One of the commenter's suggested amending proposed N.J.A.C. 13:45J-1.4, as follows (additions to proposal in bold; deletions from proposal in strikethrough):

~~8~~10. Royalties and licensing fees paid to prescribers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the prescriber hold an ownership right.

One commenter noted that it did not believe that the Attorney General intended for the proposed compensation cap to apply to royalties, licensing fees, and other arrangements regarding the purchase of intellectual property rights from New Jersey prescribers. This commenter also noted that the PhRMA Code, which the Attorney General referenced in developing the draft rules, does not in any way suggest that compensation relating to intellectual property arrangements should be capped.

RESPONSE: Payments for royalties and licensing fees were not specifically identified in the definition of bona fide services and were not referenced in the notice of proposal. Payments for such fees are clearly distinct from the promotional activities the Attorney General is addressing through this rulemaking. The Attorney General agrees with the commenters that prescribers are entitled to payments for royalties and licensing fees paid in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the prescriber holds an ownership right, and notes that it was not intended for the proposed rules to apply to such payments. Accordingly, upon adoption, the Attorney General will add N.J.A.C. 13:45J-1.4(a)10 to allow for such payments and will change N.J.A.C. 13:45J-1.6 to specifically exclude such payments from the bona fide services cap. Additional public notice of these changes is not

necessary because they do not affect the purpose of the rule to minimize potential conflicts of interest and to promote patient care, or increase the burden on the regulated community, so as to destroy the value of the original notice. The public policy purpose for patents and other legally recognized discoveries is to encourage people to engage in the discovery of new drugs, treatments, devices, etc.; the Attorney General agrees that such innovation is in the overall best interest of patients and should not be curtailed.

18. COMMENT: Commenters raised concerns that the proposed rules ignore the benefit resulting from a strong, collaborative relationship between prescribers and pharmaceutical companies, and it misrepresents the nature and intent of pharmaceutical-prescriber engagements. The commenters believe that the existence of a $10,000 aggregate bona fide services cap will adversely impact clinician education, which could potentially adversely affect patient care. The commenters noted that, after the regulatory approval of a given medicine, there is an ongoing and essential need for medical education to inform healthcare providers about the safety and efficacy of the medicine and its appropriate use to ensure the optimal treatment and safe use of products given to patients.

In particular, the commenters believe that the proposed rules will prevent a significant percentage of New Jersey's key opinion leaders (KOLs), the leading clinicians based upon their extensive therapeutic area expertise and clinical and medical experience, from engaging with their peers and other medical and clinical institutions in valuable and necessary scientific exchanges about disease state development, product efficacy, patient safety, etc. The commenters noted that, due to their extensive therapeutic area expertise, clinical trial contributions and medical experience, as well as other key criteria that are routinely evaluated by

pharmaceutical manufacturers (for example, academic appointments, publications, etc.), New Jersey's KOLs are in higher demand for critical scientific exchange activities, including speaker programs, that are designed to educate and train other New Jersey providers on the safe and effective use of drugs and biologics. The commenters stated that these speaker programs address methods of actions, important dosing approaches, critical patient safety information and drug efficacy information, based on the KOLs' extensive clinical experience. The commenters also stated that this tier of New Jersey KOLs generally enter into agreements, specifically for speaker programs, that are annual in duration and cover multiple engagements, and just one of these contracts can exceed $10,000. The commenters also stated that it is common for this tier of KOLs to enter into speaker contracts with more than one pharmaceutical manufacturer, particularly if these manufacturers are leaders in the therapeutic areas in which these KOLs practice. The commenters believe that the unintended consequence of this arbitrary cap would be that this vital community of experienced clinicians would be significantly limited in their ability to educate their peers in New Jersey on methods of actions, important dosing approaches, critical patient safety information and drug efficacy information. In addition, the commenters contended that these experts would be unable to engage in other critical arrangements in the industry beyond speaker programs. The commenters believe that the unintended consequence of this arbitrary cap would be a significant limitation on the highly experienced clinicians who we all want training and educating the broader medical community on the safe and effective use of drugs and biologics.

The commenters stated that, as compensation for speaking, the pharmaceutical companies provide a modest financial incentive, at a fair market rate, designed to offset time away from a busy clinical practice, promote content education and speaker training by clinical and research

"experts" in the field, and also finance several key clinical trials. The commenters believe that, clinical trial experience, in turn, allows a prescriber to gain a unique familiarity with the drug, in a patient population enriched for the particular target disease state. In addition, the commenters believe that all of these endeavors (speaking, education, research) benefit patients (either directly or indirectly). The commenters also stated that these endeavors are costly and would not be possible without generous pharmaceutical support.

The commenters also noted that the speaking engagements and slide content must be fully compliant with FDA mandates, such that content of the slides cannot be altered, the material presented covers the disease state, as well as clinical trial data leading to the drug's approval by the FDA, with equal and fair representation of the drug's efficacy and toxicity, and all slides or other presented material must be covered in their entirety. In addition, the commenters noted that all statements must be consistent with the FDA-approved indication for the drug. The commenters stated that if a member of the audience chooses to ignore that information and prescribe the drug in a reckless or inappropriate manner, it should not reflect poorly on the process, nor should one conclude that the pharmaceutical company promoted or endorsed such behavior. The commenters also stated that, although uncommon, one cannot deny there are pharmaceutical companies and prescribers who choose to conduct themselves unethically or even criminally, excessively promoting the inappropriate use of a drug beyond that which clinical trial data dictates or even more egregious, reaping financial reward for such behavior, and, when discovered, these individuals and companies should receive full legal reprimand.

The commenters believe that enhanced prescribing of a particular drug does not reflect coercion or influence by the pharmaceutical company, but rather reflects an enhanced knowledge

of the drug and disease state, which, in turn, allows the prescriber to more appropriately and precisely use the drug in individuals for whom it is indicated. The commenters believe that those who have a healthy relationship with pharmaceutical companies, use their enhanced knowledge of the drug/disease state to promote a patient's well-being.

The commenters are concerned that proposed N.J.A.C. 13:45J, with its payment caps would essentially end pharmaceutical-sponsored speaking events, as there would be little financial motivation for a busy clinician to familiarize himself or herself with the content (slides, journal articles), prepare for the activities (review the literature, clinical trial data, etc.) travel, spend time away from the office, etc. One commenter recommended specifying that speaker programs, both disease state and product-specific, are exempt from the proposed rules. Another commenter recommended eliminating the $10,000 bona fide services cap.

19. COMMENT: One commenter recommended amending N.J.A.C. 13:45J-1.4 to add new paragraph (a)6 to cover in-office meals that would be subject to the modest meals definition:

> 6. Modest meals as part of an in-office or in-hospital meeting provided that the manner of the presentation is conducive to a scientific or educational interchange and is not part of an entertainment or recreational event.

In addition, the commenter suggested adding the following definition for "in-office or in-hospital meetings":

> "In-office or in-hospital meetings" means an informational presentation to and/or discussion by a pharmaceutical manufacturer's agent with a prescriber or prescribers about a prescription drug or biological product."

The commenter believes that there should not be a limit to the number of these meals provided in a calendar year, as the definition of an in-office visit, as well as the language for this provision,

makes clear that the presentation must be conducive to scientific or educational exchange and not include entertainment or recreation. In addition, the commenter suggested including a definition for "in-office or in-hospital meetings" to capture prescriber-drug manufacturer interactions occurring in offices or hospitals that are necessary for educational, safety, and scientific purposes, but that are not pursuant to a service agreement.

20. COMMENT: Commenters opposed the rulemaking and noted that the $10,000 annual cap, a one-size fits all model, does not take into account differences between therapeutic areas. The commenters stated, for example, a new therapeutic area in a rare disease state would presumably have only a limited number of highly qualified healthcare professionals who could appropriately educate their peers and who may, owing to time constraints, and other factors, be unwilling to provide such services if New Jersey's cap is enacted. The commenters believe that the net effect would be the unavailability of medical experts to deliver educational presentations to their peers in order to advance provider education and thereby enhance patient care. The commenters also stated that many programs are often non-branded and deal with topics such as wellness, nutrition, symptom management, cognitive problems, disability issues, etc., that are associated with the disease, but patients would not usually get the time to discuss these issues in depth at a typical office visit due to time constraints. The commenters contended that these programs provide a valuable resource because, due to the many demands doctors face these days, it is not always possible for physicians to take time away from their practices to attend national meetings. One commenter stated that patients and physicians from states that restrict these speaking engagements (Vermont and Minnesota) are not as knowledgeable regarding complex medications, and have a tough time making a correct choice of which disease-modifying therapies should be prescribed. The commenters requested that the Attorney General reconsider

the rulemaking because the new rules will have many detrimental downstream effects.

RESPONSE TO COMMENTS 18, 19, AND 20: The Attorney General agrees that educating prescribers is an important service and that prescribers may also benefit from non-accredited educational programs that may be offered by pharmaceutical manufacturers. The Attorney General believes there is value in organized education seminars, workshops, and other similar programs, that are structured to comply with FDA guidelines concerning presentation content and materials. Moreover, the Attorney General did not intend 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. Accordingly, upon adoption, the Attorney General will change the term "continuing education event" to "education event," and change the definition to include a workshop or seminar and to remove the requirement that "responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizers in accordance with the standards of a nationally recognized accrediting entity." The following requirements will still apply to an education event: it must be held in a venue that is appropriate and conductive to informational communication and training about healthcare information, where 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. Examples of such venues may include licensed healthcare facilities and academic institutions. In addition, the Attorney General, upon adoption, will change the definition of "promotional activity" to exclude an "education event." In accordance with the exclusion for payments for speaking at continuing education events at N.J.A.C. 13:45J-1.6, which upon adoption, will be

changed to education events, payments to prescribers speaking at both accredited and non-accredited education programs that meet the definition of an education event and, are for fair market value and are set forth in a written agreement will not be included in the $10,000 cap. Upon adoption, the Attorney General will change all references at N.J.A.C. 13:45J of the term "continuing education event" to "education event." Additional public notice of these changes is not required because they do not alter the intent of the rule focused on promotional activities to minimize potential for conflicts of interest and to promote the best interests of the patient, and the changes do not increase the burden on prescribers or manufacturers.

21. COMMENT: One commenter noted that the bona fide services cap may have a chilling effect on activities critical to patient care and medical innovation. The commenter noted that manufacturers regularly interact with prescribers in other non-promotional contexts outside of continuing education events. The commenter noted, for example, that trained field personnel with specialized scientific and medical knowledge meet with a practitioner who is a key opinion leader to discuss scientific data related to a product manufactured by the company. The commenter stated that such a meeting would be conducted pursuant to a written agreement between the company and the advisor setting forth the services to be performed and the amount of compensation. The commenter also stated that manufacturers may hire practitioners to serve as consultants who provide important feedback in the development of new products or protocols. The commenter further stated that the Office of Inspector General of the United States Department of Health and Human Services has recognized that the purpose of these and other non-promotional activities is not to sell or market a product but rather to facilitate scientific and medical dialogue regarding the care of patients and the development of new treatment options.

The commenter believes that, even though such activities are critical to the safe and effective use of prescription drugs and the advancement of new therapies, they may be curbed if the proposed cap on bona fide services is implemented as proposed. The commenter suggested that the Attorney General consider revising the cap to apply only to promotional activities where the purpose of the activity is to sell or market a product.

In addition, the commenter suggested that payments or transfers of value provided by a manufacturer to actively licensed New Jersey prescribers who are employees, contingent workers, or potential job candidates participating in the hiring process for that manufacturer be exempted from the cap. The commenter believes that limiting the cap in this manner will ensure that New Jersey prescribers can continue to take part in activities that enhance patient care and contribute to the research and development of pharmaceuticals in New Jersey, while also ensuring that patients in New Jersey will benefit from these efforts on the part of their physicians.

RESPONSE: As discussed above, the Attorney General, upon adoption, is excluding research activities from the bona fide services cap. "Research" includes pre- and post-market activities that meet the definition of "research." (See the Response to Comments 5 through 15). In addition, the Attorney General 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 is not subject to the prohibitions at N.J.A.C. 13:45J-1.3. The Attorney General declines to exempt potential job candidates from the bona fide services cap. The Attorney General, however, did not intend for the rules at N.J.A.C. 13:45J to impact legitimate recruitment efforts of prescribers for employment purposes. Accordingly, upon adoption, the Attorney General will add N.J.A.C. 13:45J-1.4(a)9 to allow for reasonable payment

or remuneration to job candidates for travel, lodging, and other personal expenses associated with recruitment. Additional public notice of this change is not required because it does not alter the effect of the rule, so as to destroy the value of the original notice, nor does it increase the burden on the regulated community. The Attorney General does not believe that payment or remuneration of personal expenses to prospective applicants for employment will increase the potential for conflicts of interest.

22. COMMENT: One commenter contended that reasonable collaboration between physicians and the pharmaceutical industry should be supported, and that there should be a clear exemption for these contracted services. The commenter stated that the relationship between physicians and the pharmaceutical industry is necessary for physicians to understand the efficacy of new medications and treatment protocols, and for the industry to understand how their medications are working in the field. The commenter believes that consultation agreements can be enormously valuable to the industry and to patients and the commenter is concerned about imposing an arbitrary limit on the amount of compensation a physician may receive from the industry in a year. The commenter stated that, while one might argue that the non-consultant non-CME payments are purely promotional, the work still requires physician expertise to relate to other physician colleagues and educate them on the product. Therefore, the commenter, believes that the cap might actually have the effect of limiting knowledge about, and access to, therapeutic alternatives. The commenter contended that, if the State wants to reduce bias, educational options should be increased, not decreased. The commenter recommended that the bona fide services cap not apply to consultants or advisory roles. The commenter suggested deleting from N.J.A.C. 13:45J-1.4(a)7 “, consistent with such cap as set forth at N.J.A.C. 13:45J-

1.6," and to delete from N.J.A.C. 13:45J-1.6 ", participation on advisory boards and consulting arrangements." The commenter also suggested amending N.J.A.C. 13:45J-1.6 as follows (additions to proposal in bold):

"Payments for speaking at continuing education events **or for participation on advisory boards and consulting arrangements** are not subject to this cap."

RESPONSE: To the extent the commenter is referring to research activities, as discussed in the Response to Comments 5 through 15, the Attorney General, upon adoption, is excluding research activities, which includes both pre- and post-market activities that meet the definition of "research," from the bona fide services cap. In addition, to the extent the commenter is referring to speaking at non-accredited education programs, the Attorney General, upon adoption, is changing the rules to exempt speaking at an education event from the bona fide services cap, and expanding education event to include non-accredited education. (See the Response to Comments 18, 19, and 20) However, the Attorney General declines to otherwise exempt consultants or advisory roles from the bona fide services cap. 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.

23. COMMENT: Two commenters recommended eliminating the cap for bona fide services by deleting proposed N.J.A.C. 13:45J-1.6. One of these commenters believes that payment should be fair market value. One of these commenters believes the cap is unnecessary, untenable, and would restrict important interactions between pharmaceutical manufacturers and prescribers.

This commenter stated that, given the wide range of services the bona fide service cap would reach and the fact that it would cover payments for those services from any and all manufacturers, the commenter does not believe that the proposed cap is something that would be practical to implement. The commenter noted that manufacturers have no visibility into service arrangements that other manufacturers may have with a particular prescriber, and would be put in a position where they wished to obtain services from a prescriber but could not anticipate what problems the all-manufacturer cap could have for their arrangements.

24. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:45J-1.4(a) as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> ~~6~~**8**. Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for a promotional activity~~, consistent with such caps as set forth at N.J.A.C. 13:45J-1.6~~. A prescriber serving in this capacity also may accept reasonable payment or remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may not claim continuing education credit for participation in such activities.
>
> ~~7~~**9**. Compensation, based on fair market value, for bona fide services not covered under N.J.A.C. 13:45J-1.4(a)(**8**~~6~~) including, but not limited to, participation on advisory bodies or under consulting arrangements~~, consistent with such cap as set forth at N.J.A.C. 13:45J-1.6.~~

The commenter suggested amending paragraph (a)8 to reflect that the compensation for bona fide services as speaker, faculty organizer, or academic program consultant for a promotional

activity should be fair market value and not subjected to a cap. The commenter also suggested amending paragraph (a)9 for other bona fide services not captured in paragraph (a)8, such as participation on advisory bodies or under consulting agreements.

25. COMMENT: One commenter noted that a number of other states have imposed gift bans and reporting obligations designed to reduce manufacturer influence on healthcare professionals. The commenter stated, however, that proposed N.J.A.C. 13:45J is more restrictive than comparable proposals in other states. The commenter also stated that it is not aware of limitations in other states on payments for bona fide services. The commenter encouraged New Jersey to remain a leader in addressing the opioid epidemic, but believes that New Jersey must also remain a leader in drug research and development, which may lead to the advancement of additional medication-assisted treatment options.

RESPONSE TO COMMENTS 23, 24, AND 25: 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. In addition, as discussed in the Responses to Comments 5 through 15 and 18, 19, and 20, respectively, upon adoption, the Attorney General will change the rules to make it specifically exclude research activities and payments to prescribers for speaking at education events from the bona fide services cap.

26. COMMENT: One commenter recommended that the Attorney General modify the cap to $25,000 per manufacturer, specifically for promotional speaking engagements. The commenter noted the PhRMA Code, to which many manufacturers are signatories, requires companies to set internal caps on promotional speaking and to manage those caps. The commenter believes that a

per-manufacturer payment cap would more reasonably allow a prescriber to conduct an appropriate number of peer-to-peer speaking engagements annually, regarding multiple treatments in his or her area of expertise, and would be more practical to manage by both the prescriber and manufacturers.

RESPONSE: The Attorney General declines to increase the bona fide services cap as the commenter suggested because he believes that an aggregate $10,000 bona fide services cap is reasonable, in particular, because of changes made on adoption, and because this cap will minimize the potential for conflicts of interest to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber.

27. COMMENT: One commenter recommended, in the alternative to the elimination of the bona fide services cap, that the Attorney General increase the aggregate cap to $100,000 to ensure that the most experienced clinicians, the best and the brightest, may continue to educate and train their peers on the safe and effective use of drugs and biologics. The commenter also recommended removing the administrative requirement of having practitioners independently track each payment and allow them to rely upon the public data submitted to CMS annually under the Federal Sunshine Act.

RESPONSE: The Attorney General believes that the $10,000 bona fide services cap is reasonable and declines to increase it as the commenter suggested. The Attorney General, however, upon adoption, is changing the definition of continuing education event such that speakers at both accredited and non-accredited education programs will be exempt from the bona fide services cap. (See the Response to Comments 18, 19, and 20) In addition, the Attorney General declines to remove the requirement for the practitioners to independently monitor their

payments from pharmaceutical manufacturers to ensure that they are in compliance with the rules, as prescribers should remain accountable.

28. COMMENT: Four commenters expressed concerns with the requirement for individual healthcare professionals to track payments from all manufacturers with respect to the $10,000 cap. The commenters believe that, although individual healthcare professionals have the obligation, it will likely be expected for manufacturers to ensure that their payments do not result in healthcare professionals exceeding the cap. The commenters noted that the new rules do not include a mechanism for manufacturers to track these payments. One of these commenters stated that sharing payments made by other manufacturers could implicate antitrust concerns in that the Sherman Act restricts the sharing of competitive information between competing manufacturers, which payment information could be considered. The commenters believe that, as a result of the agreement requirements, many manufacturers will refrain from engaging New Jersey prescribers to perform bona fide services, which could result in fewer opportunities for New Jersey prescribers to perform services that contribute to drug development and patient care.

29. COMMENT: Three commenters expressed concerns regarding the practicality and feasibility of two of the State's proposed stipulations to the bona fide services written agreement with a New Jersey prescriber.

In particular, one of these commenters believes requiring prescribers to maintain records concerning their service arrangements with manufacturers would place an undue burden on prescribers. This commenter believes prescribers would be required to maintain potentially large amounts of documentation regarding their arrangements with manufacturers, which could increase the financial value of their services, thus, increasing the amounts paid to prescribers.

The commenters believe that the requirement for the written agreement to identify the manner by which the prescriber will maintain records concerning the arrangement and the services provided by the prescriber potentially makes manufacturers privy to proprietary information about New Jersey prescribers' recordkeeping methods, while simultaneously burdening those prescribers with the responsibility to maintain highly confidential company documents regarding drug development efforts. One of the commenters stated that, although the proposed rule requires providers to develop processes and systems to track their remuneration from manufacturers, it essentially requires manufacturers to develop a system to track the remuneration of all manufacturers to ensure their own payments do not surpass the provider's limits. This commenter stated that development of such as system would be extremely difficult, particularly because it would be unknown who would be the caretaker of such a system, or how the manufacturers would be forced to report, and that this type of system is fundamentally different than the Federal Sunshine rules because it would require tracking payments to physicians on an ongoing basis throughout the year, not after the fact. The commenter further noted that many of these interactions involve complex marketing strategies, which are considered proprietary trade secrets that are protected by the New Jersey Uniform Trade Secrets Act that Governor Christie signed into law in 2012, as well as Federal case law and the United States Constitution. The commenter also noted that biopharmaceutical manufacturers already must comply with Federal Sunshine rules that require reporting to the CMS Open Payments System. The commenter further noted that the broader definition of research under the Federal program is meant to include items directly associated with non-promotional activities.

In addition, two of the commenters stated that the requirement for the written agreement to identify the venue and circumstances of any meeting in which the prescriber participates is

burdensome because this information is rarely known at the time of the agreement and would require the drafting and signing of an addendum for each meeting that occurs as part of the year-long service arrangement. These commenters stated that the crafting of unique and distinct addenda for each and every investigator, consultant, or speaker arrangement would be unduly burdensome on both the manufacturer and each contracted prescriber and would discourage collaboration with respected New Jersey medical experts by both in- and out-of-State manufacturers.

One of the commenters suggested removing from the definition of "bona fide services" the provision regarding a prescriber's obligation to maintain records concerning the arrangement and the services. This commenter also suggested revising the definition of "bona fide services" (additions to proposal in bold) to generally require that meetings held in association with bona fide services occur in venues and under circumstances conducive to the services provided, and that activities related to the services be the primary focus of the meetings **(but do not require that the venue and circumstances of any particular meetings be specifically described in the written agreement).**

RESPONSE TO COMMENTS 28 AND 29: To the extent the commenters' concerns relate to clinical trials and/or research, as discussed in the Response to Comments 5 through 15, the Attorney General, upon adoption, is exempting research activities from the definition of bona fide services and the bona fide services cap. The Attorney General disagrees that the recordkeeping requirements associated with the required written agreement between prescribers and manufacturers is unduly burdensome. These requirements are necessary to ensure compliance with N.J.A.C. 13:45J. The Attorney General also disagrees that the recordkeeping requirements necessitate the disclosure of proprietary information as the rules do not require

disclosure of the specific amounts paid by each manufacturer. In addition, the Attorney General notes that the rules do not include a requirement that prescribers report this information to the State.

The Attorney General, however, agrees with the commenter's suggestion to revise the definition of "bona fide services" to remove the requirement to identify the specific venue and circumstances of any particular meeting, and to change the rule, such that the written agreement must generally require that meetings held in association with bona fide services occur in venues and under circumstances conducive to the services provided, and that activities related to the services be the primary focus of the meeting. Additional public notice of this change is not required because it does not alter the intent of the rule and makes it less burdensome for the regulated community. The changes will more likely facilitate compliance by removing obstacles for complying by establishing a standard without requiring the inclusion of specific details that may not be known at the time of the agreement.

30. COMMENT: One commenter recommended amending the definition of "bona fide services" as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> "Bona fide services" means those services provided by a prescriber pursuant to an arrangement formalized in a written agreement **for services provided by a prescriber,** including, but not limited to, presentations as speakers at promotional activities and continuing educational events, participation on advisory boards, and consulting arrangements. The written agreement shall specify the services to be provided, the dollar value of the consideration to be received by the prescriber, based on ~~their~~ fair market value of the services, and identify the following:

1. – 3. (No change.)

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

Recodify proposed 4. and 5. as **5.** and **6.** (No change to text.)

The commenter believes that adding "for services provided by a prescriber" will provide clarity. The commenter recommended deleting paragraph 4 from the contractual requirements and instead to include it in N.J.A.C. 13:45J-1.6, as a separate requirement for the prescribers to maintain records concerning their contractual agreements and services provided as part of the contract. The commenter believes that requiring how a prescriber maintains records in the contractual agreement creates a gray area where it can be interpreted that the drug manufacturer must approve and/or monitor how prescribers maintain their records.

RESPONSE: The Attorney General declines to amend the definition of "bona fide services" as the commenter suggested. The Attorney General believes including "for services provided by a prescriber" does not add clarity and is unnecessarily repetitive. In addition, the Attorney General declines to relocate the maintenance of records requirement because he believes that it should be part of the written agreement between the prescribers and pharmaceutical manufacturers. The Attorney General, however, upon adoption will make a technical amendment to delete the word "their" preceding "fair market value" and replace it with "the."

31. COMMENT: One commenter expressed support for the recommendations suggested by the commenter in Comment 30. The commenter also recommended amending the definition of "bona fide services" to replace paragraph 1 to read "A description of the service and expected output." The commenter also recommended eliminating paragraph 2 because, as part of their

compliance programs and internal controls, pharmaceutical manufacturers prepare and maintain business justifications for arrangements with prescribers that are completed prior to the execution of a contract. The commenter believes that this provision adds a redundant step and increases the administrative burden. In addition, the commenter suggested eliminating paragraph 3 because the suggested modification to paragraph 1 makes this provision redundant. The commenter also suggested eliminating paragraph 5 because, as part of their compliance programs and internal controls, pharmaceutical manufacturers evaluate the need for, and appropriateness of, meeting venues for programs with prescribers that are completed prior to the execution of a contract, therefore, this provision also adds a redundant step and increases the administrative burden.
RESPONSE: As discussed in the Response to Comments 28 and 29, the Attorney General, upon adoption, will revise the definition of "bona fide services" to remove the requirement to identify the specific venue and circumstances of any particular meeting, and to change the rule, such that the written agreement must generally require that meetings held in association with bona fide services occur in venues and under circumstances conducive to the services provided, and that activities related to the services be the primary focus of the meeting. The Attorney General, however, declines to further amend the definition as the commenter suggested because he believes the portions of the rule objected to by the commenters are reasonable and do not unduly burden prescribers or manufacturers.

32. COMMENT: One commenter opposed the new rules and noted that New Jersey's proposed $10,000 restriction fails to adequately define its scope because it does not specify whether its application is limited to services provided in New Jersey, the United States, or globally. The commenter questioned whether the $10,000 cap would apply to a New Jersey healthcare

professional presenting in Pennsylvania. In addition, the commenter stated that, given existing United States trade laws, as well as the free market competition element present in the pharmaceutical industry, there is no existing mechanism by which a pharmaceutical manufacturer can obtain timely and accurate information on a rival manufacturer's (or multiple rival manufacturers') year-to-date spending on any particular New Jersey healthcare professional to be able to comply with New Jersey's proposed rule.

RESPONSE: In accordance with the rules at N.J.A.C. 13:45J, including the definition of "prescriber," the rules apply to all New Jersey licensed prescribers regardless of where the bona fide services are provided. The Attorney General notes that the rules do not require pharmaceutical manufacturers to obtain from each other the year-to-date spending on a specific New Jersey healthcare professional. Rather, the rules require prescribers to maintain records of compensation they have received from manufacturers. A pharmaceutical company can obtain from the prescriber, the information necessary to ensure that a prescriber is operating within the cap.

33. COMMENT: Commenters expressed support for the rule incorporating strong protections to exempt accredited continuing medical education (CME) from the prohibition against industry support. The commenters noted, however, that the proposed rule may adversely impact the ability to offer CME in the State because the rule's limitations on the value of meals severely limits the venues available for multi-hour CME programs and could pose a significant hurdle for health professionals seeking to access such CME activities. The commenters noted the importance of CME in keeping healthcare practitioners up-to-date on advances in medicines and treatments, which helps patient outcomes. The commenter stated that, it is during these multi-

hour, day-long events, that clinicians are being educated on emerging science, new clinical guidelines, and paradigm shifts in order to improve their clinical knowledge and skills to ultimately improve patient outcomes. The commenters also stated that although they support limiting lavish, exorbitant meals, they believe a modest meal should be provided to participants, but modest within the cost of doing business within New Jersey.

The commenters recommended amending the definition of "modest meals" to eliminate the $15.00 threshold. The commenters stated that, based on the typical venues used for CME seminars, the $15.00 threshold would present a significant challenge for event organizers and health professionals trying to adhere to the law, rather than merely ensuring that the provided meals are modest. The commenters provided examples of the cost of a continental breakfast from local hotels in New Jersey (Newark, West Orange, and East Windsor) of respectively $25.00, $16.95 (before service charges and taxes), and $18.95 per person, and noted that lunch or dinner prices are considerably higher. The commenters further stated that each of these continental breakfasts would be described as "modest" under any reasonable standard, yet not one would meet the rule's standard. Another commenter noted that it recently hosted a two-day meeting in New Brunswick, New Jersey and the average meal at the modest three star hotel was over $75.00 per person/per meal when taxes and fees were included. This commenter noted that the conference was supported by several pharmaceutical companies who had no say on the content.

The commenters noted that CME has a direct impact on clinicians, patients, and clinical outcomes, and that eliminating refreshments from accredited CME will have an unmistakable and deleterious effect on clinicians participating in New Jersey CME events. One of these commenters further believes that, should the rule be finalized as proposed, there is a significant

chance that physicians will need to provide their own sustenance for a day of training, which is neither rational nor reasonable. This commenter also stated that this would result in discouraging physicians from taking advantage of vital educational resources due to the inadequate refreshment provided at those events, which is an unacceptable consequence for a rule that aims to benefit patients and ensure that physicians maintain their professional obligations. The commenters, therefore, requested that the Attorney General eliminate the $15.00 threshold from the proposed rule.

RESPONSE: The Attorney General declines to eliminate the $15.00 threshold for modest meals. Although the commenters noted a few examples of the cost of meals within the State, the Attorney General disagrees that $15.00 is an unreasonable limitation on the cost of meals provided to prescribers at education events. In addition, the Attorney General does not agree that the proposed new rules discourage prescriber education. The proposed new rules permit prescribers to receive compensation for serving as a speaker, faculty organizer, or academic program consultant for education events (which are not subject to the $10,000 cap) and for promotional activities. In addition, non-speakers or organizers are permitted to accept modest meals each time they attend an education event, and may accept a modest meal offered in connection with a promotional event. Although a few examples of the cost of a meal are noted by the commenters, the Attorney General does not believe this information supports the claim that modest refreshments cannot be provided within the proposed $15.00 limit. In addition, the Attorney General does not believe that, absent the offer of a meal, prescribers would choose to forego an education event or promotional activity designed to impart information that could benefit their patients.

34. COMMENT: One commenter stated that, while the proposed regulations are well-intentioned, they seem to misunderstand the already substantial prohibitions on industry influence and bias built into accredited CME programs. The commenter noted that, although CME payments are excluded from the payment cap, they are in fact nearly negligible because the Accreditation Council for Continuing Medical Education (ACCME) prohibits any commercial supporters to have any direct or indirect influence on CME events. The commenter noted that, under the ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities, any financial support from a commercial source for a CME activity must be completely unrestricted to achieve credit. The commenter also noted that the CME provider, not the commercial entity, dictates all aspects of planning and execution of continuing education events, including faculty selection, content, participant identification and evaluation, and, as such, all CME grants or payments that comply with the ethics rule are not even reported to the Open Payments database. The commenter further stated that, according to the ACCME, just 11 percent of accredited activities – activities which count for CME credits for doctors – received financial support from pharmaceutical and device manufacturers. The commenter noted that meals at CME events are exempt from the $15.00 limit, and physicians do not pay directly for those meals and cannot account for them, and more importantly, influence is already removed from CME events. The commenter suggested explicitly removing CME events from the $15.00 meal limitation because the ACCME standards effectively create a firewall between the pharmaceutical industry and physicians.

RESPONSE: The Attorney General respects the ACCME standards but declines to establish different standards for the different providers who provide continuing education to all prescribers in the State. The Attorney General also notes that, to the extent the ACCME standards for

commercial support for medical education would be more stringent than those imposed under N.J.A.C. 13:45J, those standards would continue to govern ACCME accredited continuing education programs.

35. COMMENT: Commenters expressed concern that the proposed rules at N.J.A.C. 13:45J, specifically the modest meal limitations with respect to cost and frequency, may negatively impact prescriber education within the State.

The commenters believe that the proposed rules could limit interactions between healthcare professionals and industry representatives resulting in prescribers not having the most current information regarding treatments and diagnostic tools. The commenters noted that the manufacturers' interactions with healthcare professionals provide valuable information, such as FDA-regulated information, information about a drug's risks and benefits, which may change over time as more post-marketing studies are completed, including any warnings from the FDA to discontinue use of certain medicines. The commenters also stated that these interactions provide a mechanism for healthcare professionals to receive prompt answers to questions about medical research and the proper use of drugs, and provide an opportunity for a scientific exchange between pharmaceutical representatives and providers. The commenters stated that restricting access to important educational opportunities may impact patient safety because, once a medication comes to market, providers rely on the medication's manufacturer for critical information and updates regarding preparation, administration, additional risks identified through post-market research, and information critical to patient safety and achieving optimal patient health outcomes. The commenters also noted that education empowers patients and enables providers to make the best choices when it comes to personalized treatment by informing

healthcare professionals about new therapies and diagnostic tools. The commenters expressed concern that the proposed rules would impede important interactions between healthcare professionals and drug manufacturers, which ensure that healthcare professionals and patients have the best information about lifesaving medicines. One of the commenters stated that not all interactions between employees of a biopharmaceutical manufacturer and a healthcare professional are promotional in nature.

The commenters also noted that presentations to providers and their staff by company representatives are educational in nature and facilitate a dialogue about the product and its on-label use, and the meal simply facilitates that educational exchange and product discussion, which, if it did not occur, could impact proper patient care. One commenter stated that these opportunities greatly assist physicians because of the severe time constraints posed on today's practice environment due to increased insurance and government statutory and regulatory requirements. Another commenter stated that such detailed information exchange is not easily accessible via other avenues during the course of high volume in-patient and out-patient care. The commenters believe that the proposed rules would severely restrict in-office educational programming for companies that provide multiple products to the same specialty areas, and preclude attendance at out-of-office educational programs after practice hours when prescribers cannot participate in such programs during their workday.

The commenters noted that these events often deliberately coincide with meal times when prescribers are not seeing patients and the inability to provide food may significantly reduce prescriber participation and attendance at such events, which would result in precluding manufacturers from providing important information about their products and disease states to prescribers, to the detriment of both prescribers and patients. The commenters noted that

pharmaceutical companies and others provide valuable information to prescribers to help properly prescribe and use the products. The commenters stated that modest meals in connection with educational programs about medicines help to ensure that healthcare professionals are aware of the important benefit, risk and safety information of the medicines, especially with the rapid pace of new developments.

In addition, the commenters raised concerns that the limitation of four times per year for non-faculty healthcare professionals to receive modest meals at promotional activities would prohibit on a *defacto* basis any out-of-office programs, such as speaker programs, and would likely prevent manufacturers from furnishing information concerning their products and the various disease states. The commenters noted that there are many instances where, through promotional activity, critical safety and efficacy information is shared between the manufacturer and the prescriber. The commenters also stated that limiting meals with non-faculty prescribers in connection with promotional activities to four times per year is unduly restrictive, could adversely affect patient care, and is in tension with applicable legal and regulatory requirements.

One commenter, in particular, stated that for particular classes of diseases, rapid changes necessitate frequent interactions and information exchange between prescribers and biopharmaceutical innovator companies. Another commenter believes that the limitation of four times per year will contribute to the unintended consequence of limiting the valuable contributions of New Jersey's top key opinion leaders to the education and training of their peers on the safe and effective use of drugs and biologics. In addition, another commenter noted that certain treatments are complex and require significant education and information sharing to ensure proper use to help patients achieve optimal outcomes, and the complexity of the topics could consume several hours of training and education. This commenter also noted that such

training would include new or recent updates to benefits, safety, risks, and other crucial scientific information that biopharmaceutical innovator companies regularly assemble and share with healthcare professionals. The commenter believes that arbitrarily limiting such communications to four meals per year prevents physicians from accessing this critical information, which could unnecessarily delay diagnosis or treatment for patients or otherwise adversely affect patient care.

In addition, the commenters stated that N.J.A.C. 13:45J-1.4 broadly restricts meals provided to a prescriber by a company during almost any informational exchange to $15.00, including, among others, meals provided as part of an in-office visit with a representative or a physician led peer-to-peer meeting that may be held in a restaurant. The commenters believe that the $15.00 limit would foreclose the ability to hold these events at local restaurants and stated that, even for in-office meals, the limit would be cost-prohibitive, particularly when factoring delivery, tax, and tip into the total costs. The commenters stated that the $15.00 meal limit is unreasonably low, especially for a higher cost of living state, such as New Jersey, and would inhibit companies from communicating important medical and scientific information about their medicines, to the detriment of patient care. One of these commenters stated that a survey of hotels, restaurants, and similar establishments in many New Jersey cities would show that the average cost of lunch, dinner, or even snacks and beverages, would exceed $15.00 per attendee. In addition, the commenter noted that because meals must generally take place in a venue that is conducive to learning, which often require companies to reserve private rooms or areas at restaurants or hotels, which are associated with increased costs and expenses (for example, fixed price menu, minimum purchase amount, room reservation, tips, etc.), no educational program in a hotel, restaurant or similar venue would comport with the $15.00 limit.

In addition, one commenter stated that with meals capped at $15.00, few clinicians will part with their busy day to meet with pharmaceutical representatives and take advantage of this valuable source of knowledge. The commenter stated that, with the ever-increasing complexity of medicine and limited time in a typical work week to commit to education, and with rapidly expanding pharmacopeia with evolving drug indications, efficacy or new side effects, prescribers need to maintain a strong relationship with pharmaceutical companies and their professional representatives. The commenter also stated that CME-sponsored educational activities are excellent, but less accessible, often costly, and inadequate in providing immediate access to information.

The commenters also believe the limitations are unnecessary because pharmaceutical manufacturer educational programs already must comply with applicable FDA promotional standards, the PhRMA Code, Federal Sunshine Act, government guidance, and other industry standards. The commenters further stated that existing state laws do not restrict meals to the degree New Jersey has proposed. In addition, one commenter noted that it has internal corporate standards of business conduct and ethics and follows strict protocols when interacting with third parties and healthcare professionals, which is in addition to the PhRMA Code, and that it must comply with extensive reporting requirements under the Federal Sunshine Act.

The commenters noted that all meetings where a company has any control over the content are highly regulated, such that any information shared about a product must be consistent with the drug's approved FDA label. The commenters further noted that these meetings are intended and designed to provide healthcare practitioners with balanced scientific and clinical information about a drug, which must include information about both the benefits and the risks associated with that product. The commenters stated that these exchanges enhance patient

safety, the quality of care, and can also help improve medication adherence. The commenters also stated that, in addition to being highly regulated by the FDA, laws, and regulations, manufacturers are also subject to other related laws that govern interactions with healthcare professionals, including the Federal Anti-Kickback Statute and False Claims Act.

The commenters further stated that each member company of PhRMA and many non-members abide by the PhRMA Code which, among other things, prohibits:

1. Manufacturers from offering non-educational items to healthcare professionals (for example, "reminder" pens are prohibited);

2. Manufacturers from offering entertainment or recreation to healthcare professionals;

3. Manufacturers' field sales representatives and their immediate managers from providing meals to healthcare professionals outside of an office or hospital setting; and

4. Requires the following, among other things, with respect to consulting arrangements: consulting arrangements should be based on legitimate need that are identified prior to requesting the services; consulting arrangements should be memorialized in written contracts that specify the nature of the consulting services to be provided and the basis for payment (which must be based on fair market value); the venues and circumstances of any meetings with consultants should be conducive to the services; and the retaining manufacturer should maintain records concerning, and make appropriate use, of the services.

The commenters stated that Federal law also requires all pharmaceutical manufacturers to disclose payments and other transfers of value, including those relating to research and development arrangements and charitable contributions, provided to physicians and teaching hospitals. The commenter stated that this information is provided directly to CMS and made publicly available on the Open Payments database, and that data from it highlights that the

majority of transfers of value between companies and healthcare providers are for research and development-related activities.

36. COMMENT: Two commenters expressed concern that the proposed rules would prohibit New Jersey prescribers from accepting meals from pharmaceutical manufacturers in association with manufacturers' non-promotional activities, such as to facilitate discussions regarding FDA-mandated Risk Evaluation and Mitigation Strategies (REMS), among other legitimate activities. The commenters stated that N.J.A.C. 13:45J-1.3(d) provides that "[a] prescriber shall not accept meals from any pharmaceutical manufacturer or manufacturer's agent, except as provided in N.J.A.C. 13:45J-1.4," and accordingly, the draft rules allow New Jersey prescribers to accept meals only in circumstances explicitly permitted under the rules. The commenters further stated that the draft rules do not explicitly permit New Jersey prescribers to accept meals of any value associated with manufacturers' non-enumerated non-promotional activities.

The commenters contended that there are legitimate, non-promotional reasons that pharmaceutical manufacturers meet with prescribers and for which it is reasonable and appropriate for a manufacturer to provide a meal to help facilitate the discussion and exchange of information. The commenters noted, for example, that manufacturer representatives sometimes meet with prescribers to discuss a drug's REMS, which is a risk management plan that FDA requires for certain prescription drugs that uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the drugs outweigh their risks. The commenter also stated that it is common for manufacturers' research and development personnel to have informational/scientific discussions with healthcare professionals to discuss potential development projects and areas for potential research collaboration and needs for product innovation. The commenters further noted that there are numerous other non-promotional

activities that may be conducted for which it would be appropriate to provide a meal, such as meetings with potential job candidates, or during community events.

The commenters expressed concern that the draft rules would inadvertently and unduly prohibit New Jersey prescribers from accepting meals at all from manufacturers in many legitimate non-promotional circumstances like those described above because the activities would not satisfy the proposed definition of "promotional activity," would not be third-party "continuing education events," and would not occur in the context of service arrangements. The commenters believe that these unwarranted restrictions could frustrate the exchange of important clinical and scientific information about products, as well as inhibit important scientific collaboration that occurs through the appropriate conduct of business.

The commenters also believe that it is unlikely that the Attorney General intended to prohibit New Jersey prescribers from accepting meals from pharmaceutical manufacturers in such non-promotional contexts, and noted that the draft rules do not mention research and development activities or related scientific/medical interactions at all, and it is unclear whether the scope of the rules would even encompass those activities. The commenters, moreover, noted that the proposed definition for "pharmaceutical manufacturer's agent" focuses on individuals who engage in "detailing, promotional activities, or other marketing of prescription drugs or biologics," which suggests that the Attorney General was particularly focused on restricting/limiting promotional activities, but not non-promotional activities. In addition, the commenter noted that the draft rules expressly permit prescribers to accept modest meals in conjunction with continuing medical education events, which appears to be an acknowledgement that New Jersey prescribers should be allowed to accept meals in non-promotional contexts. The commenter, moreover, contended that it would be completely incongruent if the Attorney

General intended that the rules should permit prescribers to accept modest meals from manufacturers in promotional contexts (for example, in conjunction with office visits by sales representatives to discuss products), but prohibit prescribers from accepting meals in conjunction with non-promotional activities (for example, in conjunction with office visits by medical science liaisons to discuss scientific/clinical issues related to products, such as REMS). Accordingly, the commenter requested that the Attorney General amend the rules to expressly permit New Jersey prescribers to accept modest meals provided in conjunction with a pharmaceutical manufacturer's non-promotional activities.

37. COMMENT: One commenter stated that, although it supports policies to ensure lawful, professional, and ethical interactions between prescribers and manufacturers in a way that facilitates the advancement of medicine and improves patient care, it is concerned that the proposed rules will negatively impact these invaluable interactions, and, therefore, requested that this rule proposal be withdrawn. Alternatively, the commenter suggested amending the rule such that, instead of limiting modest meals provided to non-faculty prescribers through promotional activities to no more than four times in a calendar year from the same manufacturer, have the limitations apply only to the same drug for the same labeled indication. In addition to this recommendation, the commenter suggested establishing a meal standard based upon the Federal per diem rate, which is a fair, established rate that allows for both regional variance in cost and also accounts for changes in cost over time. The commenter also suggested that the State consider clarifying that the modest meals provision applies only to promotional interactions and does not apply to any clinically oriented scientific interactions.

38. COMMENT: One commenter recommended that the Attorney General revise the proposed new rules to clarify that the annual four meal limit be applied only to peer-to-peer promotional speaker programs.

RESPONSE TO COMMENTS 35, 36, 37, AND 38: The Attorney General supports prescriber education and agrees that non-accredited education programs should not be unduly restricted. The Attorney General agrees with the commenters that education about pharmaceutical products is critical for ensuring patient safety. Furthermore, as stated in the notice of proposal, the intent of the proposed rules is to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. Accordingly, the Attorney General did not intend to unduly restrict the ability of prescribers to obtain important information about prescription medications or to limit such educational opportunities to accredited continuing education events. The Attorney General also agrees that the proposed rules could potentially have a disparate impact on those manufacturers that have more than one product because any one product may necessitate multiple meetings to discuss critical drug information.

Upon adoption, the Attorney General will change N.J.A.C. 13:45J-1.4 to specifically permit modest meals provided through the event organizer at an education program, and to remove the four times per year per manufacturer limitation as to the number of modest meals that may be offered to non-faculty prescribers through non-promotional activities. Additional public notice of this change is not necessary because they do not change the effect of the rule, so as to destroy the value of the original notice. The purpose of the rules is to minimize potential conflicts of interest and to promote patient care. The Attorney General does not anticipate additional influence as a result of removing the four meal per year limitation. The Attorney

General notes that modest meals will remain subject to the $15.00 cap, which the Attorney General believes is a reasonable amount for meals.

In addition, the Attorney General, upon adoption, is changing the definition of continuing education event, such that speakers at both accredited and non-accredited education programs will be exempt from the bona fide services cap. (See Response to Comments 18, 19, and 20)

39. COMMENT: One commenter requested that the Attorney General consider a dollar limit of $100.00 per meal per prescriber for such an encounter to allow the prescriber and certain office members to attend, when appropriate. In addition, the commenter recommended that the meeting limits be changed from four times per year to four times per month to allow for adequate meeting frequency.

RESPONSE: The Attorney General believes that a limitation of $15.00 per meal is reasonable and declines to increase it. In addition, as discussed in the Response to Comments 35, 36, 37, and 38, the Attorney General, upon adoption, is removing the four meal per manufacturer limitation.

40. COMMENT: Two commenters suggested amending the definition of "modest meals" to delete the $15.00 threshold and replace it with "the current Federal per diem rate, including areas where a New Jersey location-specific per diem rate is specified." The commenters believe that changing the value of a modest meal to an established meal standard accounts for regional variation in the cost of a meal and also mitigates the need for regular updates to the rule to account for changes in inflation.

RESPONSE: The Attorney General declines to replace the $15.00 threshold for modest meals with the current Federal per diem rate as the commenter suggested. The Attorney General believes that all New Jersey prescribers should be held to the same standard.

41. COMMENT: Three commenters recommended that instead of imposing a $15.00 limit on modest meals, which the commenters believe is too low, the State should eliminate it and replace it with a broader, more flexible definition, or that it be raised substantially. The commenters urged the Attorney General to revise the definition of "modest meals" to mean "food and/or drinks that, as judged by local standards, are similar to what a prescriber might purchase when dining at his or her own expense," which is similar to the definition used by Massachusetts under its Pharmaceutical and Medical Device Manufacturer Code of Conduct laws. One of the commenters noted that this definition follows the standard set forth in the American Medical Association Code of Medical Ethics for physicians, and is consistent with the PhRMA Code. The commenters believe that New Jersey should consider adopting a standard for modest meals that includes a similar degree of flexibility, rather than imposing a single dollar ceiling on the cost of the meal. The commenters stated that this is important given that the value of a modest meal may differ depending on the venue, type of meal, and locality of the event. The commenters believe that a degree of flexibility that recognizes local standards in determining whether a meal is modest is particularly important given that the requirements for the provision of modest meals apply to all meals provided to New Jersey-licensed healthcare practitioners at continuing education events and promotional activities, regardless of where the meal takes place.
RESPONSE: The Attorney General believes that the $15.00 cap for modest meals is reasonable and declines to change it to a subjective standard that is less easy to identify and enforce.

42. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:45J-1.4(a) as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> ~~3~~**4**. ~~Modest m~~**Meals, snacks or beverages** provided **to all participants** ~~through the event organizer~~ at a continuing education event **when the event's organizers decide to use pharmaceutical manufacturer financial support of the event for this purpose**, provided the meals facilitate the educational program to maximize prescriber learning.
>
> ~~4~~**5**. ~~Modest m~~**Meals** provided to non-faculty prescribers ~~through~~ **at** promotional activities **where a prescriber provides bona fide services as a speaker** no more than four times in a calendar year from the same manufacturer **for the same prescription drug, provided meals, are similar to what a healthcare practitioner might purchase when dining at his or her own expense, as judged by local standards.**

The commenter believes that the edits to proposed paragraph (a)3 reflects the PhRMA Code that financial support of meals at continuing education events is at the discretion of the event's organizer, and may include snacks or beverages. The commenter further stated that, as the event's organizer determines the menu at these events, PhRMA has exempted food and beverage at these types of events from the modest meal limit as a drug manufacturer does not determine the menu.

RESPONSE: The Attorney General declines to amend N.J.A.C. 13:45J-1.4(a) as suggested by the commenter because he believes the $15.00 threshold is reasonable and provides clear guidance as to what constitutes an acceptable modest meal. The Attorney General, however, upon adoption is changing N.J.A.C. 13:45J-1.4(a)4 to remove the four times per year per manufacturer limitation for modest meals provided to non-faculty prescribers through promotional activities. (See the Response to Comments 35 through 38)

43. COMMENT: One commenter recommended amending the rules such that the $15.00 meal limit and the aggregate cap would apply to only activities and the related payments associated with the use of opioid analgesics.

RESPONSE: The Attorney General declines to amend the rules to limit its application to activities and payments associated with opioid analgesics. 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 proposed rules are intended to strengthen enforcement efforts to address prescriber acceptance of items of value from drug manufacturers. As noted in the notice of proposal, because prescribers, including physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists, as part of their scope of practice, may establish financial relationships with pharmaceutical manufacturers, there is concern that these relationships influence prescriber treatment decisions. 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.

44. COMMENT: One commenter suggested that the proposed rules be modified such that the manufacturer's educational programming be required to adhere to the standards set forth in the PhRMA Code, unless the product being discussed is a Schedule 2 classified drug, in which case more stringent restrictions should be in place around the frequency and location of educational program attendance. In the alternative, the commenter suggested imposing an annual prescriber meal acceptance cap that is more consistent with the annual spending cap required of each manufacturer by the State of California, typically $1,000 to $1,500. The commenter believes that this amount would permit attendance by healthcare professionals at occasional out-of-office programs that provide opportunities for disease state and product education and do not conflict with patient treatment hours.

RESPONSE: The Attorney General declines to amend the rules as the commenter suggested and notes 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 believes that $15.00 is a reasonable amount for modest meals.

45. COMMENT: One commenter suggested amending N.J.A.C. 13:45J-1.3(a) to delete "or indirectly." The commenter is concerned that payments such as scholarships and charitable contributions made to an educational institution that employs prescribers would be prohibited under the original language. The commenter believes that such a prohibition would create an immediate and significant hardship for students.

46. COMMENT: One commenter noted that continuing medical education providers hold intensive training sessions for fellows and residents in training and that these are typically one- to two-day events held in conjunction with major medical meetings, such as ASCO or ACC. The commenter stated that the events feature skills training and lecturers that fellows and residents in training would not be able to receive in their home institutions. The commenter also stated that, while these events support the travel and lodging of medical trainees, under the rule as written, it is unclear if companies will be able to support these activities. The commenter requests that the Attorney General include fellowship support for medical trainees in the final rule.

47. COMMENT: Two commenters recommended amending proposed N.J.A.C. 13:45J-1.4(a) as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> 2. A pharmaceutical manufacturer subsidized registration fee at a continuing education event, if ~~that fee is available to all event participants~~ **the financial support from the pharmaceutical manufacturer was given to the event's organizers to reduce the overall registration fee for all participants**.
>
> **3. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows and other healthcare professionals in training to attend selected continuing education events may be offered when academic or training institutions determine which individuals will receive the funds.**

The commenter believes that the suggested edits to paragraph (a)2 clarify that financial support that lowers registration fees is given to the event's organizers, not to individual attendees. The

commenter suggested adding new paragraph (a)3 to allow for financial support of prescribers in training when an outside entity determines which prescribers receive the financial support; the commenter noted that this is allowed under the PhRMA Code.

RESPONSE TO COMMENTS 45, 46, AND 47: 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 declines to amend the rule as suggested by the commenters.

48. COMMENT: One commenter suggested amending the definition of "continuing education event" to insert "medical" into "continuing education event" to clarify an event where continuing medical education credits can be awarded.

RESPONSE: The Attorney General declines to amend the definition of continuing education event to include "medical" because the rules are intended to apply to all prescribers, not solely physicians. Accordingly, the continuing education must be inclusive of the different types of continuing education obtained. However, upon adoption, the Attorney General is changing the term "continuing education event" to "education event." (See Responses to Comments 18, 19, and 20)

49. COMMENT: Five commenters recommended amending the definition of "prescriber." Three of these commenters suggested amending the definition to exclude State officers and employees,

and special officers and employees in State agencies in the Executive Branch of State government who are required to abide by the State's Uniform Ethics Code.

In addition, four of the commenters suggested amending the definition to clarify who is a prescriber by specifying that it is a person who is authorized to prescribe prescription drugs and regularly practices in the State of New Jersey. One of the commenters specifically suggested the following language (additions to proposal in bold; deletions from proposal in strikethrough):

> "Prescriber" means a **person who is: (1) a** physician, podiatrist, physician assistant, advanced practice nurse, dentist, or optometrist licensed pursuant to Title 45 of the Revised Statutes**; (2) authorized to prescribe prescription drugs; and (3) regularly practices in the state of New Jersey.** "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**, or a state employee subject to the requirements of N.J.S.A. 52:13D-12**.

One of the commenters noted its concern that the proposed regulations would apply to many prescribers who work both in New Jersey and nearby states and, therefore, could unnecessarily restrict participation in educational or research activities by prescribers who work across multiple states.

Two commenters expressed concern that the proposed regulations would apply to prescribers who practice exclusively or primarily in another state and maintain a New Jersey license despite practicing little, if any, medicine in the State. One of these commenters believes that, if the rules were to apply to such out-of-State New Jersey prescribers, then many such prescribers would elect to deactivate their New Jersey licenses, rather than undertake the burden of complying with the rules or face the ambiguity of whether the rules apply to them. This

commenter further believes that the Attorney General's policy objective would not be served, or only minimally served, by applying the restrictions to individuals who do not regularly practice in New Jersey. The commenter contended that the minimal potential policy benefits of applying the restrictions to such prescribers is far outweighed by the practical burdens associated with requiring compliance by those individuals. Another commenter believes amending the rule to be expressly limited to prescribers who practice primarily in New Jersey would clarify the scope of the regulations and strike a more appropriate balance between regulating licensees within the State and allowing other states to regulate prescribers who chiefly practice in their state. The commenter cited as an example Vermont's sunshine law, which generally only applies to those healthcare professionals who regularly practice in Vermont.

RESPONSE: The Attorney General declines to amend the definition of "prescriber" as suggested by the commenters. 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 nor based upon their employer. In addition, the Attorney General notes that as prescribers are authorized to prescribe prescription drugs, such additional language is not necessary.

50. COMMENT: One commenter stated that the definition of "prescriber" is too broad and suggested amending the definition of "prescriber" to exempt researchers, retired physicians, insurance employees, etc. In addition, the commenter suggested that, if the focus is opioids, "prescriber" should be limited to prescribers of controlled dangerous substances who are registered with the Federal Drug Enforcement Administration.

RESPONSE: As discussed in the Response to Comments 5 through 15, upon adoption, the Attorney General is changing the definition of "bona fide services" to exclude research activities. Accordingly, researchers will not be subject to the bona fide services cap. The Attorney General declines to amend the definition of "prescriber" to exempt retired physicians or insurance employees and believes that the rules should apply to them.

In addition, the Attorney General declines to limit the application of the rules to prescribers of controlled dangerous substances. Although 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.

51. COMMENT: One commenter suggested amending the definition of "immediate family" at N.J.A.C. 13:45J-1.3(e)1 to make the rule more consistent with the State's conflict of interest law requirements by focusing on spouse or equivalent, children, and only those other relatives who reside in the same household as the prescriber, and would be a more reasonable approach for managing compliance. The commenter suggested the following language (additions to proposal in bold; deletions from proposal in strikethrough):

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

the individual's spouse, civil union partner, or domestic partner by blood, marriage, or adoption.

RESPONSE: The Attorney General agrees with the commenter that the definition of "immediate family" should be changed to be consistent with the State's conflict of interest law at N.J.S.A. 52:13D-13.i because the amendments better reflect the types of relationships, that is, those with the potential to result in undue influence, that were intended to be encompassed under the rule. Additional public notice of this change is not required because it does not change the effect of the intent of the rule to minimize undue influence through the acceptance of gifts and payments to immediate family members who would more likely be aware of the financial relationship between the prescriber and pharmaceutical manufacturer. The rule does not add any additional burden on the regulated community and continues to protect the public by minimizing the potential for conflicts of interest.

52. COMMENT: One commenter recommended amending the definition of "immediate family" to use the ACCME definition. The commenter noted that the proposed definition includes extended family, such as siblings, aunts/uncles, grandparents, and children, in-laws, and steps. The commenter contended that a physician cannot control all of these people and noted that there is no exception for related prescribers.

RESPONSE: The Attorney General, upon adoption, will change the definition of "immediate family" to focus the requirements on spouse or equivalent, children, and only those other relatives who reside in the same household as the prescriber consistent with the State's Conflict of Interest law (See the Response to Comment 51). The Attorney General is unable to comment on the suggested ACCME definition of "immediate family" as it was not specifically provided

and it is not a defined term in the Accreditation Council for Continuing Medical Education (ACCME®) and American Medical Association (AMA) Glossary of Terms and Definitions (April 2017).

53. COMMENT: Two commenters expressed concern that proposed prohibitions at N.J.A.C. 13:45J-1.3(e) would apply to New Jersey prescribers' "immediate family" members because such restrictions would be unduly burdensome and unworkable. The commenters noted that it would require myriad individuals who happen to be related to a New Jersey prescriber to be aware of, and comply with, the rules and believes it is unreasonable to expect that the aunt, uncle, niece, nephew, etc., of a New Jersey prescriber would be even be aware of the restrictions.

One of these commenters believes that, although the rules would prohibit individuals related to New Jersey prescribers from accepting items from manufacturers (and not prohibit the manufacturers from providing the items), many manufacturers will take measures to help ensure that they would not inadvertently cause the rules to be violated. The commenter believes, therefore, applying the prohibitions to New Jersey prescribers' "immediate family" members would be very difficult if not impossible because manufacturers will not be able to readily identify those individuals.

The commenters recommended that the Attorney General delete N.J.A.C. 13:45J-1.3(e). The commenters believe that it would be more reasonable for the rules to prohibit New Jersey prescribers from directing to their immediate family members payments or items of value that the prescribers themselves would be prohibited from receiving under N.J.A.C. 13:45J-1.3. The commenters believe that this approach would better balance the underlying policy reason for the Attorney General's decision to include N.J.A.C. 13:45J-1.3(e) in the draft rules (that is, to help

ensure that the rules could not be circumvented by prescribers simply directing otherwise prohibited payments/items of value to their immediate family members) with the practical difficulties of managing compliance with a restriction that involves individuals who are not healthcare professionals.

54. COMMENT: Two commenters recommended amending proposed N.J.A.C. 13:45J-1.3 to delete the definition of "immediate family" in paragraph (e)1 because it is overly broad.

RESPONSE TO COMMENTS 53 and 54: The Attorney General declines to delete the definition of "immediate family." The Attorney General, however, upon adoption, is changing the definition of "immediate family" to be consistent with the State's conflict of interest law at N.J.S.A. 52:13D-13.i to focus the requirements on spouse or equivalent, children, and only those other relatives who reside in the same household as the prescriber. (See the Response to Comment 51)

55. COMMENT: One commenter noted that the definition of "pharmaceutical manufacturer" is too broad because it applies to any "entity" that compounds drugs or biologics and that prescribers, like cancer specialty practices, compound drugs. The commenter suggested deleting "compounding." In addition, the commenter suggested that the definition should be amended to read "prescription drug or **prescription** biologics" because many biologics are not prescribed and should not be subject to the rule.

RESPONSE: The Attorney General declines to amend the definition of "pharmaceutical manufacturer" to exclude compounding. In accordance with the definition of "pharmaceutical manufacturer" prescribers and pharmacists acting within the ordinary scope of the practice for which they are licensed are excluded from the definition of "pharmaceutical manufacturer." The

Attorney General, upon adoption, will change the definition for purposes of clarification to add the modifier "prescription" before biologics.

56. COMMENT: One commenter noted that the proposed definition of "pharmaceutical manufacturer's agent" could be so broad as to cover a market research company, which would have a function that is very different than actual marketing of a drug product.

RESPONSE: To the extent that a market research company does not engage in detailing, promotional activities, or other marketing of prescription drugs or prescription biologics, by definition a market research company is not considered a pharmaceutical manufacturer's agent. In addition, as stated in the Response to Comments 5 through 15, the Attorney General, upon adoption, is changing the rules to exempt research activities from the definitions of "bona fide services" and "promotional activity," and to exclude from the bona fide services cap compensation for research activities. Accordingly, the Attorney General declines to amend the definition of "pharmaceutical manufacturer's agent."

57. COMMENT: One commenter recommended for clarity amending proposed N.J.A.C. 13:45J-1.8 as follows (additions to proposal in bold; deletions from proposal in strikethrough):

A prescriber who is ~~employed by~~ **an employee of** a pharmaceutical manufacturer and who also provides patient care shall disclose to patients either orally or in writing his or her employment by the pharmaceutical manufacturer, but is exempt from the ~~compensation prohibitions of this chapter~~ **prohibitions in subsection N.J.A.C. 13:45J-1.3 with respect to the employing pharmaceutical manufacturer.**

RESPONSE: The Attorney General declines to amend the rule language to change the exemption from the chapter's compensation prohibitions to those of N.J.A.C. 13:45J-1.3. 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 prohibitions at N.J.A.C. 13:45J-1.3. The purpose of N.J.A.C. 13:45J-1.8 is to require those prescribers who are employees of a pharmaceutical manufacturer and who also provide patient care to disclose to their patients, the employment relationship. The Attorney General, however, upon adoption will change the rule language to change "employed by" to "an employee of" to be consistent with the definition of "prescriber."

58. COMMENT: One commenter expressed concern that the proposed regulations include pharmaceutical wholesale distributor within the definition of "pharmaceutical manufacturer." The commenter noted that pharmaceutical distributors are responsible for ensuring that prescription medicines and healthcare products are delivered safely and efficiently to points-of-care nationwide (for example, pharmacies, hospitals, long-term care facilities, and clinics). The commenter further noted that wholesalers do not research, develop, or manufacture pharmaceutical products, nor do they prescribe or dispense medications. The commenter stated that wholesale distributors purchase and stock product from many authorized manufacturers, and provide their customers with a "one stop shop" to acquire virtually any drug product, medical device, or supplies. The commenter also stated that wholesale distributor services enable their customers to avoid having to invest in the infrastructure required to safely and efficiently store and manage massive quantities of products and medications from many manufacturers. The commenter believes that, due to wholesale distributors' placement and unique business model

within the pharmaceutical supply chain, regulations targeting manufacturers often unintentionally impact the wholesale distribution industry.

The commenter recommended including a definition for "wholesale distributor" and to exempt "wholesale distributor" from the definition of "pharmaceutical manufacturer." Specifically, the commenter recommended the following amendments (additions to proposal in bold):

"Pharmaceutical manufacturer" means any entity that:

1. (No change.)
2. Is directly engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or biologics, provided, however that "pharmaceutical manufacturer" or "manufacturer" shall not include a healthcare facility licensed by the Department of Health, or a pharmacy holding a permit issued by the Board of Pharmacy**, or a licensed wholesale distributor**.

"Wholesale distributor" means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in 21 U.S.C. 353(e)(4)).

RESPONSE: The Attorney General does not believe that licensed wholesale distributors should be exempted from the provisions of N.J.A.C. 13:45J because of the potential for undue influence in patient treatment decisions and declines to amend the rule as the commenter suggested.

59. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:45J-1.4 as follows (additions to proposal in bold; deletions from proposal in strikethrough):

~~10~~12. Financial assistance relating to medical treatment of or prescription drugs for a prescriber or a prescriber's immediate family member.

The commenter recommended including an exemption, so that the family of prescribers could receive financial assistance for prescription medications.

RESPONSE: The Attorney General did not intend for the proposed rules to preclude those prescribers, or their immediate family, with medical conditions who need financial assistance from obtaining necessary medications. The rules are intended to apply to prescribers in their capacity as a prescriber, not prescribers or their immediate family who are also patients. The Attorney General, in a future rulemaking, will amend the rules to address this issue.

60. COMMENTER: One commenter noted that the proposed rules should include prescribers who have an ownership interest in medical device companies and distributorships. The commenter believes that physicians having financial interests in a surgical intervention other than professional is another ethical concern worth addressing. The commenter believes that studies show that those with an ownership interest in device distributorships are more likely to proceed with surgical options than those who do not. The commenter recommended that doctors either be prohibited from having ownership interests not only in pharmaceutical companies but also medical device companies and distributorships of both pharmaceuticals and medical devices, or fully disclose to the patients that they have such ownership interests before using products in which they have an ownership interest. The commenter believes that there should be a mandatory requirement that physicians and other prescribers discuss alternatives to the medication/device or procedure being proposed when the prescriber has such financial interests.

RESPONSE: The Attorney General declines to include prescribers having ownership interest in medical device companies and distributorships. The Attorney General notes that this is a topic that continues to evolve and the immediate concern was the relationship between pharmaceutical manufacturers and prescribers. The Attorney General will continue to assess the impact of undue influence to determine if future rulemaking is necessary.

61. COMMENT: One commenter raised concerns that "trainees" are included within the scope of non-faculty participants (see N.J.A.C. 13:45J-1.3(a)4) and requested that the Attorney General consider a carve-out. The commenter stated that the prohibition on non-faculty participation is significant and may have an unintended impact on trainees. The commenter also noted that 'pharm' supports useful scientific content that is not directly promotional and not 'CME-unit' granting.

RESPONSE: The Attorney General notes that the rules at N.J.A.C. 13:45J apply to prescribers licensed pursuant to Title 45 of the Revised Statutes or practices. Accordingly, if "trainees" refers to students who are not licensed, the rules do not apply.

62. COMMENT: One commenter noted that, in 2007, a State advisory board previously considered compensation arrangements that were perceived to influence medical care or medical practice or – more specifically – doctors getting paid too much from pharmaceutical companies, and concluded that there were sufficient regulatory and voluntary safeguards coupled with robust ethical standards within the practice of medicine itself to prevent undue influence. The commenter questioned the renewed focus on this issue as a way to mitigate this rising opioid epidemic. The commenter contended that the proposed rules will not address this epidemic and

will have unintended consequences for the research and development of new cures and a chilling effect on education for physicians who seek better solutions for treating pain. The commenter, moreover, believes that if there is evidence of inappropriate influence, enforcement action should be taken under existing rules and standards and guilty parties appropriately sanctioned. The commenter noted that in December 2016, the Federal government arrested six former executives for allegedly bribing doctors to prescribe fentanyl, an extremely addictive opioid pain killer, and believes this is the proper way to address such an issue.

The commenter stated that the proposed rules will: limit a healthcare professional's education on effective products and tools to combat the opioid epidemic; reduce the number of clinical trials in New Jersey, essential to bringing research and development for new drugs for the industry in the State; and restrict the flow of pharmaceutical-related information to physicians and patients. The commenter also stated that the proposed rules distract from making the difficult choices to aggressively address the opioid problem both ruining and claiming lives. The commenter also stated that there is no evidence to support additional limitations or regulations, there have not been recent prosecutions against doctors related to this issue in New Jersey, nor complaints that current rules are inadequate. The commenter further stated that the public health need is in mitigating this opioid crisis directly, not in generating redundant regulations to make people feel better.

RESPONSE: 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 proposed rules are intended to strengthen enforcement efforts to address prescriber acceptance of items of value from drug manufacturers. As noted in the notice of

proposal, because prescribers, including physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists, as part of their scope of practice, may establish financial relationships with pharmaceutical manufacturers, there is concern that these relationships influence prescriber treatment decisions. 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, as discussed in the Response to Comments 5 through 15, the Attorney General, upon adoption, is changing the rules to make it clear that activities associated with research, including clinical trials, are not subject to the bona fide services cap. In addition, upon adoption, the Attorney General is addressing the concerns about restricting the flow of pharmaceutical-related information to physicians and patients by removing the four times per year per manufacturer limitation on the number of modest meals that can be provided by a manufacturer. The Attorney General, upon adoption, is also clarifying that education events, which include non-accredited education programs, is also permitted, subject to the modest meals restriction. (See the Response to Comments 35 through 38)

67. COMMENT: Four commenters noted that current State and Federal laws exist that already regulate interactions between manufacturers and healthcare providers. The commenters referenced the Physician Payments Sunshine Act, Federal Anti-Kickback laws, and other regulatory restrictions that establish a highly transparent system of reporting while proposed N.J.A.C. 13:45J adds more layers of complexity into the system without adding substantial value

to the existing framework.

One commenter noted that, when the PhRMA Code was developed, it was anticipated to be a voluntary, but reasonable, approach to interactions with healthcare providers. The commenter also noted that even those who do not voluntarily comply with this code or lack the resources for large scale marketing efforts, must still act in good faith within the guidance issued by the Federal Health and Human Services Office of Inspector General's Federal Compliance Program Guidance for Pharmaceutical Manufacturers, violations of which are prosecuted by the Department of Justice.

One of these commenters also noted that biopharmaceutical companies have robust compliance programs in place, designed to significantly mitigate fraud and abuse and comply with Federal healthcare program laws and regulations that already implement the controls recommended in the proposed rules.

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.

68. COMMENT: Two commenters raised concerns about the prohibition on gifts other than items primarily designed for educational purposes for the patient or the healthcare professional outside of their professional responsibilities that have minimal or no value. The commenters believe this *defacto* prohibition will inadvertently diminish patient care in instances where such things as pillboxes could be very helpful in adherence.

RESPONSE: N.J.A.C. 13:45J-1.4(a)1 permits information and materials in any form directly related to patient care, including pillboxes.

69. COMMENT: One commenter sought clarification as to whether the $15.00 threshold for modest meals applies to the permitted payments for reimbursement for travel and lodging to speakers or faculty organizers at continuing education events or promotional activities.

RESPONSE: The $15.00 modest meal limitation does not apply. In accordance with adopted N.J.A.C. 13:45J-1.4(a)5 and 6, a prescriber serving as a speaker or faculty organizer or academic program consultant for an education event, or for a promotional activity may accept reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services.

70. COMMENT: One commenter noted that it has dedicated significant financial resources to providing unbranded disease-state education across the spectrum of mental health. The commenter stated that these non-branded presentations educate mental healthcare providers at times when they are not seeing patients, on such topics as early intervention in psychosis, co-occurrence of substance use disorders with mood disorders and psychosis, and non-pharmacological strategies in mental health. The commenter stated that under the proposed rules it would be unable to conduct such programs, which are not promotional and discuss no specific drugs or treatments, and are an available resource for New Jersey prescribers to improve psychiatric disease understanding and patient outcomes.

RESPONSE: As discussed in the Responses to Comments 18, 19, and 20 and 35, 36, 37, and 38, the Attorney General, upon adoption, is making changes that will allow for non-accredited education programs. Specifically, the Attorney General, upon adoption, is changing the definition of continuing education event to education event, and will broaden it such that it encompasses accredited and non-accredited education events that meet the definition, and will remove the four times per year per manufacturer limitation for modest meals provided to non-faculty prescribers through promotional activities.

71. COMMENT: One commenter stated that she does not believe that healthcare professionals are influenced by the buying of coffee or meals and, therefore, prescribe prescription medications for patients that do not need them. The commenter noted that, an educated healthcare professional who has been treating a patient and knows the patient will prescribe what is needed for that patient. The commenter believes that a healthcare professional encourages patients to take care of themselves, eat well, and work towards being healthier individuals. The commenter does not believe that the healthcare professional is prescribing medication because a pharmaceutical representative brings coffee or a meal. The commenter stated that the healthcare professionals look at exchanges with pharmaceutical manufacturers as an opportunity to gain new information on medications available to treat their patients, which they might not otherwise know about. The commenter believes that the proposed rule speaks about a healthcare professional as a limited thinker rather than believing that the healthcare professional is an educated individual, who in some cases has been practicing medicine for years. In addition, the commenter questioned looking at the providers and pharmaceutical manufacturers, as opposed to the insurance companies, which ultimately control decisions for prescribed medications.

The commenter believes that, if the basis for the rule proposal is the current nationwide opioid crisis, the State should focus only on that class of drugs. The commenter noted that the crisis was not born from pharmaceutical manufactures alone. The commenter also noted that government failed to monitor one of its own agencies when the crisis was developing. The commenter questioned the need for more government regulation in the healthcare industry, when the country's own government agencies did not catch the opioid crisis.

In addition, the commenter believes the proposed rules could have a potential impact on the State's economy. The commenter stated that pharmaceutical manufactures spend a lot of money in the hotel and restaurant industry in the State. The commenter believes that there would be a potential trickle-down effect on the economy or a large manufacturer may choose to leave the State, which would result in job loss.

RESPONSE: The Attorney General notes that studies show that gifts, no matter their size, can influence prescriber decision making. The intent of the rule is to minimize conflicts of interest, so that prescriber treatment decisions are guided by the best interest of patients. The Attorney General believes that because of the changes made upon adoption there is less potential negative impact on the State's economy. In addition, to the extent there is any negative economic impact upon the hotel and restaurant industry in the State, the Attorney General believes that any such impact is greatly outweighed by assuring that patients' treatment decisions are based upon prescribers' unbiased judgment about the patients' best interests.

72. COMMENT: One commenter noted that it appears that the Attorney General inadvertently did not include in the proposed rules an express permission to allow New Jersey prescribers to accept reasonable travel, lodging, and meal expenses in conjunction with consulting

arrangements. The commenter noted that the draft rules would permit New Jersey prescribers to receive compensation and related expenses from pharmaceutical manufacturers in conjunction with providing bona fide services as a speaker, faculty organizer, or academic program consultant for continuing educational events and promotional activities, but the express mention of related expenses is not included in the section regarding consulting arrangements. More specifically, the commenter noted that N.J.A.C. 13:45J-1.4 would permit prescribers to accept:

- "Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for a continuing education event. A prescriber serving in this capacity may also accept reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may be granted continuing education credit for participation in such activities, if the continuing education requirements of the prescriber's professional licensing board are satisfied." N.J.A.C. 13:45J-1.4(a)5 (emphasis added)
- "Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for a promotional activity, consistent with such caps as set forth at N.J.A.C. 13:45J-1.6. A prescriber serving in this capacity also may accept reasonable payment or remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may not claim continuing education credit for participation in such activities." N.J.A.C. 13:45J-1.4(a)6 (emphasis added)

- "Compensation, based on fair market value, for participation on advisory bodies or under consulting arrangements, consistent with such cap as set forth at N.J.A.C. 13:45J-1.6." N.J.A.C. 13:45J-1.4(a)7.

The commenter presumed that the omission of an explicit mention of travel, lodging, and other personal expenses under the draft provision relating to consulting arrangements was inadvertent. The commenter noted that, with respect to expenses, there is nothing distinctly different about consulting arrangements as compared to the other types of service arrangements addressed in the new rules. The commenter expressed concern that not expressly mentioning travel, lodging, and other personal expenses under the draft provision relating to consulting arrangements will cause ambiguity and confusion. Accordingly, the commenter requested that the Attorney General amend N.J.A.C. 13:45J-1.4(a)7 to expressly include expenses, as follows (additions to proposal in bold):

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

RESPONSE: The Attorney General agrees with the commenter that the rules inadvertently omitted a provision for remuneration for travel, lodging, and other personal expenses associated with participation on advisory bodies or under consulting arrangements. As the commenter noted, a prescriber providing these services should be treated the same as a speaker or faculty organizer or academic program consultant for an education event or promotional activity. Accordingly, the Attorney General, upon adoption, will change N.J.A.C. 13:45J-1.4(a)7 as the

commenter suggested. The intent of the rule is to minimize the potential for conflicts of interest as a result of promotional activities to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber. The Attorney General does not anticipate additional influence will result from the reasonable payment or remuneration of personal expenses associated with participation on advisory boards or under consulting arrangements.

73. COMMENT: One of the commenters expressed concern that the proposed rules would unduly restrict employment relationships involving New Jersey prescribers who are employed by a pharmaceutical manufacturer and who continue to provide patient care. In addition, the commenter expressed concern that the proposed rules would prohibit New Jersey prescribers from accepting travel, lodging, and other personal expenses that a manufacturer would provide in conjunction with bona fide efforts to recruit the prescriber for employment at the manufacturer (for example, to serve as a chief medical officer).

The commenter noted that N.J.A.C. 13:45J-1.2 of the draft rules helpfully excludes from the definition of "prescriber" a "licensee who is an employee ... of a pharmaceutical manufacturer who does not provide patient care." (emphasis added) The commenter noted that it is common for prescribers employed by manufacturers to occasionally volunteer at local clinics and community health centers (for example, a manufacturer's chief medical officer who volunteers once per month at a local clinic) and that these individuals would not fall into the proposed exemption to "prescriber" because they would occasionally provide patient care. The commenter stated that although it is helpful that N.J.A.C. 13:45J-1.8 would exempt from the compensation restrictions prescribers employed by a pharmaceutical manufacturer who also provide patient care, it appears that manufacturer-employed prescribers who also provide patient

care would be subject to the other restrictions and prohibitions in the draft rules. The commenter stated that such prescribers would be subject to the prohibitions set out in N.J.A.C. 13:45J-1.3, including the prohibition on accepting "any financial benefit or benefit-in-kind" from a manufacturer, as well as the meal restrictions, among others. The commenter believes, therefore, that they would be prohibited from accepting many benefits and items of value that manufacturers would normally provide as part of the usual and customary employment relationship with their employees. For example, it appears that such manufacturer-employed prescribers would be prohibited from accepting meals and refreshments provided during internal company department meetings and employee events (for example, holiday parties), or even flu shots and other in-kind benefits that a manufacturer might provide to its employees.

The commenter expressed concern that there could be myriad unintended consequences that would arise in applying the restrictions of the draft rules to manufacturers' employees who are prescribers who also occasionally provide patient care. The draft rules would undoubtedly place a significant burden on such individuals, and likely result in fewer of them volunteering time at clinics and community health centers in New Jersey in an effort to avoid the substantial burden and ambiguities associated with the rules. The commenter contended that all stakeholders would be negatively impacted by the rules, including the prescribers, New Jersey residents who benefit from the care that they continue to provide, the State would have to find other ways to provide such care, and the manufacturers who may have reduced opportunities to employ these difference-making prescribers. The commenter also believes that the policy reasons underlying the proposed restrictions are not well-served by applying the restrictions to manufacturers' physician employees who will be already receiving salaries from manufacturers.

In addition, the commenter stated that the proposed rules provide no recourse for New Jersey prescribers who may be interviewing for bona fide employment with manufacturers, and who may receive reasonable travel, lodging, and meal expenses from a potential employer as part of the recruitment process. The commenter noted that these individuals would not yet be employees and, therefore, would not be covered by the existing exemption in the draft rules, even if they did not provide patient care. The commenter also stated, for example, that it appears that a New Jersey prescriber interviewing to be a chief medical officer at a manufacturer would be unable to accept any expenses from the manufacturer associated with the recruitment process. Such expenses are customary, appropriate, and critical to the recruitment process, which often requires candidates to decide whether they would be willing to move their families to a new location. The commenter expressed concern that the proposed rules could significantly frustrate efforts to recruit New Jersey prescribers for bona fide employment with manufacturers.

Accordingly, the commenter requested that the Attorney General amend the rules to more generally and broadly exempt from the restrictions those New Jersey prescribers who are employees of pharmaceutical manufacturers (irrespective of whether they provide patient care). The commenter supported the Attorney General's proposal to require such prescribers who occasionally provide patient care to disclose to patients their employment with the manufacturer because it believes that obligation would be an appropriate and sufficient policy measure to address any potential conflicts of interest involving prescribers who are employed by manufacturers. The commenter also suggested that the Attorney General amend the rules to expressly permit New Jersey prescribers to accept reasonable travel, lodging, and other personal expenses in association with bona fide employment recruitment efforts.

RESPONSE: The Attorney General disagrees with the commenter that N.J.A.C. 13:45J would unduly restrict employment relationships involving New Jersey prescribers who are employed by a pharmaceutical manufacturer and who continue to provide patient care. N.J.A.C. 13:45J-1.8 clearly states that a prescriber who is employed by a pharmaceutical manufacturer and who also provides patient care is exempt from the compensation prohibitions of the chapter and is subject to only the employment disclosure requirement.

The Attorney General did not intend for the rules at N.J.A.C. 13:45J to impact legitimate recruitment efforts of prescribers. Accordingly, upon adoption, the Attorney General will change N.J.A.C. 13:45J-1.4 to specifically include paragraph (a)9 to allow for reasonable payment or remuneration to prospective applicants for travel, lodging, and other personal expenses associated with employment recruitment. Additional public notice of this change is not required because it does not alter the effect of the rule, which is to minimize the potential for conflicts of interest as a result of promotional activities to ensure that patient care is guided by the unbiased, best judgment of the treating prescriber, so as to destroy the value of the original notice.

74. COMMENT: One commenter suggested amending N.J.A.C. 13:45J-1.1 as follows (additions to proposal in bold; deletions from proposal in strikethrough):

> The rules in this chapter regulate the receipt and acceptance by prescribers ~~of anything~~ **of select items and/or services of value** from pharmaceutical manufacturers to ensure that such relationships do not interfere with the prescribers' independent professional judgement.

The commenter stated that the rationale for this change is that this proposed rule will not cover all payments made to prescribers given that there will be distinct carve-out exclusions.
RESPONSE: The Attorney General declines to amend the rule as the commenter suggests because it is unnecessary as the rules apply to acceptance of value and provide for exceptions.

75. COMMENT: One commenter recommended adding a new rule that clearly defines the scope of the rules. The commenter specifically recommended including a clear statement to the fact that the proposed rules are applicable only to items and/or services provided to prescribers by manufacturers of drugs and biologics and is not applicable to items and/or services provided by manufacturers of medical devices or similar products (for example, royalty payments); if a company manufactures both drugs and biologics, as well as devices or similar products, the proposed rules will apply only to the interactions related to that company's drug or biologics business.

The commenter also suggested including a clear statement to the fact that all research and development (R&D) and R&D-related non-promotional services are exempt from coverage under the proposed rules. In addition, the commenter recommended considering the working definition of "research" currently available under the Federal Sunshine Act. The commenter stated that R&D is defined as ''a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic and applied research and product development … including pre-clinical research and FDA Phases I–IV research, as well as investigator-initiated investigation."

In addition, the commenter recommended specifying that R&D related non-promotional services related to the exchange of scientific information and sharing of clinical experience, including, but not limited to, the following examples below, are also exempt from the proposed rules (as they do not satisfy the "promotional activity" definition, they are not continuing education, and may not be captured in service agreements): scientific advisory boards, FDA-mandated REMS programs, trade conferences, development projects, and research collaboration and product innovation discussions.

The commenter also recommended specifying that grants, scholarships, and charitable contributions, intended to support research and public health programs and that are not promotional in nature, are also exempt from the proposed rules.

The commenter stated that the rationale for the exemption of R&D, R&D-related services, as well as grants, scholarships and charitable contributions, is that these are non-promotional activities and services and are designed to contribute to advancement of science and medicine, to promote the safety and efficacy profiles of drugs or biologics, to identify proper treatment options and to contribute to the overall public welfare, health, and safety.

RESPONSE: As discussed in the Response to Comments 5 through 15, the Attorney General, upon adoption, is exempting research from the definition of bona fide services and from the bona fide services cap. In addition, upon adoption, the Attorney General will change N.J.A.C. 13:45J-1.4 and 1.6 to allow for payments of royalties and licensing fees paid in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the prescriber holds an ownership right, and to exclude such payments from the bona fide services cap. (See the Response to Comment 17) 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. (See the Response to Comments 45, 46, and 47)

76. COMMENT: One commenter suggested amending N.J.A.C. 13:45J-1.5 to eliminate references to 'devices.' The commenter believes that if a company manufactures both drugs and biologics, as well as devices or similar products, the proposed rules will apply only to the interactions related to that company's drug or biologics business.

RESPONSE: Consistent with the heading of N.J.A.C. 13:45J-1.5, which refers solely to sample medications, the Attorney General, upon adoption, will change the rule to delete "devices." Additional public notice of this change is not required because it does not change the effect of this rule, so as to destroy the value of the original notice. As set forth at N.J.A.C. 13:45J-1.1 the purpose of the chapter is to regulate the receipt and acceptance by prescribers of anything of value from pharmaceutical manufacturers. In accordance with the definition of "pharmaceutical manufacturers," the rules apply to manufacturers of prescription drugs or biologics; by definition pharmaceutical manufacturers do not manufacture devices.

77. COMMENT: Two commenters opposed proposed N.J.A.C. 13:45J-1.7 because it imposes a requirement that speakers at continuing education and promotional events disclose orally or in writing if they have accepted payments from a sponsoring manufacturer during the preceding five years. One of these commenters noted that the PhRMA Code does not impose a lengthy look-back time period. One of these commenters noted that the ACCME only requires disclosure going back one year and recommends changing the look back period to one year.

RESPONSE: The Attorney General declines to change the look back period from five years to one year because the Attorney General believes the five-year requirement promotes greater transparency.

78. COMMENT: One commenter requested that the Attorney General withdraw the rule proposal. The commenter stated that, if finalized, the proposed rules will create a system that prevents valuable interactions between healthcare professionals and biopharmaceutical manufacturers, which is essential to communicating the most current and relevant on-label information about potentially life-saving approved medicines; severely curtail clinical research conducted in New Jersey by placing an unrealistically low cap on payments to clinicians conducting clinical trials in the State, a consequence with impact shared by patients and clinicians alike; and will place a tremendous administrative and operational burden on both prescribers and manufacturers due to the requirements needed to redesign processes, policies, procedures, and systems to aid compliance, above and beyond the existing regulatory requirements to ensure financial transparency.

The commenter stated that if the State determines to proceed with the proposal, it would suggest the following amendments:

"Fair market payments made for all legitimate research activities" should be specifically:

1. Included in the definition of "bona fide services" at N.J.A.C. 13:45J-1.2, subject to the six elements of a written agreement, described in that definition.

2. Included in the list of permitted payments at proposed N.JA.C.13:45J-1.4. Proposing a subparagraph (a)8 that would read, "Compensation, based on fair market value, for a bona-fide service related to the conduct of a clinical trial,

including medical supplies, staffing and physician services. A prescriber performing bona fide services related to the conduct of a clinical trial may accept reasonable payment and remuneration for travel, lodging and other expenses associated with such services."

3. Excluded from the bona fide services cap at N.J.A.C.13:45J-1.6.

As an alternative to withdrawing the proposal or amending the rules as suggested above, the commenter suggested that instead of an annual dollar value cap placed on prescribers in the State, the State consider creating a reporting requirement for payments from manufacturers for non-excluded services above a reasonable threshold. The commenter believes that this approach would allow the State to collect data over time on the actual volume and nature of true promotionally based prescriber payments in the State.

RESPONSE: The Attorney General, upon adoption, is exempting research activities from the definition of bona fide services and the bona fide services cap. (See the Response to Comments 5 through 15) In addition, upon adoption, the Attorney General is changing N.J.A.C. 13:45J-1.4(a) to specify that reasonable payment or remuneration for travel, lodging, and other personal expenses associated with participation on advisory bodies or under consulting arrangements is permissible. (See the Response to Comment 72). To the extent that participation on advisory boards or under consulting arrangements does not encompass all research activities, upon adoption, the Attorney General will add N.J.A.C. 13:45J-1.4(a)8, allowing for the reasonable payment or remuneration for travel, lodging, and other personal expenses in connection with research. Additional public notice of this change is not required because it does not change the effect of the rule so as to destroy the value of the original notice. The Attorney General does not believe that additional influence will result from the reasonable payment or remuneration of

personal expenses in connection with performing research, which is also excluded from the bona fide services cap. The Attorney General, upon adoption, is also changing the definition of continuing education event, such that speakers at both accredited and non-accredited education programs will be exempt from the bona fide services cap. (See the Response to Comments 18, 19, and 20) The Attorney General declines to eliminate the bona fide services cap or to replace it with a reporting requirement because he believes the cap is reasonable and it is an appropriate mechanism to minimize conflicts of interest.

79. COMMENT: Two commenters recommended that the Attorney General afford New Jersey prescribers and manufacturers at least a 180-day time period between when the final rules are published in the New Jersey Register and when they go into effect. The commenters believe that prescribers and manufacturers will need sufficient lead time to review and analyze the final rules, assess how they will impact their activities, develop necessary policies and procedures to help ensure compliance, and train on those policies and procedures. The commenters, in particular, noted that the final rules will likely impose for the first time, new expense tracking and related requirements on New Jersey prescribers (if the compensation and meal caps would be maintained in the final rules), which will require New Jersey prescribers to implement some form of policies, procedures, and related measures. The commenters believe that a vast majority of New Jersey prescribers will have minimal or no experience with such tracking requirements, and believe that it will take some time for prescribers to put necessary mechanisms in place. The commenters believe that even though the provisions of the final rules will more directly restrict New Jersey prescribers from accepting certain items and compensation (and not expressly prohibit manufacturers from providing such items and compensation), affected entities will

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

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

Federal Standards Statement

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

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

***13:45J-1.1A Pre-existing contracts**

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

13:45J-1.2 Definitions

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

"Bona fide services" means those services provided by a prescriber pursuant to an arrangement formalized in a written agreement including, but not limited to, presentations as speakers at promotional activities and *[continuing educational]* ***education*** events, participation on advisory boards, and consulting arrangements. ***"Bona fide services" does not include those services provided by a prescriber in connection with research activities.*** The written agreement shall specify the services to be provided, the dollar value of the consideration to be received by the prescriber, based on *[their]* ***the*** fair market value of the services, ***specify that the meetings held in association with bona fide services occur in venues and under circumstances conducive to the services provided and that the activities related to the services are the primary focus of the meeting,*** and identify the following:

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

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

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

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

"*[Continuing education]* ***Education*** event" means *[a continuing]* ***an*** education event, third-party scientific or educational conference, professional meeting ***or workshop***, ***seminar,*** U.S. Food and Drug Administration required education and training, or any other gathering *[where responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the event's organizers in accordance with the standards of a nationally recognized accrediting entity,]* held in a venue that is appropriate and conducive to informational communication and training about healthcare information, where:

1.-2. (No change from proposal.)

...

"Pharmaceutical manufacturer" means any entity that:

1. (No change from proposal.)

2. Is directly engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs or ***prescription*** biologics, provided, however, that "pharmaceutical manufacturer" or "manufacturer" shall not include a healthcare facility licensed by the Department of Health, or a pharmacy holding a permit issued by the Board of Pharmacy.

...

"Promotional activity" means any unaccredited activity, meeting, or program organized or sponsored by a pharmaceutical manufacturer, or the manufacturer's agent, that is directed at prescribers to promote the prescription, recommendation, supply, administration, use, or

consumption of the manufacturer's products through any media or medium. ***"Promotional activity" does not include an education event or services provided in connection with research activities.***

...

"Non-faculty" means a prescriber who does not serve as a speaker or provide actual and substantive services as a faculty organizer or academic program consultant for *[a continuing]* ***an*** education event or for a promotional activity.

...

"Research" means any study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies, or any systemic investigation, including scientific advising on the development, testing, and evaluation, that is designed to develop or contribute to general knowledge, or reasonably can be considered to be of significant interest or value to scientists or prescribers working in a particular field. "Research" shall include both pre-market and post-market activities that satisfy the requirements of this definition.

13:45J-1.3 Prohibited gifts and payments

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

(c) Except as permitted under N.J.A.C. 13:45J-1.4, a prescriber shall not accept from any pharmaceutical manufacturer or manufacturer's agent any item of value that does not advance disease or treatment education, including:

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

4. Any payment or direct subsidy to a non-faculty prescriber to support attendance at, or as remuneration for time spent attending, or for the costs of travel, lodging, or other personal expenses associated with attending any *[continuing]* education event or a promotional activity.

(d) (No change from proposal.)

(e) Unless an immediate family member is employed by a pharmaceutical manufacturer and receives, as part of the usual and customary employment relationship, compensation, financial benefit, or other item of value, the prohibitions listed in this section shall also apply to the prescriber's immediate family.

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

13:45J-1.4 Permitted gifts and payments

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

1. (No change from proposal.)

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

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

4. Modest meals provided ***by a manufacturer*** to non-faculty prescribers through promotional activities *[no more than four times in a calendar year from the same manufacturer]*.

5. Compensation, based on fair market value, for providing bona fide services as a speaker or faculty organizer or academic program consultant for *[a continuing]* ***an*** education event. A prescriber serving in this capacity may also accept reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services. A prescriber may be granted continuing education credit for participation in such activities, if the continuing education requirements of the prescriber's professional licensing board are satisfied.

6. (No change from proposal.)

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

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

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

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

13:45J-1.5 Sample medications

A prescriber may accept sample medications *[or devices]* that are intended to be used exclusively for the benefit of the prescriber's patients, provided the prescriber does not charge patients for such samples, and provided all dispensing standards, as applicable, set forth in the prescriber's licensing board rules are satisfied.

13:45J-1.6 Bona fide services cap

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

13:45J-1.7 Disclosure requirements

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

13:45J-1.8 Prescribers employed by pharmaceutical manufacturer

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