

**Summary of Proposed Amendments to the  
Regulation Limiting Compensation from Pharmaceutical Manufacturers to Prescribers**

**Key Points:**

- **Meals at *education events* are exempt from both the “modest meal” amount limitation and are not included in the \$10,000 cap.** These are meals provided through an event organizer, even if supported by a pharmaceutical manufacturer, so long as the meals facilitate the educational program to maximize prescriber learning, including information about disease states and treatment approaches. See preamble proposal *and* N.J.A.C. 13:45J-1.4(a)(5) *and* definition of education event at N.J.A.C. 13:45J-1.2.
- **Compensation to physicians, based on fair market value, for *bona fide* services as a speaker at an education event, even if supported by a pharmaceutical manufacturer, which facilitate the educational program to maximize prescriber learning, including information about disease states and treatment approaches is permitted under N.J.A.C. 13:45J-1.6 and also is not subject to the \$10,000 cap.** See N.J.A.C. 13:45J-1.4(a)(5).
- **The defined “Modest Meal” amount for *promotional events* has been increased from \$15 to \$30 for dinners;** breakfast and lunch continue to be limited to \$15; these amounts will no longer include delivery, service, tax, or facility rental fee charges; and, the amounts will be adjusted by the Consumer Price Index.
- **“Modest meals”** provided by a manufacturer to non-faculty prescribers through promotional activities are limited to the defined (\$15/\$30) amount, but will no longer be included in the \$10,000 cap.
- **The AG will not enforce during the rulemaking process,** so long as the prescriber is in compliance with the proposal.
- The proposal clarifies that it was meant to apply to all physicians with an active NJ license, who practice in New Jersey or who have New Jersey patients, regardless of the physician’s practice site.

The AG was persuaded by MSNJ’s position that there is a public interest in physicians learning about disease states and treatment options and believes the proposal will further the exchange between practitioners and pharmaceutical manufacturers for the benefit of patient care. That resulted in a lift of the cap on the meal cost and removal of the meal cost from the \$10,000 cap at education events. These education events must take place in a venue and under circumstances conducive to learning. The purpose should be to impart scientific, evidence-based data and important information about developments concerning treatment options to address a variety of disease states. Physician compensation for speaking at these events is also not capped. Physicians are urged to ensure that

speaking engagements at education events comply with FDA and pharmaceutical association guidelines to ensure objectivity.

Research is broadly defined under the existing regulation:

"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. N.J.A.C. 13:45J-1.2.

Compensation for research activity is not capped.

*MSNJ*

*updated June 28, 2018*