



SUMMARY OF NEW REGULATIONS REGARDING RELATIONSHIPS WITH PHARMACEUTICAL MANUFACTURERS January 2018

The Attorney General of New Jersey has promulgated new regulations regarding prescriber relationships with pharmaceutical manufacturers. Though the premise is overprescribing of opioids, the rule applies to all drugs. The Attorney General's office is expected to create FAQs and other guidance. MSNJ will continue to monitor and update members on this new rule.

SCOPE

The rule applies to all licensed prescribers, except employees of pharmaceutical manufacturers who do not see patients. Pharmaceutical manufacturers are entities that make, package, distribute prescription drugs or prescription biologics. Pharmaceutical/manufacturer agents are marketing and promotion agencies. **Device manufacturers are NOT included.**

PROHIBITED GIFTS AND PAYMENTS

A prescriber shall not accept, directly or indirectly, any financial benefit or benefit-in-kind, including, but not limited to, gifts, payments, stock, stock options, grants, scholarships, subsidies, and charitable contributions from any pharmaceutical manufacturer or manufacturer's agent.

A prescriber shall not accept, directly or indirectly, any entertainment or recreational items, such as tickets to theater or sporting events, or leisure or vacation trips, from any pharmaceutical manufacturer or manufacturer's agent.

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. Pens, note pads, clipboards, mugs, or other items with a company or product logo;
2. Items intended for the personal benefit of the prescriber or staff, such as floral arrangements, sporting equipment, artwork, or items that may have utility in both the professional and non-professional setting, such as electronic devices;
3. Any payment in cash or cash equivalent, such as a gift certificate;

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.

The definition of "immediate family" is very broad and includes: 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, 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.



CAP ON COMPENSATION

In addition to the above prohibitions, the new rule places a \$10,000 annual total cap on payments for certain services. This cap is placed on the prescriber receiving payment, not on the entity providing payment, and it is cumulative for any and all entities providing payment in one year. It is the physicians' responsibility to track and not exceed the annual cap.

The cap narrowly applies to **promotional activity by a manufacturer or agent**, not research or educational events (which are defined broadly):

"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.

Educational events and services provided in connection with research are not considered promotional activities. Educational events include both CME accredited and non-accredited events. Prescribers serving as speakers at educational events or conducting research may also accept reasonable payment and remuneration for travel, lodging, and other personal expenses associated with such services.

Research, which is exempt from the cap, "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.

The cap applies to "bona fide services", including "consulting arrangements" and "participation on advisory boards," but only for promotional activity. All agreements for services must be in writing and specify the market value of the service, a specification that meetings held in association with the services occur in venues and under circumstances conducive to the services provided and that activities relate to the services that are the primary focus of the meeting.

This cap will not apply to any contracts entered into on or before January 15, 2018.

MEALS

The rule also places a cap on meals a prescriber can receive as an attendee of an event or at her office: each meal must be equal or less than \$15 and must be tied to an educational event or promotional activity. Though many stakeholders argued that it is impossible for meals to be less than \$15 at hotel or conference venues, the rule is final. A small percentage of accredited CME is supported by pharmaceutical manufacturers.

A prescriber may not accept any other meal from a pharmaceutical manufacturer or agent.



DISCLOSURE

A prescriber serving as a speaker at 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 supporting pharmaceutical manufacturer within the preceding five years. Note: ACCME only requires disclosure going back one year, so prescribers must remember to heed New Jersey law.

This summary is provided as a guide to the final rule published on January 16, 2018. For more details, and to receive the benefit of the commentary, please consult the [final rule](#). MSNJ and other stakeholders were successful in our efforts to expand the definitions of research and education and to remove those subjects from the cap. We were also successful in removing the four meal limit from the final rule.