

COMPENSATION FROM PHARMACEUTICAL COMPANIES: **THE AMENDED RULES**

On January 16, 2018, regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers went into effect in the State of New Jersey. The rules were established to minimize conflicts of interest between health care prescribers and pharmaceutical manufacturers and to ensure prescribers use best judgment when treating patients. In August 2018, the Attorney General, Gurbir S. Grewal, proposed amendments to the rules in an effort to increase clarity and, in particular, to address concerns related to the modest meal limit and the rules' impact on educational events. After a notice and comment period, the [amended rules](#) went into effect on May 6, 2019. The key changes are briefly summarized below.

The Scope of the Rules and “Prescribers”

The revised rules make it clear that they do not apply to prescribers' interactions with pharmaceutical manufacturers concerning medical devices. Therefore, if a manufacturer manufactures pharmaceuticals and/or biologics as well as medical devices and the interactions between the manufacturer and the prescriber are devoted solely to medical devices, the rules do not apply to such interactions.

Additionally, the rules now specify that they apply only to a prescriber who holds an active New Jersey license and who: (1) practices in New Jersey; or (2) has New Jersey patients regardless of the prescriber's practice site. Accordingly, the definition for “prescriber” was amended to mirror this change. When concerns were raised about whether this criteria was too broad, the Attorney General stated, “[T]he rules should apply equally to all prescribers licensed by the State” no matter where they regularly practice.

“Modest Meals” and the “Consumer Price Index”

In response to concerns about the \$15 meal limit being untenable, the limit was reformulated to allow for a \$15 limit for breakfast and lunch and a \$30 limit for dinner. These limits were set for 2018, and the rules provide for

adjustments in line with the Consumer Price Index. A definition for “Consumer Price Index” was incorporated into the rules, which indicates that adjustments should be made in dollar increments to reflect the Consumer Price Index annual average.

Meals provided at education events are no longer subject to the “modest meal” limits, even if the event is supported by a manufacturer. In addition, neither modest meals nor meals provided at education events are subject to the bona fide services cap, and fair market value does not include the cost of standard delivery, service, facility rental fee charges, or tax.

“Education Events”

Under the amended rules, the definition of “education event” was changed to specify that so long as a program is not classified as promotional by the Food and Drug Administration (FDA), the event is considered an “education event” if it meets the definition set forth in the rules.

Moreover, the Attorney General explicitly shared his support for educational activities and discourse. As such, he altered the definition of “education event” to include events where information about disease states and treatment approaches are discussed.

Additional Insight from the Attorney General

- The bona fide services cap remains in effect and is still set at \$10,000. According to the Attorney General, the cap is a necessary component for minimizing conflicts of interest and promoting unbiased patient care. The Attorney General further reaffirmed that payments for research activities and payments for speaking at education events are not subject to the cap.
- When asked to include a safe harbor provision, the Attorney General declined. The inclusion of a safe harbor provision would have offered protection from liability under specific situations or if certain conditions were met.
- The Attorney General stated that the rules were never intended, nor should they be interpreted, to impact public health initiatives or financial assistance, scholarships, or charitable contributions that are made to, and controlled by, an educational institution.
- When met with concerns regarding whether the definition for “immediate family” is overly broad, the Attorney General disagreed and declined to amend.
- The Attorney General refused to repeal the rules. He also refused to delay the implementation of the amended rules, which are currently in effect. Similarly, a suggestion to limit the rules’ applicability to only opioids was denied. The Attorney General explained that while the original motivation for the rules was to address the state’s opioid crisis, the protections offered reach further than just opioids and instead speak to improved patient care overall. Conversely, the Attorney General recognized that the rules alone do not fix the opioid epidemic, but they do offer an additional safeguard.

You can find our [Health Law Alert](#) discussing the original rules in our [January 2018 Health Law Update](#).

For more information about these new rules or any other Healthcare Law policies or procedures, feel free to contact **Lani M. Dornfeld, CHPC**, or another member of our Healthcare Law Practice group below.



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