

LIFE SCIENCES DISPUTES REGULATORY COMPLIANCE
AND INVESTIGATIONS

PHYSICIAN, FEED THYSELF: NEW JERSEY'S RESTRICTION ON PHARMACEUTICAL PAYMENTS

Data Analysis and Implications —
New Requirements Represent Material Changes to
Common Industry Practices

A new set of requirements from the state of New Jersey has captured the attention of the pharmaceutical compliance world. The requirements became effective on Jan. 15, 2018, in a document titled "Limitations on and Obligations Associated with Prescriber Acceptance of Compensation from Pharmaceutical Manufacturers." Two requirements from this new law are making headlines, and justifiably so. Both represent material changes to common industry practices and puts the onus on healthcare professionals (HCPs) to track their own aggregate compensation.

BONA FIDE SERVICES CAP

13:45J-1.6: 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 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.¹

Nearly all pharmaceutical companies with a compliance program have installed a cap on aggregate payments to physicians for promotional activities, based on the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code requirement.² This cap amount varies among companies and is often around \$100,000 in payments per year. The \$10,000 cap recently imposed by New Jersey constitutes a dramatic reduction to industry standard practice, especially because it applies to all companies in aggregate, whereas the PhRMA code requirement cap is applied on a company-by-company basis.

New Jersey ranked 11th in most non-research payments to healthcare professionals, based on 2016 Open Payments data.³ In the same period, there were 557 healthcare professionals in New Jersey who received over \$10,000 in aggregate non-research payments and who would have violated the recent New Jersey requirement, had it been

1. Sullivan, Thomas. "New Jersey Finalizes "Gift" Ban of Physicians Working with the Pharmaceutical Industry." www.policymed.com, 08 January 2018

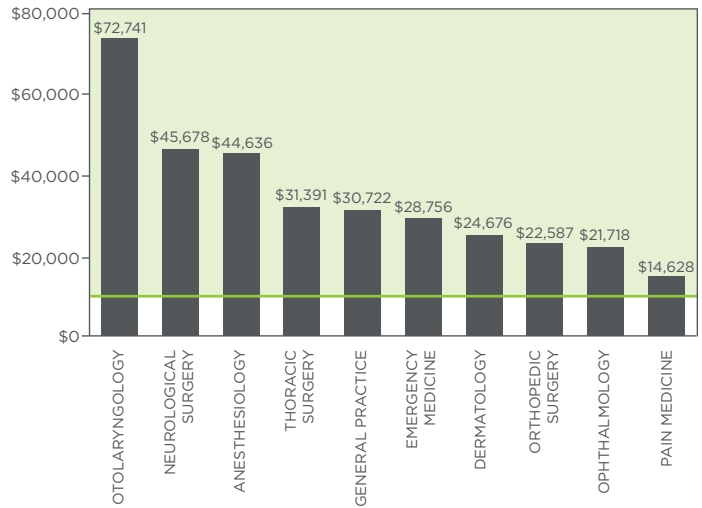
2. "Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements." Page 10, Code on Interactions with Healthcare Professionals, PhRMA, January 2009.

3. From 2016 Open Payments data where [Nature of Payment] = Consulting Fee, Compensation for Services Other Than Consulting, or Honoraria. Includes 50 states + District of Columbia.

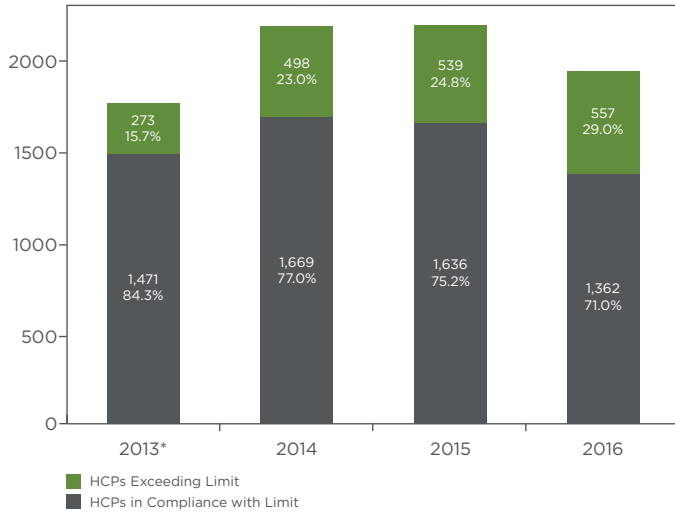


active at the time. Fifty-five New Jersey healthcare professionals in this same period received over \$100,000 in aggregate non-research payments, and will likely see dramatic reductions in their income from pharmaceutical promotional activities in 2018.

Average Annual Payment Per New Jersey HCP Top 10 Specialties in 2016



New Jersey HCPs Exceeding \$10,000 in Annual Payments



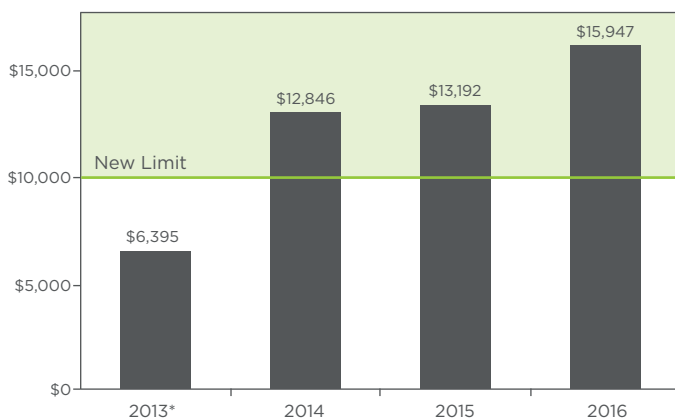
MEALS

*13:45J-1.1 Definitions: ... "Modest meals" means a food and/or refreshment, where its fair market value **does not exceed \$15.00 for each prescriber.***⁴

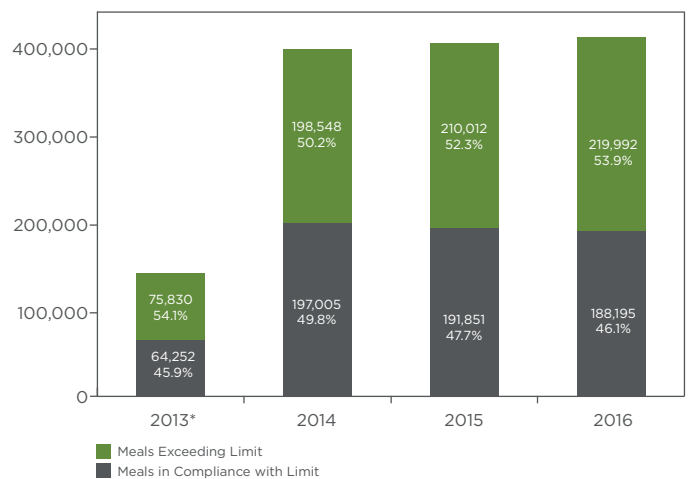
Additionally, the New Jersey requirement calculates the \$10,000 cap "in aggregate of all pharmaceutical manufacturers," another change from industry norms. A single pharmaceutical company is not traditionally aware of the payments provided to a healthcare professional by other pharmaceutical companies, making it difficult to monitor against the \$10,000 payment cap. Some pharmaceutical companies may take a conservative stance as a result and eliminate non-research consulting payments to New Jersey healthcare professionals, affecting speaker bureaus, advisory board attendance, and choice of physician consultants. Alternatively, pharmaceutical manufacturers may choose to update their consulting agreements with clauses mandating physician disclosures of payments from other pharmaceutical companies, similar to common contract language that requires physicians to disclose formulary committee relationships.

Caps on per-person meal spend are commonly implemented by pharmaceutical manufacturers. Similar to caps on payments for bona fide services, the amount varies between companies, with a cap of \$125 per-person for out-of-office dinners (e.g., promotional speaker programs) being a common control. The \$15 per-person meal cap imposed by the New Jersey requirement is materially lower than those currently enforced by most pharmaceutical companies. There have been more than 702,000 meals of over \$15 per head provided to New Jersey healthcare professionals since 2013, based on Open Payments data.

Average Annual Payment Per New Jersey HCP



Meals Exceeding \$15 for New Jersey HCPs



*NOTE: 2013 Open Payments data included payments to HCPs from August through December 2013

4. Sullivan, Thomas. "New Jersey Finalizes "Gift" Ban of Physicians Working with the Pharmaceutical Industry." www.policymed.com, 08 January 2018.

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Manufacturers will almost certainly need to update their local rules to account for this change, and should train relevant promotional and medical field personnel who service New Jersey healthcare professionals accordingly. New Jersey is already considered a high-cost state, and field personnel there will be challenged to find appropriate meal options while staying within the \$15 meal cap. Over half of all meals given to New Jersey healthcare professionals since 2013 have exceeded the recently imposed \$15 meal cap based on Open Payments data.

An increased emphasis on in-office meals is a logical next step, although counter to the trend of centers of care limiting on-site interactions between sales representatives and healthcare professionals.

ADDITIONAL REQUIREMENTS

The New Jersey rule also imposes many requirements that align with the PhRMA Code and are considered standard in today's compliance environment. For example, mandating that written agreements include a description of bona fide services at a defined fair market value rate. Prescribers are banned from accepting any entertainment or recreational items, such as tickets to sporting events. Applicable manufacturers should review these requirements to ensure they align with existing internal controls.

LOOKING AHEAD

Pharmaceutical manufacturers should work quickly to implement these requirements, given the material changes required and the immediate implementation date.

Data analysis can help create defensible controls in response to these requirements. Pharmaceutical manufacturers have a wealth of accessible internal payment data in addition to publicly available Open Payments data. This same publicly available data will make it easy for New Jersey enforcement agencies to identify pharmaceutical manufacturers and healthcare professionals who break these requirements. Open Payments data for 2018 will be submitted by March 31, 2019, and publicly released by June 30, 2019.

Questions remain about the requirement and its implementation. How will New Jersey healthcare professionals and their representatives respond, and what penalties will result if these caps are exceeded? How will the exception to the bona fide services cap for "educational events" be interpreted, and will it exclude payments for speaking at nonbranded disease state programs? Is there a future for promotional speaker programs and advisory boards in New Jersey? Will pharmaceutical companies 'import' Physicians into New Jersey to conduct modified (in terms of meals served) speaker programs for NJ healthcare professionals? Will the requirement be extended to medical device manufacturers, who are currently excluded from this requirement? How does this affect the opioid epidemic, claimed to be a primary driver of this law? Time, and legal counsel, will tell.

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