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Regulatory Compliance and Brand Solutions for Life Sciences

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Maryann Sheehan
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PO Box 45027/124 Halsey Street, 7th floor
Newark, NJ 07101
RE: 40 N.J.R. 3330(a), *Proposed new N.J.A.C. 13:45J*

October 3, 2017

Ms. Sheehan,

QPharma is a Life Sciences consulting and services firm headquartered in Morristown. Our clients include pharmaceutical manufacturers, distributors, and developers and we regularly interact with and, in our role as experts on regulatory requirements and expectations, often serve as the *de facto* representative of, the U.S. Food and Drug Administration, the Drug Enforcement Agency, the New Jersey Drug Control Unit, the New Jersey Board of Pharmacy, the New Jersey Department of Health, and other state and local regulatory bodies in New Jersey and throughout the United States. Ultimately, QPharma shares the same objective as health regulatory agencies: to ensure the demonstrable and reliable safety of the public's drug supplies.

QPharma applauds New Jersey for applying the PhRMA Code of Conduct to not only pharmaceutical manufacturers, but to physicians themselves. Both the manufacturer and the prescriber share responsibility for ensuring that the medicines prescribed are in the patient's best interest, and not driven by financial motivation. We also recognize that as a reimburser for medical charges (of which prescription drugs are a major part), the State has a duty to the taxpayer to keep drug costs down by focusing on medical necessity, and not profiting drug manufacturers and prescribers at the expense of patient health and government expenditure.

With that said, QPharma notes what appears to be a significant flaw in the rule proposed in N.J.R. 3330(a): clinical trials. Currently, the federal Physician Payments Sunshine Act, §6602 of the Affordable Care Act (ACA) of 2010, requires pharmaceutical companies who produce or market any medical product subject to federal (and indirectly, state) reimbursement to report virtually any "transfer of value" to a physician. Included in this reporting requirement are payments to doctors *for conducting human clinical trials*. These physicians, consisting of at least a Principle Investigator and often several other clinicians, operate under the oversight of an Institutional Review Board (IRB; see 21 CFR 56) and report only indirectly to the pharmaceutical developer whose product is being evaluated; by law, they are not and cannot be employees of the drug company. We note that the proposed revision of NJAC

13:45 would cap the total reimbursement that a NJ-licensed practitioner can receive from a drug manufacturer at $10,000 per year.

If this cap were to apply to clinical investigators, it would devastate the conduct of clinical studies in the state. New Jersey has one of the highest representations of developers of new and novel drug therapies in the world, and several medical institutions in the state are world-renown centers for clinical investigations. At first, QPharma assumed that physicians collaborating on a bona fide, FDA-approved and IRB-supervised clinical investigation must surely be exempt from the proposed cap; but the only exemption in the new rule is for physicians providing continuing medical education training. Indeed, the only "bona fide" activities that the proposed rule permits, even under the $10,000 cap, are speaking engagements, advisory bodies (in accordance with federal rules, we interpret this as participation in surgical or medical committees rather than actually conducting human research), and consulting arrangements (which the ACA identifies as an activity separate from clinical investigations).

We suspect that this is the result of a disconnect between the federal rules in the ACA and what New Jersey is striving to accomplish. Under the ACA, reports of payments are required to publicly acknowledge what money is passing hands and to whom, but the ACA recognizes that clinical trials are a vital link to continuing to improve the public health and does not in any way limit the financial aspects of a clinical investigator so long as the relationship is disclosed. It is completely 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. Such a cap would not even 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—no matter how much a doctor may be compensated, no practitioner can write a prescription for a drug that is not yet marketed.

QPharma therefore respectfully suggests that bona fide clinical investigations are not and should not be a target of any cap or other financial restrictions placed on payments received from drug manufacturers and developers, and that this exemption should be explicitly added to the Final Rule. Such relationships are already required by the federal Physician Payments Sunshine Act to be reported to the U.S. Centers for Medicare and Medicaid Services, and that data is readily available to state regulators.

Best Regards,

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