October 20, 2017

Ms. Denise M. Illes
Chief, Legislation and Regulation
New Jersey Department of Banking & Insurance
20 West State Street
P.O. Box 325
Trenton, NJ 08625

Sent via e-mail: legsregs@dobi.nj.gov

RE: Proposed New Rules N.J.A.C. 11:4-62, Office of Consumer Protection Services, Pharmacy Benefit Managers

Dear Ms. Illes:

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs.

Thank you for the opportunity to provide our comments on the proposed new rules at N.J.A.C. 11:4-62. PCMA and its member companies were actively involved in the negotiation of the governing statute, N.J.S.A. 17B:27F-1 *et seq.*, and want to ensure that any promulgated rules hew closely to the statute and do not impose any new mandates on PBMs. In our May 16, 2017 comment letter to the Department on the synopsis of the proposed rule, we signaled our support for the Department using: 1) definitions that track those of N.J.S.A. 17B:27F-1; 2) contract requirements that align with those outlined in N.J.S.A. 17B:27F-3; and 3) requirements for an appeals process, investigation, and dispute resolution that match those in N.J.S.A. 17B:27F-4. We thank the Department for hewing closely to the governing statute and not imposing additional requirements upon PBMs.

I. Certification Compliance

The governing statute does not provide for any such certification requirement, as is described on page 13 of the proposed rule. We believe this requirement exceeds the authority granted to the Department. If it turns out that the certification is not true, a PBM could face other penalties beyond those provided under the statute. The Department has existing authority to impose penalties if a PBM's contract does not meet the established requirements. Therefore, the language in the proposed rule that would impose further penalties is unnecessary.

II. Definition of "Multiple Source Generic Drug"

As our member companies were reviewing the proposed rule, they noticed a technical and substantive error in the definition of "multiple source generic drug" in the statute that was then carried over to the proposed rule. The technical error concerns NR and NA rated drugs, which

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were reviewed by the U.S. Food and Drug Administration (FDA) prior to the creation of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The Orange Book and almost every other state in the country that has legislative language referencing NR and NA rated drugs recognize this. The Department should amend this definition to ensure that the regulation is consistent with the intent of the law, which is to apply these requirements only to generic drugs that are reimbursed using maximum allowable cost or any related successive formula.

PCMA proposes two alternatives for the Department to fix this technical error. Option 1 would fix the definition without resolving the technical error. Option 2 would fix both the definition and the inappropriate reference to NR and NA drugs as being in the Food and Drug Administration's Orange Book (which they are not).

Option 1:

"Multiple source generic drug" means a prescription drug that is: (1) ~~listed~~ classified as therapeutically and pharmaceutically equivalent or "A," "B," "NR," or "NA" rated ~~in~~ based on the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book;" ~~and~~ (2) is available for purchase without limitations by all pharmacies in the State from national or regional wholesalers and is not obsolete or temporarily unavailable~~.;~~ and (3) is reimbursed using maximum allowable cost or any successive formula of the pharmacy benefit manager that sets a maximum reimbursement amount.

Option 2:

"Multiple source generic drug" means a prescription drug that is: (1) ~~listed~~ classified as therapeutically and pharmaceutically equivalent or "A~~,~~" or "B~~,~~" ~~"NR," or "NA~~" rated ~~in~~ based on the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book"; or "NR" or "NA" rated or similar rating by a nationally recognized reference ~~and~~ (2) is available for purchase without limitations by all pharmacies in the State from national or regional wholesalers and is not obsolete or temporarily unavailable~~.;~~ and (3) is reimbursed using maximum allowable cost or any successive formula of the pharmacy benefit manager that sets a maximum reimbursement amount.

If the Department were to choose Option 2, the following language would also need to be amended in the proposed rule:

(c) In order to place a particular prescription drug on a multiple source generic list, the pharmacy benefits manager shall, at a minimum, ensure that:

1. The drug is listed as therapeutically and pharmaceutically equivalent or "A~~,~~" or "B~~,~~" ~~"NR," or "NA"~~ rated in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book" or "NR" or "NA" rated or similar rating by a nationally recognized reference;

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We appreciate the opportunity to provide comments on this proposed rule. If PCMA can answer any questions or be of further assistance, please contact me at 202-756-5736 or swoods@pcmanet.org.

Sincerely,

R. Scott Woods
Senior Director, State Affairs
Pharmaceutical Care Management Association