April 8, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

RE: Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (OIG-0936-P)

Dear Secretary Azar:

On behalf of BioNJ's nearly 400 research-based life sciences companies, academic institutions, and other stakeholder Members, we appreciate the opportunity to comment on the proposed rule related to safe harbor protections for rebates (RIN 0936-AA08).

BioNJ represents New Jersey's life sciences ecosystem, from the largest biopharmaceutical firms to emerging companies, Patient advocacy organizations, academic research institutions, and those that support them. Delivering access to groundbreaking and lifesaving Patient therapies and cures is the mission of our Membership. We believe Patients should have access to the right treatments at the right time, and we support efforts to reduce unnecessary barriers between providers, Patients and critical, lifesaving medicines – Because Patients Can't Wait®.

BioNJ supports policies that will help Patients and produce better, more efficient health care. We strongly support reforms that ensure Patients benefit from rebates and other price concessions at the point of sale. That is why BioNJ applauds HHS for recognizing that pharmacy benefit managers (PBMs) and insurers play a large role in influencing the cost of medicines and ensuring the $150 billion in negotiated rebates and discounts will be used to lower Patients' out-of-pocket costs at the pharmacy.

The proposed rule related to safe harbor protection for rebates could have a positive impact on the price Patients pay at the pharmacy counter. The Administration is proposing meaningful reform to the rebate system. However, we encourage HHS to consider several clarifications to ensure that any final regulation related to safe harbors will help lower Patient costs and not have the unintended effect of restricting Patient care and impeding innovation.

As proposed, the rule will eliminate existing safe harbors from the Anti-Kickback Statue that allow biopharmaceutical companies to provide list price discounts to Medicare Part D and Medicaid managed care organizations (MCOs). The proposed rule will instead create new Anti-Kickback safe harbors that would protect rebates that result in lower out-of-pocket costs for beneficiaries. These new safe harbors could reduce Patient out-of-pocket costs while increasing the value of coverage and improving overall health outcomes. For these reasons, BioNJ generally supports the objectives of the proposed rule of lowering Patient costs for accessing lifesaving treatments.

Medicare's Part D has a long tradition of success in using market competition to lower costs for both Patients and taxpayers. However, the proposed rule could have the unintended impact of interfering with this market competition that has allowed Part D to thrive since its inception over a decade ago. For example, the proposed rule introduces safe harbors that allow point-of-sale discounts. Traditionally, price concessions via rebates have been used as a tool to improve Patient access to treatments through formulary placement. Under the proposed rule, these retroactive price concessions would no longer be protected from the federal Anti-Kickback Statute. However, the proposed rule appears silent on whether preferred formulary placement might meet the definition of the proposed new safe harbors allowing point-of-sale discounts. These negotiated discounts have improved Patient access to therapies while lowering costs for the Patient as well as the taxpayer. HHS should clarify whether preferred formulary placement arrangements meet the proposed standard for new safe harbors from the Anti-Kickback Statute.

Further, HHS should clarify the proposed new safe harbor related to fixed fees for PBM services paid by manufacturers to PBMs. The rule proposes to protect certain fees paid by manufacturers to PBMs based on market value, made on a fixed-fee basis, and not based on volume. However, these fees are typically allocated based on rebate contracts between PBMs and manufacturers. It is unclear as to the purpose of this safe harbor given that the underlying proposal would remove the existing safe harbors on these rebates. We would encourage HHS to provide additional clarity on the practical ramifications of this proposal.

The proposal (also) includes an effective date of 60 days following the publication of a final rule. The proposal also requests stakeholder comments on removing existing rebate safe harbors with a January 1, 2020 effective date. From a practical standpoint, rebate negotiations are already underway – if not completed – for the 2020 calendar year. Should HHS choose to move forward with a January 1, 2020, effective date, it is highly likely that plans, PBMs, and manufacturers will have insufficient time to negotiate new discounts and contracts in advance of the 2020 plan year. Moreover, a January 1, 2020, effective date could provide challenges in designing processes to ensure compliance with the new rebate structure. Government reforms to the complex U.S. healthcare system require careful consideration of incentives and input from all stakeholders to ensure an orderly transition and avoid disruption that might jeopardize patient care. We would encourage HHS to allow for additional ramp-up time for all parties to prepare for the significant changes presented in the proposed rule.

Secretary Azar, New Jersey's life sciences industry works tirelessly each and every day to research and develop cures – cures for cancer, hepatitis, and other rare disease states. While we strongly support improving Patient access while protecting innovation, some changes to the safe harbor rule are necessary to ensure unintended complications are avoided. We would encourage HHS to address these challenges in advance of issuing a final regulation.

Thank you again, Secretary Azar, for the opportunity to comment on this important proposal. Please do not hesitate to contact me at DHart@BioNJ.org or 609.890.3185 should you have any questions.

Sincerely,

Debbie Hart
President and CEO