VIA ELECTRONIC SUBMISSION

July 20, 2020

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2482-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability Requirements (CMS-2482-P)

As leading state life sciences organizations from across the country, we appreciate the opportunity to submit the following comments regarding the Centers for Medicare and Medicaid Services' (CMS) notice of proposed rulemaking (NPRM) CMS-2482-P.

Our organizations represent biomedical innovators dedicated to researching, developing, and delivering innovative life-enhancing and life-saving treatments and cures, which provide value to the health care system and greater quality of life for Patients and caregivers. In the past months, our member companies and research institutions have rallied around developing COVID-19 vaccines, therapeutics, and diagnostics, while pursuing groundbreaking innovation in many other areas, including gene, cell and other therapies for cancers and rare and infectious diseases. Our organizations are committed to ensuring Patients have access to the treatments they need and support policies aimed at improving access to medicines and lowering the costs Patients pay at the pharmacy counter.

We commend CMS on working to implement value-based purchasing agreements (VBPs) to enhance reimbursement for transformative therapies and provide adequate Patient access. We believe that the VBP provisions in the NPRM are a step in the right direction, but request additional clarity to ensure that they can be used broadly across the health care system.

Separately, we are very concerned by other provisions in the NPRM related to Patient assistance programs ("copay accumulators"), as well as the expanded definitions of line extension and "new formulation", which depart from statutory intent and may significantly harm Patient access.

Therefore, we urge CMS to continue to refine the VBP provisions so the Agency can continue its work on these new payment arrangements, and withdraw the provisions related to copay accumulators, line extension, and new formulation, as currently proposed.

CMS has in recent years worked to provide possible pathways to reimbursement, rewarding positive outcomes for new and innovative therapies through supplemental rebates and other Medicaid payment mechanisms. However, current Medicaid reporting requirements for Average Manufacturer's Price (AMP) and Medicaid "best price" can stand as a barrier for biopharmaceutical manufacturers to enter into VBP arrangements. We appreciate that the NPRM attempts to address these issues that can keep manufacturers from demonstrating the value of medical innovation, and support increasing the ability of manufacturers to enter into VBP arrangements for innovative treatments under certain circumstances.

We recommend that CMS provide assurance that the offering of a VBP to a state Medicaid agency be voluntary and not required by the proposed rule. Additionally, we recommend CMS not finalize the proposed change to the definition of best price that includes a reference to "varying price points" until guidance has been developed and all of the implications on program integrity and other prices have been thoroughly considered. We also encourage CMS to consider the applicability of VBPs for chronic disease therapeutic areas that could help increase access and lower costs to the healthcare system. Lastly, we are concerned that the Federal Anti-Kickback Statue (AKS) may hinder programs aimed at the success of VBPs. Manufacturers' concerns regarding establishing an artificially skewed best price, or possibly not complying with the AKS, have hampered widespread adoption of VBP arrangements in both the commercial and public markets. Therefore, we recommend that CMS work with a coalition of stakeholders to continue to develop the VBP proposal to ensure it is operationally feasible.

However, despite our appreciation for CMS' efforts to improve the capabilities of manufacturers to implement value-based arrangements, we have significant concerns with the NPRM's changes to how copay cards are calculated for purposes of best price, and efforts to expand the definition of line extension. As proposed by CMS, both of these changes meaningfully depart from statutory intent, may significantly harm Patient access to critical copay assistance, and negatively impact future innovation.

First, as you are aware, many biopharmaceutical manufacturers provide Patient assistance programs to ensure affordable Patient access to necessary treatments. These Patient assistance programs help provide meaningful access to prescription treatments for thousands of Americans. The NPRM would require manufacturers to include the value of any coupon or other Patient copay assistance in "best price" if a Patient is covered by a health plan with a copay accumulator program. The proposal is based on the incorrect assumption that manufacturers intend for their cost-sharing assistance to benefit health plans or plan sponsors, rather than Patients. Given that manufacturers do not have control over, or specific knowledge of, the health plan benefit designs of individuals using Patient assistance programs, the copay accumulator provisions of the NPRM are unworkable and would reduce Patient access to necessary prescription treatments. We believe Patients should have access to treatments when they are needed most, and we urge CMS to not finalize this proposal given the likely harmful impact to Patient access.

In addition, we are concerned with the new definitions of "line extension" and "new formulation" included in the proposed rule. The proposed rule would significantly expand the definition of new formulation to include "any change to the drug, provided that the new formulation contains at least

one active ingredient in common with the initial brand name listed drug. New formulations include, but are not limited to: extended release formulations; changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties; changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device."

The proposed expanded definition exceeds the authority granted to CMS by Congress, will be unnecessarily burdensome on our members, and would inadvertently target innovative treatments – especially those for rare diseases and infectious diseases. The proposed definition would penalize important innovations for Patients, such as combination therapies, and is inconsistent with the U.S. Food and Drug Administration's (FDA) incentives that encourage those innovations. Further, we do not believe it is appropriate to penalize manufacturers for these innovations given the significant investment and rigorous FDA approval process required to bring these therapies to market. We encourage CMS not to finalize this provision to ensure continued investment in innovative research and development.

Finally, we respectfully request a comment period longer than 30 days. Given the magnitude of provisions in the NPRM, we believe a 60-day comment period is more appropriate. Should an extended comment period not be practical, we ask that CMS withdraw the copay accumulator and line extension provisions from the NPRM. This will give CMS the opportunity to solicit appropriate input from stakeholders to formulate a proposed rule that does not detrimentally impact Patient access to life-saving medications.

Thank you again for the opportunity to comment on this proposal. Should you have any questions, or to discuss our views further, please contact John Slotman (BioNJ) at jslotman@bionj.org, Laure Fabrega (Biocom) at lfabrega@biocom.org, Molly Fishman (CLSA) at mfishman@califesciences.org, Kurt Imhof (LSPA) at kimhof@lifesciencespa.org, Steve Issenman (HINJ) at issenman@hinj.org, and Stephen Rapundalo (MichBio) at Stephen@michbio.org. Thank you for your consideration.

Respectfully,

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