PILMA
Pharmaceutical Industry
Labor-Management Association

July 22, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–2482-P

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

Dear Administrator Verma:

We appreciate the opportunity to comment on the recent proposals set forth in the aforementioned proposed regulations as described in CMS-2482-P. The current COVID 19 pandemic is a stark reminder of our dependence on a robust, innovative pharmaceutical industry to develop and produce effective therapeutic and preventive medicines and implement the means for their distribution.

The Pharmaceutical Industry Labor Management Association (PILMA) is a partnership of manufacturers of prescription drugs and the skilled craftsmen and women of North America's Building Trades Unions who they employ to build, retrofit and maintain the facilities in which our nation's ground-breaking research, development and production of life-saving prescription drugs takes place. In addition to the direct benefits of these employment relationships, these workers and retirees are covered by many of the jointly managed health and welfare trust funds, funded by contributions arising from such employment, which provide comprehensive prescription coverage.

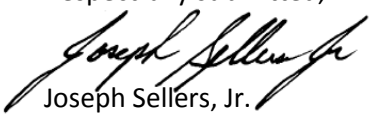
For more than fifteen years this relationship has worked to advance public policy issues of mutual interest to the partners. PILMA has clearly stated its opposition to policies which could undermine patient access to medicines and inhibit future medical innovation. They have also supported the concept that rebates, discounts and other favorable price savings should be passed on directly to benefit patients and jointly managed plans to reduce out-of-pocket costs which can prevent patients from receiving the benefit of these drugs. We note the manufacturer sponsored patient assistance {"coupon"} programs as originally conceived were designed specifically for that purpose.

While consistent with the intent of these pronouncements, the proposed amendment to the treatment of manufacturer coupon programs raises concerns that the potential administrative obstacles associated with demonstrating that benefits of the program are limited to patients

present sufficient challenges to produce precisely the opposite result. Instead of helping to reduce patients' out-of-pocket costs, the revised language of proposed §447.505(c), the AMP regulations under §447.504 and the cost implications for best price determinations could threaten the continuation of manufacturer sponsored patient assistance programs. Accordingly, we urge that these proposed changes to these regulations be reconsidered.

We appreciate your consideration of these concerns and look forward to continuing to work with the Administration to achieve our mutual goals relative to managing patient prescription drug costs.

Respectfully submitted,



Joseph Sellers, Jr.
Chairman