AMERICAN PSYCHIATRIC ASSOCIATION

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April 8, 2019

Department of Health and Human Services
Office of Inspector General
Attention: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 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" (RIN 0936-AA08; OIG-0936-P)**

To Whom It May Concern:

I am writing on behalf of the American Psychiatric Association (APA), the medical specialty society representing approximately 37,800 psychiatric physicians and their patients and families, to respond to the Administration's efforts to reduce the cost of prescription drugs. As physicians who treat patients with mental health and substance use disorders, we want to ensure that our patients have access to high quality care, including affordable prescription drugs.

The Proposed Rule would eliminate the safe harbor protection from current antikickback laws for rebates paid on prescription drugs by manufacturers to plan sponsors under Medicare Part D and Medicaid managed care organizations or pharmacy benefit managers under contract with them. The proposed rule would also add two new safe harbors: 1) protection from discounts given at the point of sale to beneficiaries, and 2) protections from certain administrative fees pharmaceutical manufacturers pay to pharmacy benefit managers for services. We support the Administration's efforts to enhance price transparency and lower out-of-pocket costs of medications. However, we are concerned about unintended consequences that may result from the proposed rule, such as additional use of utilization management protocols.

As you move forward with this effort, we urge you to include protections to prohibit the use of additional utilization management tools (i.e. step therapy, prior authorization, and formulary restrictions). These tools increase provider burden while reducing patient access to critical, life-saving mental health and substance use disorder medications. Delaying, limiting, or denying vulnerable patients access to

these medications will diminish patient outcomes and increase costs elsewhere in the health care system. We appreciate your thoughtful consideration of these comments. If you have any questions, please contact Michelle Dirst, APA's Director for Practice Management and Delivery Systems Policy, at mdirst@psych.org or 202-559-3716.

Sincerely,

Saul Levin, M.D., M.P.A, FRCP-E
CEO and Medical Director