



800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

January 24, 2019

Board of Trustees
2018-2019

Altha J. Stewart, M.D.
President

Bruce J. Schwartz, M.D.
President-Elect

Philip R. Muskin, M.D., M.A.
Secretary

Gregory W. Dalack, M.D.
Treasurer

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
CMS-4180-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Anita S. Everett, M.D.
Maria A. Oquendo, M.D., Ph.D.
Renée L. Binder, M.D.
Past Presidents

Dear Administrator Verma,

Eric M. Plakun, M.D.
Vivian B. Pender, M.D.
Roger Peele, M.D.
Cheryl D. Wills, M.D.
Jenny Boyer, M.D., Ph.D., J.D.
Melinda L. Young, M.D.
Annette M. Matthews, M.D.
Ayana Jordan, M.D., Ph.D.
Ramaswamy Viswanathan,
M.D., D.Sc.
Richard F. Summers, M.D.
Tanuja Gandhi, M.D.
Rana Elmaghraby, M.D.
Trustees

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 express our concerns regarding the Medicare Part D and Medicare Advantage proposed rule (CMS-4180-P). The proposed regulation would impede patients' access to life-saving medications under Medicare Advantage and the Part D protected classes. Specifically, Medicare Advantage plans would be allowed to apply step therapy to Part B drugs and additional utilization management tools (e.g., indication-based prior authorization and indication-based formularies) could be applied to the Part D protected classes, including for antidepressants and antipsychotics. On average, plans currently cover just over two-thirds of drugs across all six of Medicare's protected classes and this incentivizes plans to further limit the availability of life-saving medications.¹ In addition, physicians are already overburdened by utilization management tools. The need for patients to have access to the medications is crucial with suicide rates rising across the United States and emergency room boarding of patients with serious mental illness becoming a crisis for many hospitals. This proposal would exacerbate these issues without achieving the financial benefits expected. **We strongly oppose CMS authorizing additional utilization management tools. We are also very concerned about applying the Part D proposal to existing therapy. Below are our specific concerns.**

Assembly
2018-2019

James (Bob) R. Batterson, M.D.
Speaker

Paul J. O'Leary, M.D.
Speaker-Elect

Seeth Vivek, M.D.
Recorder

Administration

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

¹ Partnership for Part D Access. Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs. November 2018. Retrieved from <http://www.partdpartnership.org/newsroom/medicares-six-protected-classes-policy-ensures-patient-access-to-medications-while-simultaneously-driving-high-rates-of-generic-utilization>

Complexity of Psychotropic Drugs

If finalized, the APA is deeply concerned about the impact on the well-being of people who suffer from mental illness. It is essential to acknowledge that individual drugs within the therapeutic classes used to treat psychiatrically ill patients have very different clinical indications, mechanisms of action, and side effect profiles. Drug prescribing is therefore complicated given the nature of a drug in the classes for the treatment of psychiatric disorders. These drugs are not clinically interchangeable. ***No two psychotropic medications have the same therapeutic effect or identical duration and intensity characteristics.*** For example, individuals with serious mental illness have an average shortened lifespan of at least a decade, with much of the decrease related to increased rates of co-occurring physical conditions.² Physical disorders such as – cardiovascular disease, obesity, and diabetes mellitus – can be exacerbated by psychiatric medications, even leading to death. The pharmacological treatment that may be most effective depends on a patient’s preference, potential side effects, situation, and interaction with other medications. A patient may need a long-acting injectable to improve adherence, and other medications (such as Haloperidol) may be best for short-term emergencies but not as a first-line medication. Also, a medication such as Abilify is classified as both an antidepressant and antipsychotic. If it is only on the formulary based on its antidepressant indication, then it limits the option for patients with psychosis. While the rule requires a “therapeutic equivalent” medication be available, as noted previously, psychotropic drugs are not interchangeable, and people react differently. The proposal would also likely leave out many important, lifesaving drugs for dual eligible children with psychiatric issues given the challenge with researching medication use in children to identify intended use. In addition, individuals sometimes require more than one drug for a condition, and the proposal would likely limit or delay their ability to access more than one drug for an indicated use. ***By reducing the pharmacological treatments available, clinicians are limited in delivering patient-centered care and following clinical practice guidelines that identify a range of evidence-based medications to be effective based on the unique needs of patients.***³

Potential Harm to Patient Outcomes and Increased Cost

Furthermore, many mental illnesses are chronic, lifelong conditions with both acute and stable phases, characterized by a broad array of symptoms, even among patients who have the same or similar diagnoses. If these mental illnesses go untreated, or are inappropriately treated, a patient’s risk of hospitalization, persistent or significant disability, or death is heightened. Although this is particularly true when a patient needs treatment for acute symptoms like suicidality or psychosis, it is also of concern during his/her ongoing “maintenance” treatment. Clinical evidence from population-based studies clearly indicates that the risk of suicide attempts and completed suicide increases for patients with any psychiatric disorder, and this risk can increase exponentially for patients who suffer from disorders like

² Parks J, Svendsen D, Singer P, Foti ME: Morbidity and mortality in people with serious mental illness. NASMHPD. Alexandria VA 2006

³ APA Psych Eval PG, 2016

depression and anxiety, who are unable to access the antidepressants that can control their symptoms. This also burdens emergency room departments that are struggling with boarding. In a survey conducted of American College of Emergency Physicians (ACEP) members, 48 percent of respondents said that psychiatric patients are boarded one or more times a day in their emergency department (ED). When asked how long the longest patient waiting in the ED for an inpatient bed was boarded, nearly 38 percent of respondents said 1 to 5 days.⁴ A 2017 report from the Agency for Healthcare Research and Quality found mental health and substance abuse-related emergency department visits increased 44 percent between 2005-2014.⁵ ***It is widely recognized that doctors need to have complete discretion to prescribe the most appropriate medication for patients with psychiatric illnesses to optimize patient outcomes.***

Part D spending on antidepressants and anticonvulsants have lower average per-prescription costs than other Part D drugs, which would mitigate any costs savings CMS anticipates. Already, these medications have a higher overall rate of generic utilization with over 80 percent of antipsychotics and 90 percent of antidepressants prescriptions being generic.⁶ ***Given that most savings would come from negotiating for brand name drugs, any cost savings would be offset by the increased costs in other areas of the program, and for society in general, that are created by the clinical harms that will result from delaying, limiting, or denying vulnerable patients access to these medications.***

Physician Burden and Interference with Patient Relationship

A 2011 study by the American Psychiatric Institute for Research and Education (APIRE), found that Medicaid patients receiving Medicare prescription drug benefits, who were previously stable on their medications but had to switch medications because clinically-indicated refills were not covered or approved, experienced significantly higher adverse events (62% versus 37%), including emergency department visits, hospitalizations, homelessness, and incarceration.⁷ Plans already have tools available to limit drug costs among the protected classes such as formularies, coinsurance, and “fail first” policy. “Nearly three-quarters of all drugs in the protected classes are placed in a non-preferred or specialty category, with 78% of branded products categorized as non-preferred or specialty and 66% of generics also subject to placement on the higher tiers.”⁸ These utilization management tools create consternation

⁴ American College of Emergency Physicians, “ACEP Physician Poll on Psychiatric Emergencies September 28 – October 6, 2016,” available at: [newsroom.acep.org/download/psychemergencypolloct2016.pdf](https://www.acep.org/newsroom/psych-emergencies-poll-oct-2016)

⁵ Moore BJ, Stocks C, Owens, PL. Trends in Emergency Department Visits, 2006-2014. HCUP Statistical Brief #227. September 2017. Agency for Healthcare Research and Quality, Rockville, MD.

⁶ The Pew Charitable Trusts. Policy Proposal: Revising Medicare’s Protected Classes Policy. March 2018. Retrieved from https://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicare_protected_classes_policy.pdf

⁷ Clinically Unintended Medication Switches and Inability to Prescribe Preferred Medications Under Medicare Part D. West JC, Rae DS, Mojtabai R, Rubio MS, Kreyenbuhl JA, Alter CL, Crystal S. Journal of Psychopharmacology; 2011, June 21.

⁸ Partnership for Part D Access. Medicare Part D’s Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs. November 2018. Retrieved from <http://www.partdpartnership.org/newsroom/medicare-six-protected-classes-policy-ensures-patient-access-to-medications-while-simultaneously-driving-high-rates-of-generic-utilization>

and burnout for clinicians and confusion for patients trying to navigate an already complex system. According to a recent report by the American Medical Association, 92 percent of physicians' report that "prior authorizations programs have a negative impact on patient clinical outcomes." The AMA study revealed that "every week a medical practice completes an average of 29.1 prior authorization requirements per physician, which takes an average of 14.6 hours to process—the equivalent of nearly two business days."

For psychiatric patients, adherence to medication is a challenge due to lack of awareness about the need for medications, forgetfulness, and intolerable side effects. The proposals to Medicaid Advantage and Part D will add additional complexity for a patient and clinician. If the clinician and patient decide on a medication and it is unavailable or if a patient has been successful on a medication and needs to switch due to formulary changes, a clinician may be unable to receive consent from a patient to switch medications or the patient may forgo the use of a necessary medication during the delay. In addition, clinicians need the flexibility to make timely changes to a patient's medication and dose. For some psychotropics, it takes at least four weeks to know if a medication is effective and 3-4 tweaks may occur before the most effective treatment is found. ***Having to clear the numerous administrative hurdles to deliver quality care takes valuable time away from patients. The proposal is counter to the Administration's "Patients over Paperwork Initiative" and interferes with the patient/doctor relationship.***

We appreciate your thoughtful consideration of these important issues and recommend you reconsider adding barriers to patients needing to access life-saving and life-improving medications. If you have 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, MD, MPA, FRCP-E
CEO and Medical Director