



Congress of the United States
House of Representatives
Washington, D.C. 20515

January 25, 2019

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

Dear Secretary Azar:

Medicare Part D was established by Congress in 2003 to provide much-needed prescription drug coverage for seniors and people with disabilities. The program's Six Protected Classes policy is a key part of its success because it established critical access protection for many of our most vulnerable Medicare beneficiaries. Beneficiaries currently living with mental illnesses, HIV-AIDS, cancer, epilepsy and organ transplants depend on the Six Protected Classes because of their complex medical needs and highly personalized treatments.

We are troubled that the Center for Medicare & Medicaid Services (CMS) is now considering changes that would effectively strip these crucial medicines of their protected status. Such a change directly targets some of our most vulnerable citizens, many of whom are low-income. The proposed rule published on November 30, 2018 would allow stable patients to be forced to undergo a sometimes-lengthy prior authorization or fail-first in order to stay on the medicine(s) that have already proved to be effective treatments that keep them alive. Other dangerous changes CMS is proposing would further allow plans to limit access to medicines for vulnerable patients. If patients are unable to obtain the medicines they need, many will experience avoidable complications that could reduce their quality of life or life itself and further tax our health care safety net.

The proposed changes are particularly worrisome given the unique medical needs of Medicare beneficiaries living with mental illness. For example, beneficiaries with schizophrenia who are on stable medication and then forced to try another medicine, are at risk of a relapse. This would lead to higher medical costs in the form of potentially avoidable psychiatric hospitalizations, as well as impacts on their co-morbid medical conditions. Also, individuals living with depression often need to try several medicines before finding one that works for them. Tragically, we are



already seeing suicide rates increase in the United States, particularly in rural areas, and asking patients with depression to change their medicine regimen could have disastrous implications especially for seniors.

CMS has stated that patients will be able to use the lengthy appeals and exceptions processes to gain coverage for medicines if plans deny access to needed medicines. However, those processes are difficult for patients to navigate and are likely to quickly become overwhelmed with patients desperate to stay on the medicines they have been using to successfully manage complex conditions.

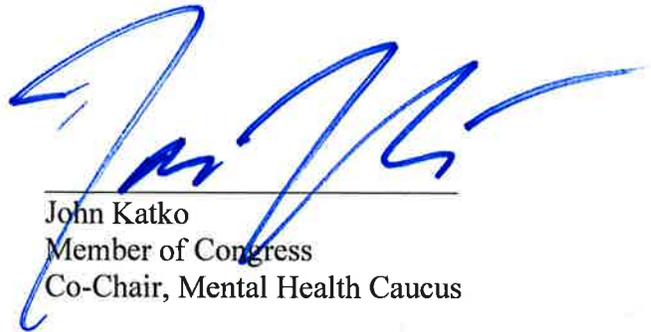
We are also perplexed as to why CMS's efforts to lower drug costs include a focus on the Six Protected Classes policy. New data shows that 91% of all prescriptions filled in the Six Protected Classes were for generics, which demonstrates that plans already have sufficient tools to encourage use of generic when appropriate. This is one reason why the Pew Charitable Trusts concluded that changes to this policy may have limited potential for savings, and the resulting restrictions in access could lead to higher medical costs for other parts of Medicare in some cases.

Given our concerns about the negative impact that your proposed changes to the Six Protected Classes policy would have on Medicare beneficiaries living with mental illness, we ask that you protect these patients by not finalizing any of these dangerous changes. Thank you for your prompt attention to this serious matter.

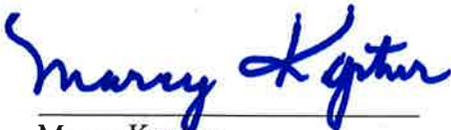
Sincerely,



Grace F. Napolitano
Member of Congress
Co-Chair, Mental Health Caucus



John Katko
Member of Congress
Co-Chair, Mental Health Caucus



Marcy Kaptur
Member of Congress



Alan Lowenthal
Member of Congress



Sheila Jackson Lee
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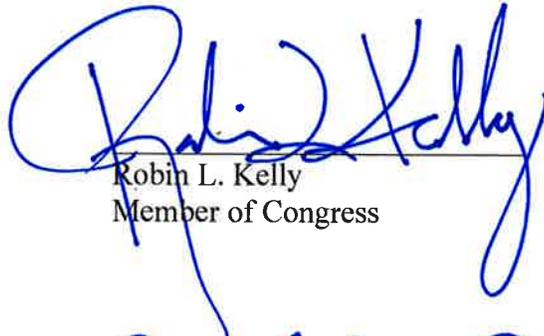
Steve Stivers
Member of Congress



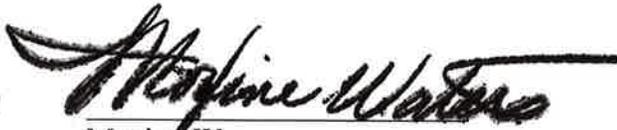
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Member of Congress



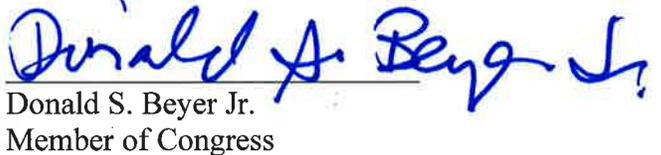
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Robin L. Kelly
Member of Congress



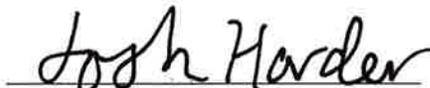
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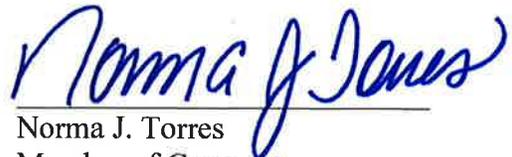
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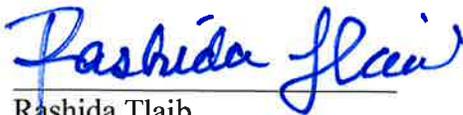
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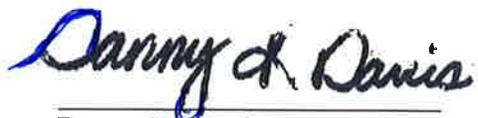
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