

**Congress of the United States**  
**Washington, DC 20515**

July 1, 2019

The Honorable Alex M. Azar  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

As Members of the House GOP Doctors Caucus, we commend the Administration's focus on lowering drug prices and reducing costs for beneficiaries and will continue partnering with the Administration to achieve these goals. However, we remain concerned with any policy that would require patients to try and fail certain treatments before allowing access to treatments that may be deemed more appropriate by a medical professional, a practice commonly referred to as "step therapy." In response to an August 2018 decision by the Centers for Medicare and Medicaid Services (CMS), many Medicare Advantage (MA) plans have begun initiating step therapy this year. We continue to hear concerns from both patients and providers across our Districts about the implementation of these onerous step therapy protocols.

We appreciate the Administration's decision in the Fiscal Year 2020 Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F) to include some protections for patients from step therapy policies, but have concerns that Medicare's most vulnerable patients will remain at risk under the fail-first requirements for Part B drugs. Given its potential negative impact on patient health and safety outcomes, we believe the Department of Health and Human Services (HHS) and CMS should reconsider its step therapy policy for Medicare Advantage plans and work with Congress, patients, providers, and other key stakeholders to develop alternative solutions that would ensure Medicare beneficiaries continue to have timely access to the critical treatments they need, while lowering the cost of medications for patients and the Medicare program.

Medicare beneficiaries receiving Part B covered drugs are some of the most vulnerable patients in the program, including those with cancer, progressive blinding eye diseases, rheumatic diseases, multiple sclerosis, Crohn's disease, compromised immune systems, hemophilia, and end-stage renal disease, among others. Requiring these beneficiaries to step through a plan's arbitrarily selected drug regimen before accessing the treatment appropriately recommended by their provider can have devastating consequences. For many patients suffering from complex, life-threatening diseases, step therapy could cause a critical delay in receiving the medicines they need, which could quickly become a matter of life or death. With this policy's potential to result in irreversible disease progression or death, complications

and hospitalizations, as well as increased costs for Medicare and its beneficiaries, we ask the Administration to reconsider this policy, thereby protecting our most vulnerable patients.

While we appreciate the Administration's recognition that patient safeguards are necessary, we feel the protections currently included in the recent guidance are insufficient to address patient needs and may drastically interfere with the provider-patient relationship. These consequences are increasingly amplified due to the seriousness of diseases often treated by Part B medicines and the special provider attention required to treat them. Clinical decisions must remain focused on the specific needs of each individual patient – not one-size-fits-all treatment protocols. Treatment options are often not interchangeable, and the most appropriate course of treatment for a given medical condition should depend on each patient's unique clinical situation, not an arbitrary formulary. Failure to receive the most appropriate treatment in the first instance can alter the progression of diseases and impede the effectiveness of subsequent treatments. The decision as to which treatment option to pursue must remain a provider-patient decision.

Once again, we sincerely appreciate the Administration's push to lower the cost of prescription drugs. As both Members of Congress and members of the physician community, we will continue working with the Administration and other stakeholders to improve access to safe, innovative, and affordable therapies for all Americans, while simultaneously promoting the financial sustainability of Medicare.

Thank you for your consideration.

Sincerely,



Andy Harris, M.D.  
Member of Congress



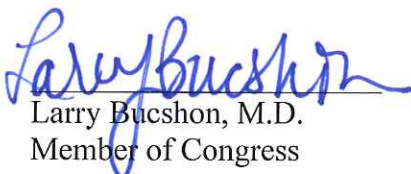
David P. Roe, M.D.  
Member of Congress



Ralph Abraham, M.D.  
Member of Congress



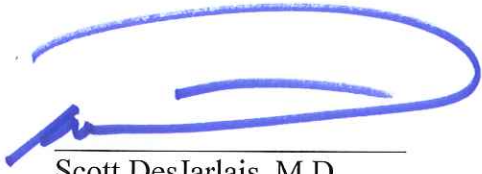
Brian Babin, D.D.S.  
Member of Congress



Larry Bucshon, M.D.  
Member of Congress



Earl L. "Buddy" Carter  
Member of Congress



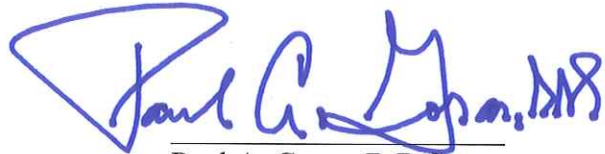
Scott DesJarlais, M.D.  
Member of Congress



Neal Dunn, M.D.  
Member of Congress



A. Drew Ferguson, IV, D.M.D.  
Member of Congress



Paul A. Gosar, D.D.S.  
Member of Congress



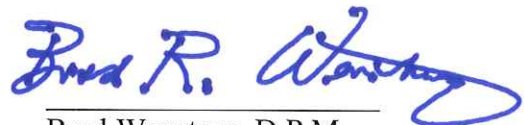
Mark E. Green, M.D.  
Member of Congress



John Joyce, M.D.  
Member of Congress



Roger Marshall, M.D.  
Member of Congress



Brad Wenstrup, D.P.M.  
Member of Congress