

Congress of the United States

Washington, DC 20515

March 13, 2019

Dear Secretary Azar –

We write to express our strong opposition to certain provisions in the Centers for Medicare and Medicaid Services' (CMS) proposed rule that would modify Medicare Part D and Medicare Advantage. Specifically, we are concerned that the Department has not adequately considered and addressed the public health implications of the changes proposed in CMS's rule dealing with the six protected classes of drugs. While we all agree that high drug pricing must be addressed, we do not believe that these provisions in the proposed rule would result in significant cost savings and would result in pushing access to critical medication out of reach for patients in need.

When Congress enacted the Medicare Part D program, it required all Part D plans to have adequate coverage for each therapeutic area. CMS subsequently identified six categories of drugs where patients could face serious risks and complications without access to medicines, and CMS therefore required Part D plans to cover all or substantially all of the drugs within these categories. This rule has been extremely important to ensuring that patients have access to critical therapies combating HIV, cancer, mental health conditions, and other serious illnesses. Congress has periodically reviewed the protected classes and reaffirmed the six categories identified by CMS.

We are concerned that prior authorization and step therapy requirements could have devastating public health outcomes for those receiving treatment of HIV and the additional 5 protected classes. Today, the most advanced treatments for HIV begin therapy immediately without testing for viral load and other factors, unlike earlier HIV therapies that required additional lab tests prior to treatment. Research has indicated that rapid start – that is, starting treatment on the same day or within one week of diagnosis – results in better engagement and retention in care, shorter time to viral suppression, and increased rates of viral suppression.¹ A prior authorization requirement that delays early treatment of HIV could place patients at risk and reverse the significant gains we have made in reducing new infections and improving HIV-related health outcomes.

Moreover, these provisions of the proposed rule put vulnerable patients at risk of declining health by imposing suboptimal therapies if step therapy is expanded. For example, older generations of HIV therapies have well-known side effects, including depression and risk of suicide. These side effects are particularly concerning for HIV patients, as data indicate that many patients with HIV already face mental health challenges. Additionally, older therapies

¹ Liz Highleyman, *START Trial Shows Benefits of Early Treatment, Supports ART for All*, Beta Blog (July 22, 2015), <https://betablog.org/start-trial-shows-benefits-of-early-treatment-supports-art-for-all/>.

generally use multi-tablet treatment regimens. Multi-tablet regimens have shown lower rates of adherence than newer single-tablet regimens, leading to higher costs, less effective treatment, and increased risk of drug resistance.

Finally, we are concerned that these provisions of the proposed rule will have reverberating effects for patients suffering from multiple conditions that are currently covered and exacerbate health disparities among poor and minority communities. For example, many people experience co-morbid conditions, such as HIV or cancer and a mental health condition. Without adequate access to appropriate care and treatment for a mental health conditions, achieving positive health outcomes and adherence to medications are at risk.

Considering the public health implications of the proposed changes to Part D protected classes related to prior authorization and step therapies, we respectfully request that you withdraw the relevant provisions of the rule.

Thank you for your prompt attention to these important questions.

Sincerely,



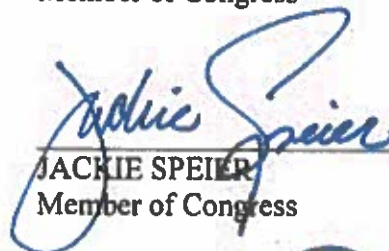
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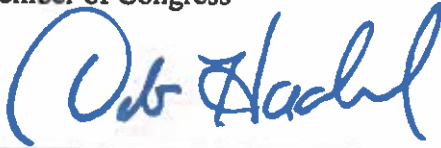
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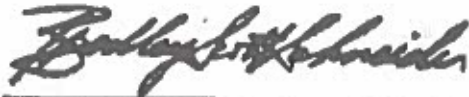
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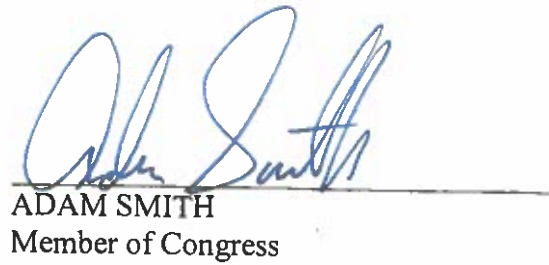


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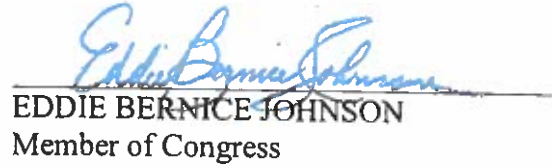


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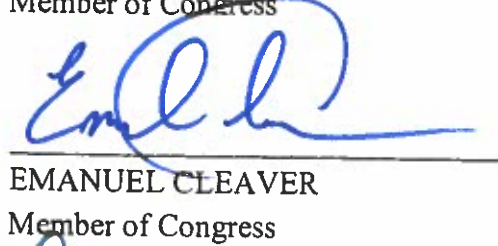

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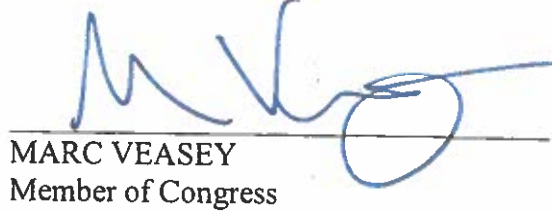

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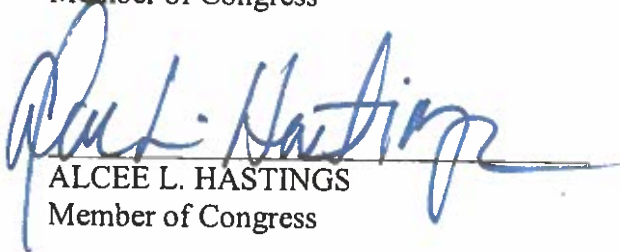

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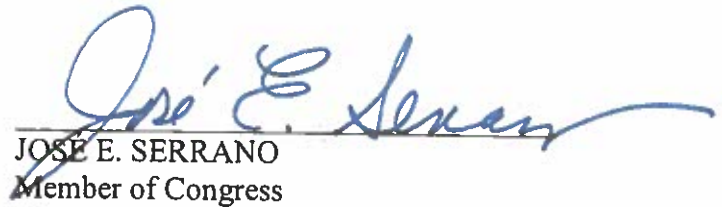

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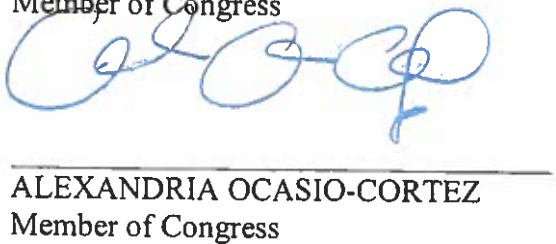

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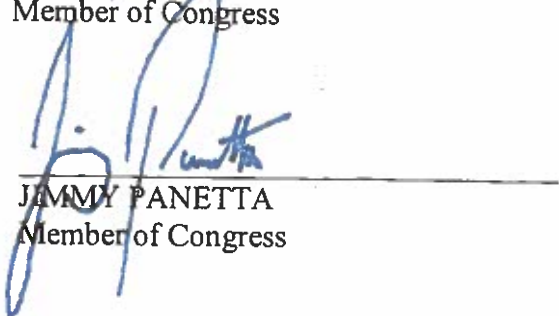

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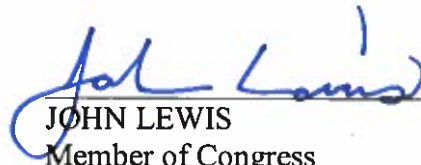
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