United States Senate

WASHINGTON, DC 20510

June 30, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Slavitt:

As Members of the Senate Committee with jurisdiction over the Medicare Program, we write to reiterate our strong support for maintaining the current "six protected classes" policy under the Medicare prescription drug benefit (Part D).

Since its enactment, Medicare Part D has helped provide access to necessary prescription drugs for millions of Medicare beneficiaries. Although Part D plans are not required to cover all Part D drugs, plans must cover "substantially all" drugs in six protected classes of drugs: immunosuppressant (for the treatment of transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. The Centers for Medicare and Medicaid Services (CMS) created this policy to safeguard access to lifesaving medicines for vulnerable Medicare beneficiaries who rely on these classes of prescription drugs to protect them from potential challenges associated with any interruption of therapy.

Despite Part D's success and the effectiveness of the six protected classes policy, the Medicare Payment Advisory Commission (MedPAC) report released earlier this month included a recommendation to make changes to this popular policy. In its recommendation, however, MedPAC acknowledges that "the degree to which plans could achieve additional savings is unclear." Regardless of potential savings, we maintain serious concerns with MedPAC's recent proposal and urge CMS to maintain the six protected classes policy as it currently exists.

As you may recall, in February 2014, the entire Finance Committee wrote to your predecessor, the Honorable Marilyn Tavenner, to express concern with the CMS proposal that MedPAC endorsed in its June report. *(see attached)*. In that letter, we expressed concern that any changes to the six protected classes policy could disrupt care for millions of Part D beneficiaries. After a variety of input from Congress and other stakeholders, CMS decided not to move forward with its proposal. Two years later, Congress remains steadfast in its commitment to maintaining this important patient protection.

We remain interested in policies that have the potential to strengthen the Part D program, but do not believe these changes represent a sound path forward. We look forward to working with you on this and other matters in the future.

Sincerely,

Chuck Grassley
Chuck Grassley
United States Senator

Sherrod Brown
Sherrod Brown
United States Senator

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

February 5, 2014

Via Electronic Transmission

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare program in the Senate. As members of this Committee, we have a responsibility to ensure that its beneficiaries have access to high quality health care. We are writing to express our concern over the recent proposal to reduce the number of "protected classes" under the Medicare prescription drug benefit known as Part D, and strongly urge the Centers for Medicare & Medicaid Services (CMS) to continue this important beneficiary protection as it exists today.

Since the creation of Medicare Part D, Congress and the Administration have recognized that for certain types of conditions and therapies beneficiaries should have access to all available medication. However, in an attempt to reduce Medicare costs, CMS is proposing to limit these protections. While we applaud any effort to reduce unnecessary spending, we strongly believe this proposal will diminish access to needed medication, and we remain unconvinced significant cost savings will be achieved.

We are very concerned this change will lead to decreased access to medication, especially for those beneficiaries afflicted by mental health problems. These vulnerable individuals rely on multiple medications to control and treat their illnesses. Unfortunately, over the course of treatment, certain medications may cause undesired side effects or become ineffective. As a result, certain beneficiaries must have a wide range of treatment options available. By limiting the number and type of medications offered under a Part D plan, a beneficiary may be forced to rely, if only temporarily, on medication that simply does not work or results in adverse side effects.

We are unconvinced this change will lead to significant cost savings. CMS presents little data to support its claim and relies in part on a Department of Health and Human Services Office of Inspector General (OIG) report that describes interviews with unnamed Part D plans. However, the OIG report concedes the information gathered by these limited interviews, "is not

generalizable to all [Part D plans]" and the report as a whole "presents general information and does not include specifics about the rebate amounts and rebate agreements." We feel that a stronger case must be presented to the public before making such a dramatic change to Part D.

Further, we remain concerned that if beneficiaries do not have access to needed medication, costs will be incurred as a result of unnecessary and avoidable hospitalizations, physician visits, and other medical interventions that are otherwise preventable with proper adherence to medication. In fact, the Congressional Budget Office recently affirmed policies that increase access to prescription drugs actually decrease spending on medical services, such as hospitals and physicians. We are concerned that the attempt to find cost savings in Part D could result in cost increases for the Medicare program at large.

Finally, if this limitation were to be finalized, many beneficiaries would be forced to rely on the Part D appeals process to receive coverage of a drug not provided on a Part D plan's formulary. Unfortunately, this appeals process is inadequate and confusing to beneficiaries. The Medicare Payment Advisory Commission (MedPAC) recently conducted focus groups and interviews with beneficiaries, physicians and beneficiary counselors. MedPAC found "most interviewees were unaware of how the exceptions and appeals process works" and "a majority [of beneficiaries] did not know they had appeal rights." MedPAC also found that physicians "pointed to at least one [Part D] plan with processes that were especially burdensome." We recommend improving the Part D appeals process before any change to drug coverage. For instance, we encourage CMS to explore ways to allow the beneficiary to initiate the appeals process at the pharmacy counter when he/she is first notified the drug is not covered by the Part D plan.

Part D has been successful in providing affordable drug coverage to Medicare beneficiaries. We know you share our goal of continuing this success. Unfortunately, we are concerned that limiting the number of protected classes under Part D jeopardizes the fulfillment of this goal. We ask that you retain the six protected classes as they exist today. We look forward to working with you on this important issue.

Sincerely,