October 31, 2011

The Honorable Patty Murray
Co-Chair
Joint Select Committee on Deficit Reduction
United States Congress
448 Russell Senate Office Building
Washington, DC 20510

The Honorable Jeb Hensarling
Co-Chair
Joint Select Committee on Deficit Reduction
United States Congress
129 Cannon House Office Building
Washington, DC 20515

Dear Chairwoman Murray, Chairman Hensarling, and Committee Members:

On behalf of the undersigned patient advocacy and physician organizations and the patients we serve, we write to you and members of the Joint Select Committee on Deficit Reduction to address a crucial issue which may impact the therapeutic needs of patients with serious and often life-threatening disorders, such as serious mental health disorders, cancer, HIV/AIDS, epilepsy, and others. We strongly urge your Committee to support continuing the Medicare Part D classes of clinical concern policy that requires plans to cover "all or substantially all drugs" for six critical lifesaving drug classes. This policy has successfully protected patients of vulnerable populations who need access to important, non-interchangeable medications. It is intended to ensure additional protections beyond the statutory minimum of two drugs per therapeutic class.

As Congress and the Centers for Medicare and Medicaid Services (CMS) have noted, preserving this policy is imperative to address the clinical needs of Medicare's most vulnerable beneficiaries. Moreover, protecting patient access through the "all or substantially all" policy can save the health system significant costs by preventing hospitalizations, relapses, and other serious consequences that result when patients with serious conditions cannot access medications prescribed by their physicians.

I. We Are Deeply Concerned About a Threat to Existing Patient Protections.

It has come to our attention that certain stakeholders—including pharmacy benefit managers (PBMs) and their trade association the Pharmaceutical Care Management Association (PCMA)—are pushing to scale back this life-saving Medicare Part D policy, which protects vulnerable patient populations. We strongly urge the Joint Select Committee to reject this misguided effort and to support the long-standing, important protections that exist for Part D patients with certain categories of serious and often life-threatening conditions, such as cancer, HIV/AIDS, schizophrenia, and epilepsy, as well as organ transplant recipients.

Specifically, we understand that PCMA has advocated eliminating the Medicare Part D classes of clinical concern or "all or substantially all" policy. This position has no merit. The Part D "all or substantially all" policy has enjoyed strong, bipartisan support since its inception in 2006. CMS initiated the policy, and Congress has affirmed it as a critical mechanism for the most vulnerable and medically fragile Medicare beneficiaries.

It would be devastating to vulnerable patients—and costly to our health care system—if patients who rely on treatments in these six protected classes were no longer offered meaningful access to the specific physician-directed drug therapy that is most effective for the individual patient.

II. The Part D "All or Substantially All" Policy Is Vital to Patient Access.

Under current Part D requirements, Congress and CMS have mandated that prescription drug plan sponsors' formularies include "all or substantially all drugs" in certain identified classes. Since 2006, six classes have been protected under this policy: immunosuppressants (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants (*e.g.*, epilepsy treatments), antiretrovirals (for HIV/AIDS), and antineoplastics (cancer treatments). For these classes, Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer patients to other drugs that the plan prefers, but which are not necessarily clinically optimal or medically appropriate for a particular patient.

According to CMS, the Medicare Part D "all or substantially all" policy was instituted "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations." The potential for these discriminatory practices continues, as does the risk for serious harm to the individuals who rely on these six classes of drugs.

III. The Existing Part D "All or Substantially All" Policy Must Be Preserved.

Therapies in the six protected drug classes are not interchangeable, and patients with these conditions need access to the medication or combination of medications most effective in treating the condition based on factors unique to the individual. As much as plans or third party pharmacy benefit managers may want to choose just one or two drugs to preserve their profits, it is not medically safe for our patients to be restricted, nor is it financially advisable to the Medicare program as increased health care costs are inevitable, if patients are prevented from accessing needed therapies. Patients often react quite differently to the available treatments. As a result, managing these serious—often chronic and life-threatening—conditions requires meaningful access to the full range of therapies available. Failure to effectively manage these conditions will result in unintended consequences for patients, as well as for the health care system and society, through increased hospitalizations, relapses, deteriorating conditions which necessitate additional and expensive care, and cause loss in productivity.

For the vulnerable patients in the six protected classes, it is essential that physicians be able to prescribe medications that are best for the patient, based on independent clinical judgment, and that patients are afforded access to these medications under Part D plan coverage. We are concerned that the proposed elimination of the "all or substantially all" policy does not consider the impact such a change would have on the health status of many patients and the even greater costs to the health care system and to society that would result from poor clinical outcomes. These outcomes—stemming from inappropriate therapy—can lead to hospital admissions and readmissions, relapses, derailment of recovery goals, unemployment, homelessness, and other costly negative consequences. Though Part D plans may be willing to take this chance since they do not pay for the medical repercussions that would be placed on the Medicare program, Congress must not let private profit lead to government costs.

The existing Part D classes of clinical concern or "all or substantially all" policy must remain intact. Recent data show that Part D is costing <u>less</u> than the original CBO score projected and that the average Medicare Part D premium will <u>decline</u> next year. The "all or substantially all" policy has been included in the Part D program since 2006; the policy clearly is not creating unanticipated costs under Part D.

Therefore, restricting vulnerable patients' access to necessary and appropriate medications is classically penny wise and pound foolish: it will lead to poor clinical outcomes; which, in turn, results in greatly increased costs to the health care system and to society.

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In order to provide appropriate health care to vulnerable patient populations, it is critical to ensure that clinical decisions continue to be made by the patients' health care providers—the medical experts who have direct contact with the patients—and that these clinical decisions are not impaired unreasonably by burdensome barriers to access. Medication restrictions or interruptions are harmful and ultimately are not cost-effective. Preserving the existing Part D classes of clinical concern or "all or substantially all" policy is vitally important to both protect these patient populations and to contain systemic health care costs.

Thank you for your attention to this very important issue. We look forward to discussing this matter with you in more detail as you consider these critical issues.

Sincerely,

AIDS Healthcare Foundation
AIDS Institute
American Academy of Neurology
American Cancer Society
American Epilepsy Society
American Kidney Fund
American Psychiatric Association
American Society of Nephrology
American Society of Pediatric Nephrology
American Society of Transplant Surgeons
American Society of Transplantation
Child Neurology Society
Citizens United for Research in Epilepsy (CURE)
Epilepsy Foundation of America
Dialysis Patient Citizens
HIV Medicine Association
Kids v Cancer
Mental Health America
NATCO, The Organization for Transplant Professionals
National Alliance on Mental Illness
National Council for Community Behavioral Healthcare
National Kidney Foundation
National Patient Advocate Foundation
Renal Physicians Association
Renal Support Network
The Association of Organ Procurement Organizations
The Leukemia & Lymphoma Society
Transplant Recipients International Organization

cc: The Honorable John Boehner
Speaker of the U.S. House of Representatives
The Honorable Harry Reid
U.S. Senate Majority Leader
The Honorable Nancy Pelosi
U.S. House of Representatives Minority Leader
The Honorable Mitch McConnell
U.S. Senate Minority Leader