Congress of the United States
Washington, DC 20515

December 21, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madame Secretary:

As Members of Congress with deep concerns about patients with serious and, many times, life-threatening health conditions, we urge you to modify the prescription drug provisions in the proposed rule on *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits (EHB), Actuarial Value, and Accreditation.* While we believe that the proposed rule does reflect improvements to prescription drug coverage as compared to the 2011 HHS Bulletin, more should be done to ensure meaningful access to medicines for the seriously ill. This is imperative as a matter of enrollee access and plan affordability, as demonstrated by numerous studies and a new report from the Congressional Budget Office (CBO) released on November 29, 2012.

As the law makes clear, plans subject to the EHB, beginning in 2014, include all non-grandfathered plans both within and outside of the exchanges; thus, the proposed rule will affect tens of millions of Americans. With respect to prescription drug coverage—one of 10 statutorily required categories of benefits—the proposed rule requires EHB plans to cover the greater of one drug in every category and class or the same number of drugs in each category and class as the state's EHB Benchmark plan. While this policy improves the HHS Bulletin's "one drug per class" approach, it still may ignore the clinical needs of those with serious mental illness, cancer, HIV/AIDS, epilepsy, and other chronic illnesses. We are concerned about how these patients could be affected if they do not have access to these necessary, and often non-interchangeable, drugs. In addition, access to these drugs may save both the health system and society significant costs by preventing hospitalizations, emergency room visits, joblessness, homelessness and incarceration.

To address these concerns, the Medicare Part D program includes the successful "all or substantially all" policy for six classes of drugs to protect vulnerable patients from inappropriate access restrictions or interruptions in therapy. These six drug classes include antidepressants, antipsychotics, anticonvulsants, antiretrovirals, antineoplastics, and immunosuppressants. As a result, Part D beneficiaries treated by these therapeutic classes have access to full range of drug therapies, and, according to the CBO, the Part D program is costing less than original projections.

As HHS finalizes this rule, we want to offer constructive ways to improve the prescription drug coverage requirement in order to balance access with affordability. It is our hope that you will include the following policies in the EHB final rule.

Ensure Meaningful Access. Rather than covering only a minimal quantity of drugs per therapeutic class (without regard to the quality of coverage), we urge HHS to include an open formulary with reasonable utilization management tools. We believe this type of formulary will provide seriously ill patients with meaningful access to their medicines. Many employer health plans, including the Federal Employee Health Benefits program, use this mechanism to provide enrollees with access to most medicines and affordable health coverage. It also is not medically safe or cost effective for seriously ill patients to be restricted from accessing effective therapies. In the six "classes of clinical concern" under Medicare Part D, as HHS has recognized, patients may react quite differently to available treatments. Therefore, we believe the final rule should replicate the "all or substantially all" policy in the EHB.

Preserve Medical Decision-Making by Doctors and Patients. The EHB proposed rule provides no details on EHB plans' drug formularies. When creating formulary standards, it is essential that these standards not impede providers' independent clinical judgment. It also is imperative that the formularies do not limit drug access to vulnerable patients who have been stabilized.

The proposed rule also lacks substance and specificity regarding an appeals process. A robust appeals process, with specific requirements, must be included to allow patients access to the drugs they need if an initial coverage request is denied. Otherwise, we are concerned that patients with serious and chronic illnesses may be denied access to needed medications.

Strengthen Non-Discrimination Requirements—and Enforcement of Those Requirements. The proposed rule lacks specificity on the non-discrimination requirements included in the Affordable Care Act. We are concerned that the proposal has limited information on how patients, particularly those with serious and chronic conditions, are protected through the statutory non-discrimination policy. We believe that the EHB final rule should offer more information on who will be responsible for monitoring, evaluating, and, when necessary, intervening in situations when utilization management tools become discriminatory. We also recommend that the final rule provide specific standards on how to review and identify discriminatory benefit practices.

Periodic Review of the EHB Package. The proposed rule promises "periodic review" of the EHB standards and benchmarks, but provides little detail on how the review will be conducted. It is important that the final rule include strong guidelines and transparent procedures for periodic reviews of the EHB to address gaps in access to care.

Limitations of Avalere's Review of State Benchmark Plans. The EHB proposed rule references an Avalere study, which found that typical employer plans' formularies cover more than one drug per class—beyond the HHS Bulletin's one drug per class policy. While that is an important finding, it is important to note that Avalere evaluated proposed benchmark plans in only eight states and only nine classes of drug therapies. Only one of the nine classes, antineoplastics, is included in the Medicare Part D six protected classes. While the study's conclusions clearly support a policy broader than the one drug per class policy in the HHS Bulletin, we also urge HHS to recognize the limitations of this study. Simply put, there is no guarantee, based on these findings, that adequate coverage is available in other states. The proposed rule is an improvement over the Bulletin, but, we fear, it remains insufficient.

Balance Access and Affordability. In developing the EHB proposed rule, HHS attempted to balance health access and affordability. If the proposed rule is finalized without changes, however, the drug coverage could be too restrictive and, thus, result in higher overall health costs. In fact, data indicates that drug restrictions could cause higher health care costs in other EHB categories such as hospitalization, emergency services, and mental health and substance use services. In its November 2012 report, CBO reviewed several relevant studies on drug coverage and concluded that plans with "generous" drug benefits through Medicare Part D had "fewer hospitalizations and used fewer medical services."

In conclusion, history shows us that sever medication restrictions or interruptions will not only be harmful to vulnerable patient populations, but, ultimately, could cause significant increases in overall health care costs. Therefore, HHS should consider replicating the "all or substantially all" policy in the EHB not only as a way to protect chronically ill patients, but also to contain costs to both our health system and society. It is our hope that we may work with you on a solution that balances both access to important health services, such as quality prescription drug coverage and affordability. We appreciate the opportunity to share our views on this important issue and we look forward to discussing this matter with you in more detail as you consider these pressing issues.

Sincerely,

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cc Ms. Marilyn Tavenner, Acting Administrator
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