

Congress of the United States
Washington, DC 20515

July 12, 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, DC 20201

Dear Secretary Sebelius,

We are writing about a critical issue affecting the health and well-being of Americans with serious and often life-threatening disorders, such as cancer, mental health disorders, HIV/AIDS, epilepsy, and others. As your Department implements the essential health benefits (EHB) requirements, we strongly urge you to replicate the Medicare Part D “all or substantially all” policy as part of the EHB. This is imperative as a matter of both patient access and fiscal responsibility.

We are deeply concerned that, on December 16, 2011, the Centers for Medicare and Medicaid Services’ (CMS) Center for Consumer Information and Insurance Oversight issued a Bulletin indicating that it does not intend to include the Part D protected class of drug policy in the EHB. The Bulletin’s suggestion that the Department may consider permitting EHB plans to cover only “one drug” per therapeutic class also troubles us. Such a policy would be overly restrictive and would ignore the clinical needs of our constituents who have serious conditions and rely on vital, non-interchangeable prescription drug therapies. We further emphasize that such a policy would be classically penny-wise and pound foolish, as it would result in poor clinical outcomes and other consequences that greatly increase costs to the health care system.

The appropriate policy is to protect vulnerable patients’ access to medically necessary prescription drugs by adopting the successful, bipartisan Part D “all or substantially all” policy in the EHB. This would ensure appropriate protections for patients with serious, chronic, and often life-threatening conditions. It also would save significant health care costs by preventing costly hospitalizations, relapses, and other consequences that result when patients cannot access the medication recommended by their physicians.

It is widely known that annual hospitalization expenditures substantially exceed annual prescription drug costs—about 36% compared to 14% in 2009. To bend the health care cost curve, we must recognize the value of managing serious and chronic conditions through medication therapy where possible. This is unquestionably more cost-effective than hospitalizations or other interventions.

The Medicare Part D “all or substantially all” policy has been successful since its inception in 2006. It has enjoyed support from Congress as well as CMS because it has been effective in protecting patients’ access to medically necessary care, while saving taxpayer dollars. We

continue to believe that this policy is essential to ensure that vulnerable patients will not be placed at risk of inappropriate restrictions or interruptions in therapy. Importantly, the policy is a critical safeguard to prevent discrimination based on health status. These anti-discrimination principles are a crucial aspect of the Department's statutory responsibilities both under Part D and in defining the EHB. We believe our constituents with serious health conditions, who may participate in the Exchanges, should have the same access and protections as our constituents who participate in Part D.

Longstanding Part D rules require Part D prescription drug plan formularies to include "all or substantially all drugs" in six classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, antineoplastics, and immunosuppressants. For drugs in these classes, the policy is crucial for several reasons, including that data consistently demonstrate all of the following:

- ***The products are not clinically interchangeable.*** Individual drug products in each of these classes are unique as compared to other drugs in the category. Results from clinical trials and real-world patient experiences demonstrate that different individuals often experience vastly different reactions and outcomes in response to various available therapies.
- ***A high discontinuation rate exists in these product classes,*** for several reasons, such as lack of efficacy of a specific drug in particular patients, inability for a patient to tolerate certain drugs' side effects, and relapse. This underscores the importance of including all therapies in each of these classes on plan formularies, and ensuring that access to such therapies is not undermined by restrictions like harmful "fail first" policies or unduly onerous prior authorization criteria.
- ***Patients with conditions in these six classes often may need to access multiple products*** before finding one that successfully treats their disease. Moreover, effective treatment for many of these conditions often requires "cocktail" therapies that combine two or more drugs within the class. This is why plan formularies must include the broadest possible range of products for the identified classes of clinical concern.

Several studies have documented the relationship between gaps in patient access (whether caused by restricted drug coverage or a patient's failure to use antipsychotic medications as prescribed) and relapse or hospital readmissions for patients with schizophrenia. Data further show that the consequences of poor access and adherence to antipsychotic medications are serious and costly in terms of derailed recovery goals, increased health care expenditures, and reduced quality of life. Thus, these studies reinforce the important link between access and affordability.

In fact, a study of 2002 data, conducted by a prominent research team including health economics and policy experts from the Analysis Group, Tulane University, and Harvard Medical School, found that total U.S. costs associated with schizophrenia were \$62.7 billion. *Less than one-tenth (about \$5 billion) of those costs were associated with drugs.* The largest portion of the total (\$32.4 billion) was indirect costs (*e.g.*, costs of lost or decreased productivity, unemployment, premature mortality from suicide, and family care-giving). The second largest portion was direct health care costs (\$22.7 billion), including long-term care (\$8 billion),

inpatient care (\$2.8 billion), outpatient care (\$7.0 billion), and pharmacy (\$5 billion). The final \$7.6 billion came from direct non-health care costs (e.g., costs from homeless shelters, law enforcement, and training/research efforts). These data show that the \$5 billion in drug spending for schizophrenia in 2002 was lower than all but one category of direct health care costs associated with schizophrenia that year—and was dwarfed by the impact of indirect costs. Homeless shelter costs alone exceeded \$6 billion. This underscores that open access to these medications is not just good medicine, but also smart fiscal policy.

Replicating the “all or substantially all” policy in the Exchanges for the six classes of clinical concern will help to manage the symptoms of patients with serious health conditions, control systemic health care and other societal costs, and ensure that individuals covered by Exchange plans will have meaningful coverage and appropriate access to available therapies. It also will ensure that vulnerable patients are treated in the non-discriminatory manner that the law requires. Just as in Medicare Part D, individuals who enroll in the Exchanges should be able to obtain this essential benefit without facing barriers to access such as non-coverage, “fail first” policies, or burdensome prior authorization hurdles.

Thank you for your attention to this very important issue. We look forward to your prompt response and are deeply interested in having a continuing dialogue with you regarding this matter.

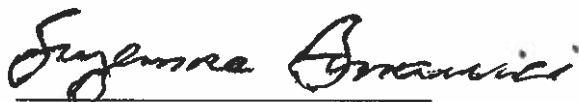
Sincerely,



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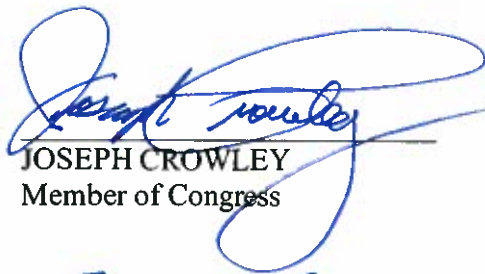
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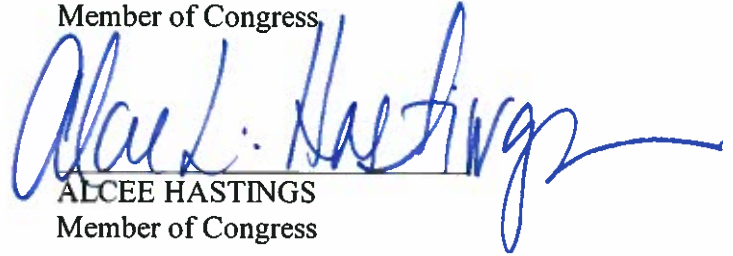

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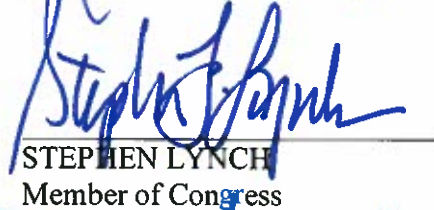

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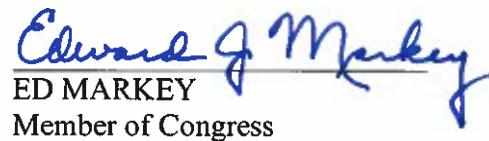

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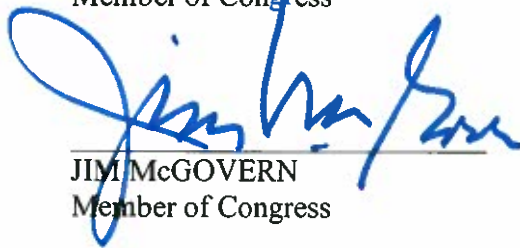

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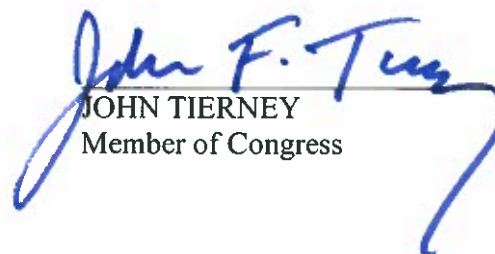

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