



November 15, 2007

The Honorable Ron Wyden  
230 Dirksen Senate Office Building  
Washington, D.C. 20510  
202-228-2717

Dear Senator:

We write to enlist your support in an issue of life-and-death importance to many older adults and people with chronic diseases and disabilities. We need to ensure that the best evidence-based medical treatments are available in both Part B and Part D of Medicare.

Recently the Centers for Medicare & Medicaid Services (CMS) added ten journals to be considered in making coverage determinations for the off-label use of prescription drugs under Part B. CMS also recently outlined a new process for including new compendia to the group of compendia approved by CMS for coverage of off-label drug uses. These two actions will significantly increase the availability of evidence-based sources of information on safe and effective drug uses. We believe these actions will improve patient care and thus we strongly believe that the same changes made for Part B should be made for Part D.

Currently, Medicare regulations<sup>19</sup> are overly stringent. They exclude Part D coverage of medications – no matter how medically necessary – when they are prescribed for uses that are not listed on the U.S. Food and Drug Administration (FDA) label or supported by a citation in one of three specific medical compendia.

The undersigned organizations, which serve Medicare beneficiaries, have found that this exclusive reliance on FDA indications and a limited number of compendia can prevent access to medically necessary, life-sustaining prescriptions. Medicare Access for Patients-Rx (MAPRx) is a coalition of patient, family caregiver and health professional organizations committed to safeguarding the well-being of patients with chronic diseases and disabilities under the Medicare Prescription Drug coverage. We are joined by additional national health and beneficiary organizations in expressing our collective concerns to you on this issue.

We seek legislative action to ensure access to “off-label” prescription drug treatment under Medicare Part D based on the following concerns:

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<sup>19</sup> 42 C.F.R. § 423.100.

*Concern: Current regulation interferes with physician/patient treatment decisions.* The people affected by the current Medicare coverage exclusion have, generally, lived with medical conditions over an extended period and tried treatment after treatment to no avail – finally finding relief only after their physicians prescribed drugs for off-label, non-compensated uses. Off-label prescribing is a common medical practice. People with cancer, HIV/AIDS, lupus, multiple sclerosis, debilitating pain, mental health conditions, and other rare and serious conditions are routinely prescribed “off-label” drugs to manage disease symptoms and progression. Denied coverage for these medications, a number of these individuals have subsequently required hospitalizations or other more drastic, expensive treatments that could have been avoided if they had access to their prescribed medicines. Additionally, people living with rare conditions often rely on off-label, non-compensated treatments when there is no drug approved by the FDA for their condition or the subject of a clinical trial in relation to their specific diagnosis.

*Concern: Disease compendia are inconsistent and incomplete.* The compendia now used to determine Part D coverage are known to be inconsistent sources of information on safe and effective drug uses. CMS itself has noted that the Part D compendia vary in the evidence they cite.<sup>20</sup> CMS has also reported that each of these compendia falls short as a comprehensive guide for safe and effective drug therapies.<sup>21</sup>

*Concern: There is a disparity between Medicare Part B and Part D definitions of “medically accepted indication” for drug treatment.* The Part B definition of “medically accepted indication” is more expansive than the Part D definition, recognizing the limitations of the compendia and allowing for the consideration of evidence of effectiveness in peer-reviewed literature, in certain cases. The inconsistency between Part B and Part D means that Part D plans exclude coverage for appropriately prescribed off-label prescriptions, with no possibility of coverage upon appeal, even when the usage would meet the standard for coverage under Part B.

### **We Seek Congressional Action**

The undersigned organizations work on behalf of some of the most vulnerable Americans. We represent older adults, people with disabilities, those suffering from chronic and severe diseases, and the family and professional caregivers who serve them.

- *We urge Congress to fulfill the purpose of the Part D benefit and require coverage of medically necessary prescriptions for which there is clinical support.*

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<sup>20</sup> 72 Fed. Reg. 38177 (July 12, 2007).

<sup>21</sup> 72 Fed. Reg. 38178 (July 12, 2007).

- *More specifically, we urge Congress to amend the statute to standardize the criteria for a medically accepted indication consistent under Part B and Part D. By this action, Congress will ensure that the definition of “medically accepted indication” allows for consideration of peer-reviewed literature – in addition to FDA labels and compendia – to support a determination that a Part D enrollee’s use of a prescription drug is one that falls within Part D.*

This change will protect people’s health and save lives.

Our organizations, and the people we represent, look forward to working with you on this critical access issue under Medicare Part D. Please feel free to contact Julie Venners, Vice President, Government Relations for further information and to set up an appointment for the letter’s signers to meet with Congressional leadership to explore this topic in more detail.

Signing organizations:

The AIDS Institute\*  
AIDS Project Los Angeles  
ALS Association\*  
American Academy of HIV Medicine  
American Autoimmune Related  
Diseases Association (AARDA)\*  
American Cancer Society Cancer  
Action Network  
American Psychiatric Association  
Center for Medicare Advocacy  
CHAMP – Community HIV/AIDS  
Mobilization Project  
Easter Seals\*  
Epilepsy Foundation\*  
Health and Disability Advocates,  
Chicago, IL  
HIV Medicine Association\*

Lupus Foundation of America\*  
Medicare Rights Center  
Men’s Health Network\*  
Mental Health America\*  
National Alliance of State &  
Territorial AIDS Directors  
National Alliance on Mental Illness\*  
National Council for Community  
Behavioral Healthcare\*  
National Health Council\*  
National Multiple Sclerosis Society\*  
National Organization for Rare  
Disorders (NORD)\*  
Parkinson’s Action Network\*  
RetireSafe\*  
Title II Community AIDS National  
Network

\* Member, MAPRx