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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

March 7, 2014

Re: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program

Dear Administrator Tavenner,

The Alzheimer's Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid's (CMS) proposed changes to the Medicare Advantage and Part D programs.

The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support, and research. Today, there are more than 5 million Americans living with Alzheimer's disease. Alzheimer's is the sixth leading cause of death in the United States, and the only cause of death among the top 10 without a way to prevent, cure or even slow its progression. Many Medicare beneficiaries with Alzheimer's disease or related dementias will be significantly affected by the changes CMS proposes.

Specific Comments

Beneficiary Communications

The Alzheimer's Association encourages CMS to make all beneficiary communications materials, such as the Annual Notice of Change (ANOC) for Part D, as clear and consumer-friendly as possible. As CMS notes, the information contained in these documents can be complex. This is particularly true for many individuals with dementia. The Association agrees that timely notice of changes, particularly changes regarding medications, is critical to beneficiaries; the manner in which it is communicated is just as critical. The format, language, and timing of Medicare communications must make sense to both beneficiaries and their caregivers. We encourage CMS to work with plan sponsors to ensure simple, straightforward communication to all consumers.

Classes of Clinical Concern

The Association is concerned by CMS's proposal to remove antidepressants and, eventually, antipsychotics from the six categories of clinical concern. Both of these drugs are used to treat individuals with dementia.

CMS bases its proposal on two criteria: 1) that a 7-day delay in initiating therapy with these drugs would generally not put the typical individual at risk of hospitalization, incapacity, disability, or death and 2) that the drugs within these classes are "therapeutically interchangeable." First, individuals with Alzheimer's disease face significant challenges that "typical" Medicare beneficiaries do not. Individuals with moderate or advanced dementia often have difficulty communicating, so a change in regimen, even if it does not induce an immediate risk of harm, could still result in adverse

impacts that go unaddressed.

CMS's approach fails to consider the complexity of older, vulnerable adults experiencing irreversible cognitive decline. Some drugs are only effective in some of these individuals some of the time. The high incidence of chronic diseases in this population frequently means a regimen of several medications, creating drug interaction implications. Individuals have different tolerances and experience different side effects, regardless of drugs' comparable efficacy or "interchangeability." Nor is it realistic for these individuals and/or their caregivers to rely on the protections CMS believes will safeguard against access issues. Given their cognitive decline, most individuals are unlikely to be able to comprehend multiple notice requirements and navigate a complex appeals process if they do experience problems. CMS's proposal will limit therapeutic options for this vulnerable population.

The Alzheimer's Association shares CMS's concerns about the improper use of antipsychotics. Though we advocate exhausting non-pharmacologic approaches before using pharmacologic therapy to manage behavioral and psychotic symptoms of dementia, we recognize that antipsychotic use may be necessary in some instances.¹ As with antidepressants, we believe that CMS's proposed approach oversimplifies complex circumstances.

We discourage CMS from removing the protected status of these classes and encourage you to ensure beneficiaries' access to these drugs, which can have a profound effect on the quality of life of those with Alzheimer's disease and related dementias.

Medication Therapy Management Program

The Alzheimer's Association applauds CMS's proposed expansion of the Medication Therapy Management (MTM) Program eligibility requirements. Our constituents could benefit enormously from the MTM Program due to the prevalence of co-existing chronic illness in individuals with Alzheimer's disease. We believe that the proposed changes will increase access and adherence to medications central to health and quality of life, and simplify the process for beneficiaries and caregivers. We also support the proposed requirement that sponsors have plans to assess medication use by at-risk enrollees and establish strategies to ensure their access to the program. Finally, the Association appreciates CMS's recognition of Alzheimer's as a core chronic disease. We believe that Alzheimer's disease is a condition around which others must be managed.

Thank you for the opportunity to comment on CMS's proposed changes to Medicare Parts C and D. Please contact Laura Thornhill, Manager of Regulatory Affairs, at 202-638-7042 or lthornhill@alz.org if you have questions or if we can be of additional assistance.

Sincerely,



Robert Egge
Vice President, Public Policy

¹ Alzheimer's Association. (2011). Challenging Behaviors. Available at https://www.alz.org/national/documents/statements_antipsychotics.pdf.