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alzheimer's association®

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244–1850

May 3, 2016

Re: Medicare Program; Part B Drug Payment Model

Dear Acting Administrator Slavitt,

On behalf of the Alzheimer's Association, I write to express concerns about the Centers for Medicare & Medicaid Services' (CMS) proposed Part B Drug Payment Model.

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. As the size and proportion of the United States population age 65 and older continue to increase, the number of Americans with Alzheimer's disease and other dementias will grow.[1] Caring for individuals with Alzheimer's disease will cost $236 billion in 2016 with Medicare and Medicaid bearing $160 billion--68 percent--of that figure.[2]

Currently, there is no pharmacologic treatment that slows or stops Alzheimer's disease and the pursuit of one has been difficult: Between 2002 and 2012, only one out of 244 drugs for Alzheimer's tested in clinical trials registered with clinicaltrials.gov received approval from the Food and Drug Administration (FDA).[3] It is critical that the pace of this research accelerates. Given the surge of beneficiaries who will experience some form of dementia and the mounting costs to the Medicare program, CMS must encourage the development of effective therapies. The Alzheimer's Association is concerned that the proposed Part B model may stifle the innovation that underpins drug development.

Specifically, the Association is troubled by the potential impact of reference pricing on innovation. The development of effective dementia therapies will likely be an iterative process: small improvements will be made on existing therapies over time. If CMS employs reference pricing—establishing a standard payment amount for therapeutically similar but ultimately different drugs—manufacturers may have less incentive to make significant financial investments in additional research once a drug comes to market. As it considers what drugs are therapeutically similar, CMS should ensure that its policies are consistent with those of the FDA, which requires that sponsors demonstrate improvement on current therapies for approval. CMS must balance cost savings with the research investments that beneficiaries need.

The Alzheimer's Association is also concerned by the size and scope of this demonstration project. We do not believe that anyone can fully understand the consequences of an abrupt, broad, and mandatory change in policy that is likely to immediately affect beneficiary care. We caution CMS against employing this approach without thorough and meaningful stakeholder engagement.

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[1] Alzheimer's Association. (2016). *2016 Alzheimer's Disease Facts and Figures*.
[2] Ibid, 45.
[3] Ibid, 13.

Thank you for the opportunity to comment. The Alzheimer's Association is glad to serve as a resource to CMS as it considers these important issues and how they relate to individuals living with Alzheimer's and related dementias. 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
Executive Vice President, Government Affairs