Healthcare Quality Expert Committee  
U.S. Pharmacopeial Convention (USP)  
12601 Twinbrook Parkway  
Rockville, Maryland 20852-1790  
October 27, 2016

Re: USP draft Medicare Model Guidelines v7.0

To Whom It May Concern:

The Alzheimer’s Association appreciates the opportunity to comment on the USP’s draft Medicare Model Guidelines v7.0.

The Alzheimer’s Association is the 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. 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.

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. 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, we strongly encourage USP to incorporate a new class under the Antidementia Agents category titled “5-HT6 Receptor Antagonists.” In light of new research, clinical trials, and potential new treatment options in the next few years, USP must encourage swift access to new therapies, improving patients’ quality of life.

Thank you for the opportunity to comment. The Alzheimer’s Association is glad to serve as a resource to USP 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

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2 Ibid.  
3 Ibid.