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

September 6, 2016

Re: Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt,

The Alzheimer's Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed updates and changes to the Calendar Year 2017 Physician Fee Schedule (PFS).

The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's disease care, support, and research. Today, there are more than 5 million Americans living with Alzheimer's disease, and it is the only cause of death among the top 10 without a way to prevent, cure, or even slow its progression. 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 We applaud the important changes CMS proposes throughout this rule, and we encourage you to consider the following comments as you work to improve care for this growing population of beneficiaries.

Improving Payment Accuracy for Primary Care, Care Management, and Patient-Centered Services

The Alzheimer's Association commends CMS's ongoing efforts to encourage and improve care management services and its willingness to adjust how it pays for services that are not acute in nature. Please note that because the bulk of our comments addresses the proposed GPPP6 code, we offer those first, and our comments on other provisions follow.

Assessment and Care Planning for Patients with Cognitive Impairment (GPPP6)

The Alzheimer's Association deeply appreciates and applauds CMS's proposal to pay physicians and other appropriate practitioners to assess and create care plans for beneficiaries with cognitive impairment.

¹ Alzheimer's Association. (2016). *2016 Alzheimer's Disease Facts and Figures*.

² Ibid.

Because Alzheimer’s disease is degenerative and lacks effective treatments, care planning is fundamental to affected persons and caregivers. It allows persons with the disease to participate in decision-making while they are still able, and it can reduce stress and confusion for affected individuals as well as for their family and friends. It can also lead to more effective care management by providers, many of whom do not feel that they have the necessary time and resources to care for these complex beneficiaries.³ In proposing this code, CMS directly addresses the elements needed to allow clinicians to deliver appropriate, high-quality care plans to persons living with the disease and their caregivers. Implemented and communicated effectively, the GPPP6 code as part of the final 2017 PFS will have a profoundly positive impact on thousands of beneficiaries and clinicians.

While we note the temporary nature of the proposed GPPP6 code, we commend CMS for taking steps to make these services available beginning in 2017. This will give providers and beneficiaries alike access to the support and care they need sooner. We hope CMS will consider the Alzheimer’s Association a resource as it adopts and implements the Current Procedural Terminology code for 2018.

The Association recognizes that even after the publication of the final 2017 PFS, much implementation and operational work will remain. We look forward to assisting CMS in the coming weeks and months. With regard to the proposed and final PFS, we offer the following on the code elements for CMS’s consideration.

Cognition-focused evaluation including a pertinent history and examination

The Alzheimer’s Association requests that CMS clarify its meaning of “assessing” and “evaluating” persons with cognitive impairment. These words often refer to the process of diagnosing an individual; this provision could also be read, however, to mean assessing a person’s needs post-diagnosis to inform the care plan. Considering the entirety of the code, the Association believes that CMS means assessment as it relates to care planning. Although a diagnosis must precede any care planning, the amount of time CMS proposes is not sufficient to encompass the often iterative and complex diagnostic process, an extensive (and necessary) evaluation of needs, *and* the development of a comprehensive care plan. A truly effective care plan cannot be developed until all assessments are complete. If this reading is correct--that CMS means an assessment of current level of cognitive impairment and function and not all the elements required for a full diagnosis--we ask that CMS offer guidance to providers on how to connect diagnostic services with use of this code. Recognizing the challenges of detecting cognitive impairment and communicating a diagnosis of Alzheimer’s disease or other forms of dementia, we are pleased to offer to CMS and providers the Association’s recommendations on detecting cognitive impairment in primary care settings,⁴ our Cognitive Assessment Toolkit⁵ that we developed for provider use in Annual Wellness Visits, our 2015 special report on “Disclosing

³ Ibid.

⁴ Cordell CB, Borson S, Boustani M, et al. Alzheimer’s Association recommendations for operationalizing the detection of cognitive impairment during the Medicare Annual Wellness Visit in a primary care setting. *Alzheimers Dement.* 2013 March;9(2):141-150. Available at: http://www.alz.org/documents_custom/jalz_1528.pdf.

⁵ Alzheimer’s Association. (2013). *Cognitive Assessment Toolkit*. Available at http://www.alz.org/documents_custom/141209-CognitiveAssessmentToo-kit-final.pdf.

a Diagnosis of Alzheimer's Disease,"⁶ and other clinician resources available on the Alzheimer's Association website: alz.org/hcps.

Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity

We support CMS's inclusion of a functional assessment in this code. Functional assessments are central to living safely and optimizing someone's quality of life. They also help to recognize patterns or triggers that can lead to challenging dementia-related behaviors and can provide enormous support to caregivers. These assessments depend on the individual's needs and can be extensive. Thus, many kinds of professionals may be involved, including social workers, occupational therapists, psychologists, and more. Billing clinicians--particularly those in small practices--need to be aware of appropriate local providers and be prepared to refer accordingly. CMS will also have to consider the practicalities of documenting and billing among multiple providers.

Additionally, we respectfully request that CMS clarify its meaning of "decision-making capacity." We believe establishing *legal* decision-making capacity to be beyond the scope of most practitioners providing functional assessments and ask that CMS elaborate on its definition and intent.

Use of standardized instruments to stage dementia

The Alzheimer's Association respectfully requests that CMS expand on the standardized instruments it envisions providers using to stage dementia. We are not aware of any such instruments. We believe CMS has included this element to the extent that it might help in the development of a care plan, but in the absence of such tools, we suggest that CMS consider rewording this element to read "structured validated assessment," as the Association does in our Cognitive Assessment Toolkit.⁷

Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized instrument(s)

We support CMS's inclusion of neuropsychiatric and behavioral assessments. Studies have found that more than 90 percent of people with dementia develop at least one dementia-related behavior⁸ like hallucinations and aggression, and a significant percentage of these individuals have serious clinical implications. Depression and anxiety are also common among people with dementia. Such assessments can help affected individuals and caregivers to manage these issues and live better with the disease.

⁶ Alzheimer's Association. (2015). *2015 Alzheimer's Disease Facts and Figures*.

⁷ Alzheimer's Association. (2013). *Cognitive Assessment Toolkit*. Available at http://www.alz.org/documents_custom/141209-CognitiveAssessmentToo-kit-final.pdf.

⁸ Alzheimer's Association. (2015). *Dementia-Related Behaviors*, available at http://www.alz.org/documents_custom/statements/Dementia_Related_Behaviors.pdf.

As we noted in the above section on functional assessments, neuropsychiatric and behavioral assessments will require the expertise of a range of professionals, such as psychologists, psychiatrists, and skilled therapists, many of whom may not be located within a single practice. Practices that will need to refer to external experts must be aware of appropriate local providers, and CMS should provide guidance on documenting and billing among multiple providers.

Evaluation of safety (for example, home), including motor vehicle operation, if applicable

We appreciate CMS's inclusion of safety assessments for these beneficiaries. Alzheimer's disease causes a number of changes in the brain and body that may affect safety, including judgment, a sense of time and place, confusion, and physical issues like balance and vision. The appropriate assessments and interventions, however, can enable people with dementia to live safely in their homes, arrange for forms of transportation other than driving, and address other potential risks.

Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregivers to take on caregiving tasks

The Alzheimer's Association is deeply grateful to CMS for its inclusion of caregivers and their needs. More than 15 million Americans provide unpaid care for people with Alzheimer's disease and other dementias.⁹ In 2015, these individuals provided an estimated 18.1 billion hours of unpaid assistance, and the results of a recent Alzheimer's Association survey showed that care contributors spent an average of \$5,155 of their own money per year to take care of their relative or friend with Alzheimer's or another dementia.¹⁰

Caregivers arrange appointments, find resources, manage medications, and handle family relationships. But their most significant role is managing the daily needs and health of persons living with dementia. For this reason, it is crucial that they be able to communicate directly with health care providers whether or not persons with the disease are present. This access and communication must be regular and ongoing. Caregivers should also be documented in beneficiaries' medical records, including contact information.

We applaud CMS for considering caregiver needs in this code. This is a critical element since caregivers' needs directly impact the health and well-being of beneficiaries with dementia. Although many caregivers report positive feelings about caregiving, they also report high levels of stress when providing care: twice as many caregivers of those with dementia indicate substantial financial, emotional, and physical difficulties compared with caregivers of people without dementia.¹¹ CMS should ensure that practitioners are prepared to provide information about local community entities that offer education, support groups, and other resources, such as the Alzheimer's Association and Area Agencies on Aging.

We agree with CMS that noting caregiver willingness is important, but equally important is assessing caregiver capacity. One in five (22 percent) caregivers of people with Alzheimer's disease or another dementia has difficulty with medical/nursing tasks, compared with 11 percent

⁹ Alzheimer's Association. (2016). *2016 Alzheimer's Disease Facts and Figures*.

¹⁰ Ibid.

¹¹ Ibid.

of caregivers of individuals without dementia,¹² and many are themselves frail or ill. Providers should assess not only a caregiver's individual needs but the supports he or she has or requires to continue to care for a beneficiary. Providers should document these and refer accordingly.

Unfortunately, a small percentage (8 percent) of older adults with dementia do not receive help from family members or other informal care providers.¹³ Arguably, the services proposed here are even more important for these individuals who do not have support. We ask that CMS consider how providers may document the absence of a caregiver but remain eligible to bill under the code.

Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference

We fully support inclusion of advance care planning and palliative care needs per the beneficiary's preferences. Advanced directives, like Durable Powers of Attorney for Health Care and other legal forms, allow the affected person to participate in decision-making while he or she is still able and can reduce stress and confusion for friends and family in the future. Similarly, palliative care — managing symptoms, pain, and stress, and increasing comfort — improves quality of life, controls costs, and enhances patient and family satisfaction.

Creation of a care plan, including initial plans to address any neuropsychiatric symptoms and referral to community resources as needed (for example, adult day programs, support groups); care plan shared with the patient and/or caregiver with initial education and support

Broadly speaking, care plans should be individualized, person-centered, comprehensive, and updated regularly and as needed. They should be written and documented in the patient's medical record. Copies should be given to beneficiaries *and* caregivers, and they should be available to all relevant providers. In addition to the plan elements CMS proposes above, we recommend including in any care plan:

- A diagnosis, information on the disease, its progression, and what to expect;
- Treatment options and information on clinical trials;
- Consideration of any co-morbid conditions and how to manage them;
- How to access information on legal and financial planning, driving and safety issues, long-term care, and palliative and end-of-life care;
- Importance of caregiver respite; and
- Persons or entities that can assist in implementation of the plan. This code will not serve beneficiaries unless the care plans it creates are implemented.

In addition to the elements proposed by CMS, the Alzheimer's Association encourages CMS to consider the following to ensure the successful implementation and uptake of GPPP6:

Eligible Practitioners

We note that in addition to physicians, CMS will allow "other appropriate billing practitioners" to use GPPP6. Because the care needs of persons with dementia and their caregivers are so complex, CMS

¹² Ibid.

¹³ Ibid.

should anticipate the involvement of a variety of practitioners in addition to physicians. Advanced practice nurses and physician assistants can make medical decisions and develop care plans. Clinical psychologists can provide neuropsychiatric assessments. Clinical social workers can educate beneficiaries and caregivers and connect them to community-based resources. Pharmacists can provide medication reconciliation. Skilled therapists can provide functional assessments and evaluate caregiver needs. The practices that will use this code will vary in size and capacity just as the needs of beneficiaries vary. Small primary care practices, for example, will need to refer some beneficiaries to some of these other professionals. By including as many practitioners as possible, CMS will not only improve beneficiary access to services, but it will also make the code easier to implement and improve the chances of uptake.

Frequency

We respectfully request that CMS clarify that a provider may bill under this code more than once per beneficiary. Alzheimer's disease and related dementias are progressive and degenerative, so the needs of affected persons change over time. Thus, a care plan built around those needs will need to change. We recommend that this be available to physicians and beneficiaries at least annually and in the event of a significant change in circumstances that warrants reassessment, such as changes in caregiver circumstances or the emergence of new or acute health care needs.

Quality Measurement

As it proceeds with implementation of this code, we encourage CMS to consider how it will evaluate and improve these services through quality measures. The Alzheimer's Association would be pleased to serve as a resource to CMS in this effort.

Implementation and Provider Education and Outreach

Based on low uptake of the Annual Wellness Visit and the difficulties with the first iteration of the Chronic Care Management (CCM) code, the Alzheimer's Association is concerned about the successful implementation of GPPP6, particularly for small primary care practices. As we discuss below, we applaud CMS's willingness and ongoing efforts to refine and improve the CCM code, and we anticipate that refinements will be needed to GPPP6. Generally, we encourage CMS to simplify documentation requirements as much as possible and make sure the code is flexible and intuitive.

Specifically, we suggest:

- In order to address the multiple providers likely to be involved in delivering this comprehensive care, CMS should consider existing codes and how they relate to GPPP6. CMS should offer guidance to providers on how to integrate this with other codes--perhaps existing evaluation and management (E/M) codes--including for the coordination and plan updating that will occur between physician visits.
- In addition to offering guidance on this code and how to bill for it appropriately, including any needed ICD-10 codes, CMS should provide information on various forms of cognitive impairment and cognitive impairment diagnoses, including Alzheimer's disease and dementia.
- CMS should consider different ways to collect information on some of these elements. For instance, an initial caregiver assessment might be able to be done over the phone or through a questionnaire that is followed by discussion. Others might be collected effectively via telehealth.

- Similarly, CMS should consider various ways to meet the documentation requirements. For example, a recent, existing advance directive could satisfy that component of the code.

Finally, we urge CMS to develop a strong communication plan to ensure that it achieves the underlying intent of this proposal: to support the providers who care for these vulnerable beneficiaries. In the coming months, the Alzheimer's Association will develop a plan to educate and inform our practitioner colleagues and constituents, and we would be pleased to share that plan with CMS.

We recognize the substantial work that will need to be done after the publication of the final rule and remain a committed partner to CMS in the coming months and years. Once again, we are grateful to CMS for this transformative proposal.

Non-Face-to-Face Prolonged Evaluation & Management (E/M) Services

We support the proposed add-on codes for E/M visits and CMS's proposal that they may be billed concurrently with the GPPP6 code. As has been noted, persons with dementia have extensive needs that evolve as the disease progresses. These additional codes can provide practitioners with the time and resources they need to help beneficiaries who cannot effectively manage the many challenging and changing aspects of their own care.

Care Management for Behavioral Health Conditions

The Association appreciates CMS's efforts to integrate behavioral health services into primary care through its proposed temporary codes. As noted above, individuals living with dementia may experience behavioral and psychotic symptoms of dementia (BPSD) during the course of their disease due to the alteration in processing, integrating, and retrieving new information. These can include depression, hallucinations, delusions, aggression, and agitation, among others. These behaviors can be difficult for family caregivers to manage and cause considerable stress. Furthermore, they can result in physical consequences, like falls, weight loss, and infections.¹⁴ These proposed codes will help primary care physicians to equip themselves and their practices with the tools they need to assist beneficiaries with behavioral health needs, including persons with dementia experiencing BPSD.

Reducing Administrative Burden and Improving Payment Accuracy for Chronic Care Management Services

Medicare beneficiaries with Alzheimer's disease and other dementias are more likely than those without dementia to have other chronic conditions. While 12 percent of Medicare beneficiaries age 65 and older with Alzheimer's disease and other dementias have five or more chronic conditions, only 2.5 percent of Medicare beneficiaries without dementia have five or more chronic conditions. Furthermore, people with Alzheimer's or another dementia and a serious coexisting medical condition are more likely to be hospitalized than people with the same coexisting medical condition but without dementia.¹⁵ Thus, persons with dementia can benefit enormously from CCM services. We commend CMS's ongoing efforts to refine and improve the CCM billing codes and particularly appreciate inclusion of the option for non-face-to-face care planning under the GPPP7 add-on billing code, as well as allowing a beneficiary or

¹⁴ Alzheimer's Association. (2015.) *Challenging Behaviors*, http://www.alz.org/documents_custom/statements/challenging_behaviors.pdf.

¹⁵ Alzheimer's Association. (2016). *2016 Alzheimer's Disease Facts and Figures*.

caregiver to receive a written or electronic copy of a care plan. The degenerative nature of dementia will eventually render a person unable to manage his care or follow a care plan. Thus, we encourage CMS to require that clinicians provide copies of care plans to both beneficiaries *and* caregivers where caregivers have been identified.

Medicare Telehealth Services

The Alzheimer's Association supports CMS's proposed approval of an initial advance care planning session and an additional 30 minutes for those services to be delivered via telehealth. Planning for the future can improve the quality of life for both persons with dementia and their caregivers. Advanced directives, like Durable Powers of Attorney for Health Care and other legal forms, are an important part of this. We believe that these services are appropriate for delivery via telehealth.

Thank you for the opportunity to comment. On behalf of all persons touched by Alzheimer's disease and other dementias, we are grateful for CMS's leadership in making these services available to beneficiaries with cognitive impairment, their caregivers, and the practitioners caring for them. The Alzheimer's Association looks forward to assisting CMS in its efforts to implement the GPPP6 code and all of the important proposals in the CY 2017 PFS. 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,

A handwritten signature in black ink, appearing to read 'R. Egge', with a stylized flourish extending to the right.

Robert Egge
Executive Vice President, Government Affairs