

ALZHEIMER'S ASSOCIATION'S EXPERT TASKFORCE¹ CONSENSUS STATEMENT ON CMS PROPOSED BILLING CODE FOR ASSESSMENT AND CARE PLANNING FOR INDIVIDUALS WITH COGNITIVE IMPAIRMENT

On July 15, 2016, the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* a proposed update to the payment policies under the Medicare Physician Fee Schedule.² Included in that notice was a proposed new billing code for assessing and creating a care plan for beneficiaries with cognitive impairment. In response, the Alzheimer's Association convened an expert Taskforce to review the proposed billing code and advise the Association on its ideal implementation. This document represents the consensus of the Taskforce.

I. INTRODUCTION

Only about half of all individuals living with Alzheimer's and other dementias have been diagnosed,^{3,4,5,6} and less than half of those who have been diagnosed or their caregivers are aware of the diagnosis.^{7,8} There are numerous reasons for these dismal diagnosis and disclosure rates. But two are particularly prominent and relevant to the issue at hand: (1) a sense among many in the medical profession that "nothing can be done" for an individual with Alzheimer's and other dementias; and (2) a lack of time and reimbursement available to providers to undertake the necessary discussions, including care planning, following a diagnosis.

We commend CMS for proposing this new billing code for assessing and creating a care plan for those with cognitive impairment because we believe it addresses these two

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² Centers for Medicare and Medicaid Services. Revision to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY2017. *Federal Register* July 15, 2016;81(136):46162-46476.

³ Boustani M, Peterson B, Hanson L, et al. Screening for dementia in primary care: A summary of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 2003;138(11):927-937.

⁴ Bradford A, Kunik ME, Schultz P, et al. Missed and delayed diagnosis of dementia in primary care: Prevalence and contributing factors. *Alzheimer's Disease and Associated Disorders* 2009;23(4):306-314.

⁵ Kotagal V, Langa KM, Plassman BL, et al. Factors associated with cognitive evaluations in the United States. *Neurology* 2015;84(1):64-71.

⁶ Alzheimer's Association. Special Report. 2011 Alzheimer's Disease Facts and Figures. *Alzheimer's and Dementia* 2011;7(2):232-235.

⁷ Healthy People 2020. Dementias, Including Alzheimer's Disease. Available at www.healthypeople.gov/2020/topics-objectives/topic/dementias-including-alzheimers-disease/national-snapshot. Revised August 25, 2014. Accessed on September 6, 2016.

⁸ Alzheimer's Association. Special Report. 2015 Alzheimer's Disease Facts and Figures. *Alzheimer's and Dementia* 2015;11(3):363-369.

obstacles to better care and quality of life for individuals with Alzheimer’s and other dementias. Not only does the proposed billing code provide reimbursement specifically for care planning services – making it easier for physicians and others to provide the service – but its very existence will send a signal that diagnosis, disclosure, and care planning are vitally important for people with Alzheimer’s and other dementias. It will serve as a signal that while there are currently no pharmacological treatments that change the underlying course of the disease, there are many things that can be done to benefit patients and there is value in diagnosis and care planning.

Another recent Workgroup convened by the Alzheimer’s Association to recommend care and support milestones for the National Alzheimer’s Plan called for the reimbursement of “high-quality care planning” immediately after an individual is diagnosed with Alzheimer’s or another dementia.⁹ As some members of this Taskforce also served on the previous Workgroup, we can attest to the fact that several members of the Workgroup believed care planning for individuals diagnosed with Alzheimer’s and other dementias was one of the, if not *the*, most important steps to better care. It can get individuals with the disease “on the right path” in their care, connect them and their families to important support services, and improve their quality of life. We agree and think **CMS’s proposed new billing code can be truly revolutionary in the care of those with Alzheimer’s and other dementias.**

II. RECOMMENDATIONS

A. Meaningful and Widespread Use of the Proposed Billing Code

To be revolutionary, the billing code must be widely used in practice. That is, the service elements of the billing code must be provided to a vast number of Medicare beneficiaries with Alzheimer’s and other dementias – and the elements must be provided in a truly meaningful way. If this billing code is not used or becomes merely a pro-forma set of “check-boxes,” the potential benefits to patients and families will simply not be realized and precious time will be lost.

To that end, we make the following recommendations:

1. Ensure Flexibility in the Provision of the Service Elements

We strongly believe the best and most meaningful way to implement the proposed billing code is through a team-based approach. A few of the proposed service elements and a portion of the eventual care plan must necessarily be provided or developed by a physician, nurse practitioner, or physician assistant. These include medication reconciliation and management of medical issues, including co-morbidities. But the service elements of the proposed billing code address – rightly – many non-medical services (such as psychosocial issues, caregiver identification, driving and other safety issues, and referral to community resources) for which physicians may not be the best qualified persons to provide the service. These elements can and, where practical, should be provided by medical assistants, care coordinators, nurses, social workers, counselors, clinical psychologists, physical and occupational therapists, and behavioral health consultants, among others.

⁹ Alzheimer’s Association National Plan Care and Support Milestone Workgroup. Report on milestones for care and support under the U.S. National Plan to Address Alzheimer’s Disease. *Alzheimer’s and Dementia* 2016;12(3):334-369.

To ensure that ideal implementation is possible, there must be flexibility in how the various service elements are provided to patients. Adjustments to the CMS proposal can further that end. First, in a couple of instances, the proposal refers to “work of a physician (or other appropriate billing practitioner)” and “services that are personally performed by the physician (or other appropriate billing practitioner).” **CMS must make clear in the final regulation that the service elements of the proposed billing code do not all need to be provided by the billing practitioner and that many of the service elements can be provided by other professionals, with active oversight of the entire process managed by the billing practitioner.** Second, we believe that because of the medical nature of some of the service elements and provisions of the care plan as well as the need to integrate the care plan into the overall clinical care of the patient, **use of the proposed billing code – that is, “appropriate billing practitioners” – should be limited to physicians, nurse practitioners, and physician assistants.** And, third, while a team-based approach where members of the team all work in the same practice may be ideal, it should not be mandatory. There are circumstances where the best qualified or most appropriate individual to provide a specific service element does not work in the same practice as the billing practitioner. **Billing practitioners should be allowed to contract out for the provision of one or more service elements, as long as they maintain meaningful overall oversight of the process.**

This team-based approach would most easily be implemented in academic settings, geriatrics clinics, memory care practices, and patient-centered medical home models where full multi-disciplinary teams are likely already present or the capacity exists to expand staffing to build such teams. Many primary care practices, however, do not have such infrastructure, the financial wherewithal to create it, or the volume of patients with Alzheimer’s and other dementias to make such an investment worthwhile. Furthermore, the service elements of the proposed billing code, particularly the non-medical elements, do not fit well within the current culture and workflow of most small group practices. As a consequence, integrating the service elements into these practices will be challenging, thus potentially severely limiting the use of the proposed billing code.

To address this specific issue, our previous recommendation to allow the provision of service elements to be contracted out is important. In addition, **CMS should allow flexibility for solo and small group practices to share resources**, particularly for the implementation of the non-medical service elements of the proposed billing code, and **CMS could offer a one-time incentive for practices to integrate the service elements into their workflow.**

2. Establish an Appropriate Valuation of the Billing Code

CMS has proposed a Relative Value Unit (RVU) of 3.30. This is based on a Level 4 office visit for a new patient combined with the incremental effort related to supervising a Medicare patient who is receiving home health services that require complex and multidisciplinary care. In addition, for direct practice expense units, CMS has proposed “70 minutes of time for RN/LPN/MTA.”

For several reasons, we believe CMS has undervalued the proposed code, both in terms of the RVU and the time needed.

First, individuals with Alzheimer’s and other dementias are, in and of themselves, complex cases. Additional complexity can derive from a specific individual patient’s health, behavioral status, and life circumstances. A visit under the proposed code is equivalent to treating a very complex geriatric patient requiring multi-disciplinary care. While CMS has recognized this, to a

degree, by adding to the Level 4 office visit an increment based on a complex case of someone who is receiving home health services, this increment is too limited to fully recognize the complexity of Alzheimer's and other dementia cases, to account for the completion of all the service elements required under the proposed billing code, and to communicate effectively with patients, those who care for them, and others who must be involved in implementing the care plan.

Second, the proposed code entails an extensive list of elements that must be completed. This includes both an assessment of multiple domains of the individual's status and needs as well as the development of a care plan. Comprehensive care planning and the initial assessment on which the plan is based cannot both be done within a 70-minute time frame unless the individual has very mild impairment, no co-morbidities, no behavioral or psychiatric symptoms, and low caregiver stress. This describes very few individuals with Alzheimer's and other dementias. Furthermore, the crucial but often delicate conversations at the core of care planning can be extremely time consuming and appear not to have been taken into account in the valuation of the proposed code. The extensive list of service elements also increases the amount of time needed for documentation.

A typical visit of this nature takes an hour, at minimum. It is commonly recognized that comprehensive geriatric assessments can require 90 minutes or more, and the UCLA Alzheimer's and Dementia Care program, which has received funding from the Center for Medicare and Medicaid Innovation (CMMI), allocates 90 minutes of face-to-face time (which does not include the additional time needed for documentation, communication with primary care physicians and other key providers, and the mailing of care plans). Combining all elements that must occur – an interview, patient history, medication review, obtaining vital signs, functional assessment, family/caregiver discussion, advance care planning, neuropsychiatric and behavioral evaluation, safety evaluation, and the development of and discussion regarding the care plan itself – can easily last two hours.

Third, given the importance of care planning to individuals diagnosed with Alzheimer's and other dementias – in terms of quality of care and reduced health care expenditures – it is vital this proposed code be widely adopted and used. We fear that when the proposed RVU is converted to a reimbursement rate, the rate will be too low to encourage a significant number of providers to utilize the proposed code.

Therefore, to more accurately reflect the reality of the case complexity involved – and to avoid the risk of the development of only cursory, pro forma care plans – **the RVU should be based on at least a Level 5 office visit. However, the amount of work required is likely 1.5 times to two times greater than a Level 5 visit, and the RVU should reflect such an adjustment. Furthermore, a 120-minute time frame should be designated for this billing code.**

3. Permit Use of the Billing Code at Regular Intervals

The CMS proposal is silent on the issue of how often the proposed billing code may be used per patient. The Health Outcomes, Planning, and Education (HOPE) for Alzheimer's Act, which has been introduced in Congress,¹⁰ would create a one-time care planning benefit for newly-diagnosed individuals. While we believe an initial care plan is the most important – there is a desperate need to change the usual practice of what happens when an individual is first

¹⁰ S. 857/H.R. 1559, Health Outcomes, Planning, and Education (HOPE) for Alzheimer's Act of 2015. Available (S. 857) at www.congress.gov/114/bills/s857/BILLS-114s857is.pdf. Accessed on September 6, 2016.

diagnosed – it is clear that a static one-time care plan is inadequate for the proper care of individuals experiencing a progressive and increasingly complex condition over the life-span of the disease.

A progressive disease such as Alzheimer's and other dementias requires constant monitoring. Needs change as the disease progresses; individual life circumstances and living arrangements change; behavioral patterns change; the individual's caregiving situation – indeed, the individual's specific caregiver – may change. Proper care for a person with Alzheimer's and other dementias requires ongoing management and constant re-evaluation. A care plan, by definition, is a static document. To bridge the gap between ongoing management and a fixed care plan, the proposed billing code should be available for use at least once a year. While it does not appear that such is precluded by the CMS proposal, **we believe, for clarity, CMS should be explicit about the frequency at which the code may be used for each patient – and that frequency should be no less than once per year.**

However, an annual use of the proposed billing code does not – and should not – mean a care plan changes only once per year. The proposed new billing code will not cover (and was not intended to cover) all of the dementia care that those with Alzheimer's and other dementias need throughout the year. Because care management of individuals with Alzheimer's and other dementias should be an ongoing and constant process – that is, in practice, a care plan should be under constant re-evaluation and amendment – **CMS should make clear to providers that if adjustments to a care plan need to be made in the interval between permissible uses of the proposed billing code, providers can use the E&M codes for this purpose.** An explicit statement in this regard from CMS will help educate providers about the proper care of an individual with Alzheimer's and other dementias and will positively influence the way care is provided. Furthermore, much of the ongoing care of monitoring, coordinating, and adjusting care plans can be conducted in non-face-to-face settings, such as by telephone and e-mail. As a result, **we strongly support the CMS proposal included elsewhere in the physician fee schedule update to create an E&M code specifically for such non-face-to-face consultations.**

4. Ensure Proper Documentation of Care Plan

More than 85 percent of individuals with Alzheimer's and other dementias have one or more other chronic conditions, such as diabetes, coronary artery disease, and kidney disease.¹¹ And more than 25 percent have four or more other chronic conditions.¹² Care for these other conditions, specifically tailored to an individual who is cognitively impaired, must be an integral part of an individual's care plan. And all providers treating that patient must be aware of that care plan. Therefore, as part of the regulation establishing this new billing code, **CMS should require providers who utilize the billing code to note in a patient's medical record, in a readily identifiable manner, that a care plan has been developed,** consistent with the provision included in the HOPE for Alzheimer's Act currently pending in Congress.¹³ Such a notation would inform all health care providers of the existence of a care plan, provide other practitioners with the opportunity to review and contribute to the care plan if they were not already consulted, and improve the coordination of care for those with Alzheimer's and other dementias.

¹¹ Unpublished tabulations based on data from the National 5% Sample Medicare Fee-for-Service Beneficiaries for 2014. Prepared under contract for the Alzheimer's Association by Avalere Health, January 2016.

¹² *Ibid.*

¹³ S. 857/H.R. 1559, *op. cit.*

5. Promote Provision of Services by Medicare Advantage Plans

The proposed billing code is for use in the Medicare fee-for-service setting. There are no provisions with respect to patients in Medicare Advantage (MA) plans, even though one-third of seniors are now enrolled in MA plans, with that number rapidly increasing.¹⁴

If the services under the proposed code are truly to have a wide-spread impact – and are made available to all individuals with Alzheimer’s and other dementias – it is imperative for CMS to engage MA plans on this issue. In fact, the structure of MA plans makes them well-suited to provide the services under the proposed billing code in an efficient and effective manner, and they should not be overlooked. When issuing the final rule, **CMS must specify the steps it plans to take to encourage and ensure the service elements of the proposed billing code are provided by MA plans.**

One way to enhance MA-plan uptake is to demonstrate the cost benefit of care planning through savings in acute care, emergency department visits, and hospitalizations, among other things. One analysis recently showed care planning for individuals newly-diagnosed with Alzheimer’s and other dementias would save Medicare \$692 million over 10 years.¹⁵ Similar micro-level analysis could encourage MA plans to provide the services under the proposed code, and **CMS should undertake such ongoing research and analysis.** This should include analysis of the CMMI-funded UCLA and Indiana University dementia care programs and the Dementia Cal MediConnect program funded by the Administration on Community Living.

Also, while outside the scope of the current proposal, **CMS must incorporate the services under this proposed billing code in regulations implementing the Medicare Access and CHIP Reauthorization Act (MACRA), specifically the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).**

6. Undertake an Extensive Education and Outreach Effort

The utilization of the Medicare Annual Wellness Visit (AWV) has been disappointing nationwide. We believe a major reason for the low uptake rates has been the lack of an education and outreach campaign as part of CMS’s implementation efforts. Similarly, a recent survey of over 700 physicians found that while most doctors strongly supported another recently created billing code – for advance care planning – they lacked information and education on providing the service,¹⁶ potentially limiting its use.

These oversights should not be repeated with the proposed new billing code on assessing and building a care plan for individuals with cognitive impairment. CMS should increase awareness of this new billing code and encourage its use with multiple efforts, including **providing sub-regulatory guidance to providers on exactly how to conduct such a visit, offering training to providers both on-line and through the education departments of health systems,**

¹⁴ Centers for Medicare and Medicaid Services. Strengthening Medicare Advantage and Part D. Fact Sheet. April 4, 2016. Available at www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-04.html?DLPage=1&DLEntries=10&DLFilter=medicare%20ad&DLSort=0&DLSortDir=descending. Accessed on September 6, 2016.

¹⁵ Healthspieren. Analysis and estimate of the federal budget impact of the Health Outcomes, Planning and Education (HOPE) for Alzheimer’s Act of 2015. 2016. Available at act.alz.org/site/DocServer/HOPE_Act_model_report_for_ADVOCATES.pdf?docID=50924. Accessed on September 6, 2016.

¹⁶ The John A. Hartford Foundation. Conversation Stopper: What’s Preventing Physicians from Talking with Patients About End-of-Life and Advance Care Planning. April 14, 2016. Available at www.jhartfound.org/news-events/news/advance-care-planning-poll. Accessed on September 6, 2016.

educating practitioners on how to code for and document the services provided under the proposed billing code, and conducting an awareness campaign about the existence and benefits of the proposed new billing code among Medicare beneficiaries and their family members.

We further suggest **CMS develop a “tool kit” for practitioners that spells out step-by-step what should be done during a visit and how it should be done.** This will make it easier for practitioners to use the billing code – increasing the likelihood that they will – and help ensure consistency in the comprehensive provision of the service elements.

We call on CMS to partner and work with providers, professional associations, and patient groups in the development of the tool kit and in the broader education and outreach effort.

B. Other Recommendations

In addition to the above recommendations aimed at ensuring meaningful and widespread use of the proposed billing code, we also make the following recommendations:

1. “Assessment”

The proposed billing code is for “Assessment and Care Planning for Patients with Cognitive Impairment.” Conducting an assessment of an individual’s cognitive status (such as the “detection of possible cognitive impairment” element of the Annual Wellness Visit) and undertaking a diagnostic evaluation – that is, establishing an individual’s diagnosis – is a separate step and process from the purpose of the proposed new billing code. In fact, the practitioner who diagnoses an individual’s dementia may be different than the practitioner who undertakes the mostly non-clinical service elements under the proposed billing code.

These two steps – diagnosis followed by care planning – must be kept separate in the coding and billing process, and we believe that is CMS’s intent. However, the use of the word “assessment” in describing the new code can be confusing. “Assessment” is a term often used and understood as a step in the diagnostic process. In the context of this proposal, we believe CMS used the word “assessment” to refer to a needs and status assessment of the previously-diagnosed individual that would inform the development of an appropriate and comprehensive care plan for that individual.

If CMS intended to include a clinical diagnostic assessment as part of the proposed new billing code, it must be removed and remain as a separate visit and billing code. If, however, CMS intended what we believe was the intent – “assessment” referring to a needs assessment – CMS must avoid any confusion and **either define “assessment” in the context of this proposed billing code or use a different term.**

2. Proposed Service Elements

The proposed billing code includes 10 specific required service elements. We have the following recommendations with regard to some of the required service elements included in the CMS proposal. Any of the proposed 10 service elements on which we do not comment should be construed as having our support as written.

“Cognition-focused evaluation including a pertinent history and examination”: As noted above, an assessment of cognitive impairment and a diagnostic evaluation of an individual should not

be, and we believe is not intended to be, included as part of the proposed billing code. We fear this service element might be interpreted otherwise. The pertinent history of an individual and aspects of a clinical examination (both physical and cognitive) are certainly relevant to the development of an appropriate care plan. But, the proposed billing code must not be interpreted to include the diagnostic process, and thus **this particular service element should be clarified or deleted**. One possible way to clarify is to amend the service element to state, “Documentation of previously conducted diagnostic evaluation as well as assessments of related history and relevant elements of a physical examination.”

“Functional assessment (for example, Basic and Instrumental Activities of Daily Living), including decision-making capacity”: Measuring an individual’s decision-making capacity, such as assessing the individual’s ability to be autonomous within or outside the home or the ability of an individual to be involved in his/her own functional assessment, is important in developing an appropriate care plan, at least at a basic level. However, to avoid any potential confusion that assessing “decision-making capacity” in any way refers to an assessment of competency in a legal context, we believe **the wording should be clarified or amended**. For example, CMS could instead refer to “the ability of the patient to keep him/herself clean, safe and fed.” Or, in defining the term either in the final regulation or in sub-regulatory guidance, CMS could specifically indicate that “decision-making capacity” refers to the individual’s ability to be safe at home and if left alone, to understand one’s own health care and support needs, and to manage basic legal and financial affairs.

Furthermore, we note that a functional assessment and an assessment of decision-making capacity are two separate assessments. A functional assessment focuses on the tasks that individual patients are able to perform, while an assessment of decision-making capacity involves measuring a person’s cognition, judgment, and executive function. Therefore, we recommend **separating these two items**.

Finally, we believe it is important not just to determine the patient’s decision-making capacity but also to **identify and determine who other decision makers might be**. Often, different family members are involved in the care and support of the individual with Alzheimer’s and other dementias, each with different roles and divergent viewpoints. Knowing who the decision makers are both helps in the development of the care plan and in the ongoing management of the patient’s care.

“Use of standardized instruments to stage dementia”: We note there are significant challenges and difficulties in determining the severity of an individual’s dementia, including whether a standardized tool that stages dementia appropriately actually exists. The MMSE is the only easily administered cognitive scale that has evaluated cut points associated with the stages of dementia. However, it is not free and widely available. Both the Clinical Dementia Rating and the Dementia Severity Rating Scale have shown reasonable correlation with each other; however, little is known about their performance in non-Alzheimer’s dementias. The GDS/FAST system relies too heavily on clinician experience for accurate staging and has limitations when used in non-Alzheimer’s dementias. The Functional Assessment Questionnaire, which measures a person’s ability to manage activities of daily living, may not be comprehensive enough and is, to some extent, culturally biased.

Clinicians who are highly experienced in dementia care are fairly well versed and capable of recognizing the various stages of dementia. Most practitioners, however, are not well versed and will not be aware of staging instruments or how to use them.

Given the problematic nature of using existing tools and since the most important factors in developing a care plan for individuals with Alzheimer's and other dementias are the individual's circumstances and the resources the individual needs – with the stage of the disease a fairly minor consideration – **CMS should consider deleting this service element.**

If this service element remains in the final regulation, we strongly encourage CMS to assist practitioners by developing a list of validated, standardized tools for staging dementia, similar to the process CMS undertook in developing a list of assessment tools that could be used during the Annual Wellness Visit. In addition (or alternatively), CMS should consider developing a new tool that would involve a very simple checklist to approximate disease stage solely for the purpose of developing a care plan.

“Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks”: As noted above, we believe it is important to identify the decision makers involved with each individual with Alzheimer's and other dementias. So, we strongly support the inclusion of this element as part of the required elements of the billing code. We also believe the identification of the caregiver(s) is not only necessary in the development of the care plan, but is also an essential element of the care plan itself and the ongoing care of the patient. Therefore, **CMS should require the inclusion of the names and contact information of all identified caregivers in both the care plan and the patient's medical record.**

In addition to the aspects of this service element listed in the CMS proposal, we believe it **should be expanded to also include (1) assessment of caregiver stress and depressive symptoms; (2) the caregiving skills of the caregiver; and (3) the caregiver's educational needs.**

This service element focuses on the assessment of the caregiver such as his/her knowledge and needs. There is no mention in this service element, in the service element regarding the development of the care plan, or in the CMS proposal in general of the caregiver's involvement in the development and implementation of the care plan. **CMS should include language recommending the care plan be developed in consultation with both the patient and caregiver, including asking the caregiver about the feasibility of the care plan.**

Often times, it is advantageous and necessary for a provider to consult with the caregiver of an individual with Alzheimer's and other dementias outside the presence of and without the explicit permission of the patient. We believe this is particularly true in the development and implementation of a comprehensive care plan. Under previously issued guidance, the Health Insurance Portability and Accountability Act (HIPAA) allows, in certain circumstances, such consultations and conversations to occur. Given the importance of the issue, we believe **CMS should include a statement in the final regulation reminding physicians of the HIPAA-permissible consultations with caregivers and the occasional necessity of such conversations in the development of a care plan for individuals with Alzheimer's and other dementias.** Such conversations could occur as part of this billing code, but **CMS should also ensure such conversations are reimbursable under E&M codes.**

Finally, we believe this service element should be taken to its logical conclusion by **requiring that a plan for the support of the caregiver – meeting the needs of the caregiver and the referral of the caregiver to appropriate services – be included as a provision of the care plan itself.** The needs of a caregiver are inextricably linked to and have a direct impact on the care of the individual with Alzheimer's and other dementias. Positive supports for caregivers are

important to the outcomes of the patient with dementia. And when the caregiver is a spouse, he/she is sometimes frail and often has extensive health care issues of his/her own, which can be exacerbated when serving as a caregiver. Development of the caregiver provisions of the care plan should be done in consultation with the caregiver's primary care practitioner, if different than the practitioner using this billing code.

“Advance care planning and addressing palliative care needs, if applicable and consistent with beneficiary preference”: We strongly support the inclusion of this service element and suggest **adding specific language regarding the establishment of a Durable Power of Attorney for Health Care.**

“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”: This is the heart of the proposed new billing code, and we cannot understate our strong support of Medicare reimbursement for providers to undertake care planning. As noted previously, we believe care planning is one of the, if not *the*, most important steps to providing better care for individuals with Alzheimer's and other dementias.

To strengthen the impact of a care plan, we believe CMS should add language to this service element to indicate **the care plan should include initial plans not just to address neuropsychiatric symptoms, but also to address other medical and non-medical issues relevant to the individual's dementia care and identified during the course of the evaluations and reviews conducted as part of the required service elements.**

We further recommend that, consistent with our previous comments regarding the ongoing, not static, nature of a meaningful care plan, **CMS should require the care plan include a schedule for follow-up monitoring and evaluation, either face-to-face or by other appropriate means.** (Some of the work involved in this ongoing activity could be billed, as noted previously, using the E&M codes; CMS should inform and instruct practitioners about this.) And, as mentioned previously, **the care plan should be developed in consultation with both the caregiver and patient.**

We commend CMS for proposing to require the care plan be “shared with the patient and/or caregiver.” This is important for adherence to the care plan and in making the care plan a truly guiding document for the care and support of the individual with Alzheimer's and other dementias. However, among individuals with a cognitive impairment, adherence to a treatment regimen and utilization of additional services (such as psychosocial services) that would be included in a care plan is often dependent on written documentation. Therefore, we believe the language should be amended to **require a *written* copy of the care plan be provided to the patient and his/her caregiver.**

Finally, **the “care plan” should be listed as a “person-centered care plan.”**

3. Additional Service Elements

Our biggest concern with the proposed list of service elements as a whole is the lack of references to the medical components that should be evaluated and, when appropriate, included in the care plan. The proposal is heavy on psychosocial and other non-medical gaps and needs, and we believe those are key elements of any comprehensive and meaningful care plan. But, medical issues, such as management of other health conditions and coordination of

care across all co-morbidities, are equally important to ensure proper and better care of those with Alzheimer's and other dementias.

In the previous discussion on the proposed care plan service element, we recommended strengthening the language by specifically requiring the care plan include all medical issues relevant to the individual's dementia care. In that light, **the following additional items should be added to the list of required service elements:**

- Evaluation of relevant medical problems, including review of laboratory and imaging tests.
- Review of co-morbidities, particularly those that are dependent on self-care (such as diabetes) and providing guidance on the management of those conditions by or on behalf of an individual with cognitive impairment.
- Evaluation of the risk of falls and recommendations for falls prevention, including physical modifications of the home, if necessary.

In addition, **the list of required service elements should also include the following non-medical components:**

- Evaluation of possible elder abuse.
- Documentation of financial issues, if any, and identification of who manages the finances of the individual.

C. "Cognitive Impairment"

The proposed billing code is for beneficiaries with "cognitive impairment." However, "cognitive impairment" is *not* a medical diagnosis, and CMS does not define the term in its proposal. Thus, it is unclear for whom the proposed billing code is intended to be used.

We believe it is self-evident the proposed billing code could and should be used for any individual with a clinical diagnosis of Alzheimer's or another dementia. Beyond that, the issue becomes murky. Individuals with mild cognitive impairment (MCI), which is a medical diagnosis, and other states of cognitive impairment short of MCI and dementia that do not have diagnostic codes may eventually develop dementia. But, at these earlier stages they may have different needs or few, if any, needs at all.

Extending eligibility for the proposed billing code beyond those individuals with a dementia diagnosis has both its benefits and pitfalls, and we could not reach a consensus. Some members of the Taskforce argue that all individuals with a cognitive impairment, even if it is not a medical diagnosis, could benefit from a care plan; they support leaving the term undefined, with the proposed billing code to be used at the discretion of the provider. Others believe it makes sense to include those with MCI, not only because they would benefit from a care plan but also because many physicians use that diagnosis to avoid conducting a full diagnostic evaluation for dementia or having to tell a patient he or she actually has dementia. These members of the Taskforce do not, however, support including individuals defined vaguely as having "cognitive impairment." Still others argue that a comprehensive care plan is not appropriate or necessary for people with MCI and that the MCI diagnosis itself is fraught with problems, not least of which is that many physicians do not understand the condition or how to diagnose it properly; these Taskforce members believe the proposed billing code should be available for use only where there is solid evidence of a benefit from a care plan – and that is among individuals with Alzheimer's and other dementias.

Because we could not reach a consensus, we are not making a recommendation to CMS on how to address this issue – or even whether to address it. We raise the issue, however, because we believe that in whatever way CMS addresses it in the final regulation, if at all, **CMS must closely monitor its implementation over the first few years.** This monitoring should focus on the stage of cognitive impairment of the individuals for whom the billing code is being used and what benefits are accruing to individuals in various different stages. Based on that monitoring and evaluation, CMS must be prepared to revise the eligibility criteria one way or another (either more broadly or more narrowly) in the future.

We also believe CMS should be aware the issue is further complicated by ongoing discussions in the medical community regarding the shifting nature of scientific consensus around the definition of Alzheimer’s disease, dementia, and MCI. For example, under the diagnostic criteria in existence since 1984, a diagnosis of Alzheimer’s requires the individual have symptoms of dementia. But, under proposed new diagnostic criteria,^{17,18,19} there may come a day when an Alzheimer’s diagnosis includes those who are asymptomatic – that is, the presence of beta amyloid exists in the brain but the individual is not yet displaying any symptoms, even of mild cognitive impairment. As this diagnostic consensus shifts, there could be implications for the eligibility of the services provided under the proposed billing code, and those implications could necessitate the revision of the eligibility criteria in the future.

III. CONCLUSION

The lack of care planning is perhaps the most concerning gap in the current system of dementia care. It prevents most individuals with Alzheimer’s and other dementias from “getting on the right path” following a diagnosis, hinders the quality of care throughout the course of the disease, and degrades the quality of life for both the individual and caregiver. The proposed billing code for assessment and care planning for Medicare beneficiaries with cognitive impairment is a giant step forward, and CMS is to be commended for the proposal. This consensus statement contains several recommendations we believe will make the services provided under the proposed billing code even more meaningful to the care of those with Alzheimer’s and other dementias – and will increase the likelihood that practitioners will use the billing code.

Regardless of whether our recommendations are adopted by CMS in the final regulation, the key to success of this proposed billing code – the key to making significant strides in the care of those with Alzheimer’s and other dementias – is in the implementation. In the months ahead, this Taskforce will continue to work with the Alzheimer’s Association on implementation issues, including ensuring that physicians are properly educated and equipped and that beneficiaries are aware of the availability of the services and the importance of developing a care plan. Both collectively as a Taskforce and individually as those who work with people with Alzheimer’s and other dementias, we are available to advise and assist CMS on this effort as well.

¹⁷ McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia due to Alzheimer’s disease: Recommendations from the National Institute on Aging-Alzheimer’s Association workgroups on diagnostic guidelines for Alzheimer’s disease. *Alzheimer’s and Dementia* 2011;7(3):263-269.

¹⁸ Albert MS, DeKosky St, Dickson D, et al. The diagnosis of mild cognitive impairment due to Alzheimer’s disease: Recommendations from the National Institute on Aging-Alzheimer’s Association workgroups on diagnostic guidelines for Alzheimer’s disease. *Alzheimer’s and Dementia* 2011;7(3):270-279.

¹⁹ Sperling RA, Aisen PS, Beckett LA, et al. Toward defining the preclinical stages of Alzheimer’s disease: Recommendations from the National Institute on Aging-Alzheimer’s Association workgroups on diagnostic guidelines for Alzheimer’s disease. *Alzheimer’s and Dementia* 2011;7(3):280-292.