September 14, 2026

Re: CMS-1848-P, Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz and CMS Staff:

On behalf of the 372 undersigned members and allies of the LEAD Coalition (Leaders Engaged on Alzheimer's Disease)[1], we thank you for the opportunity to comment on the Calendar Year (CY) 2027 Physician Fee Schedule (CMS-1848-P). We appreciate CMS's recognition of the urgent need to address cognitive health and aging, particularly in light of the growing body of evidence that intensive lifestyle interventions (ILIs)—addressing physical activity, nutrition, sleep and stress management, among others[2]—may help slow cognitive decline and reduce the risk of Alzheimer's disease and related disorders (AD/ADRD). In response to the Request for Information (RFI), we welcome the opportunity to provide information that may assist CMS in better understanding the resources, infrastructure, and implementation requirements necessary to develop and deliver these interventions effectively and at scale to all communities nationwide.

Prevalence:

The U.S. population is aging rapidly – currently, there are 58 million individuals aged 65 and older and this number is projected to rise to nearly 82 million by 2050. Age is the biggest risk factor for AD/ADRD, which include Alzheimer's disease (AD), Lewy body dementia (LBD),

[1] Leaders Engaged on Alzheimer's Disease (LEAD Coalition) is a diverse and growing national policy coalition committed to overcoming Alzheimer's disease and related disorders (AD/ADRD), including vascular contributions to cognitive impairment and dementia, Lewy body dementia, and frontotemporal degeneration. The Coalition serves as the uniting voice of more than 260 member and allied organizations and over 500 researchers to focus the nation's attention on accelerating transformational progress to reduce risk, enhance detection and diagnosis, improve care and support, and develop increasingly effective treatments and eventual cures.

[2] As per the RFI, this response is only considering ILIs, "which would be in concert with but would not specifically include risk factor reduction in modifiable behaviors such as controlling contributing conditions (for example, hypertension, diabetes), eliminating tobacco use (in any form), and addressing hearing loss."

frontotemporal degeneration (FTD), vascular contributions to cognitive impairment and dementia (VCID), and mixed etiology dementia. As our nation's aging population grows, the number of Medicare beneficiaries with mild cognitive impairment (MCI, often considered a precursor to dementia) or dementia is expected to increase exponentially. In addition to individuals over the age of 65, an estimated 200,000 Americans under 65 years old are living with younger-onset dementia and may qualify for Medicare coverage. The disparate impact of AD/ADRD on specific communities is significant. For example, women comprise nearly two-thirds of the AD population in the US. African Americans are about two times more likely than white Americans to have AD/ADRD, and Hispanics about 1.5 times more likely than whites to have AD/ADRD – yet these populations are less likely to have a clinical diagnosis of MCI or dementia. Additionally, individuals with Down syndrome (DS) are living longer; nearly all people with DS will have AD pathology by age 40, and lifetime risk for developing symptomatic AD exceeds 90%.

In light of our country's shifting demographics, CMS must take transformative steps now to ensure healthcare systems, community-based organizations, public health agencies, employers, and other relevant entities throughout the U.S. address immediate needs and are prepared for the years to come. CMS should begin by implementing ILI programs to target modifiable risk factors for cognitive decline. **Starting early is essential**; the science is clear and compelling that biological changes associated with AD/ADRD begin in the brain 15-20 years or more before clinically-apparent cognitive symptoms. Delaying action until symptoms emerge means missing decades during which multi-domain risk reduction strategies, and potentially disease-modifying therapies, could have their greatest opportunity to prevent, delay, or alter AD/ADRD progression. Intervention well before symptom onset will promote and protect brain health, improve quality of life for individuals and families, strengthen the economy, and conserve tax-payer resources.

Evidence:

The 2024 Lancet Commission report on dementia prevention, intervention, and care identifies 14 potentially modifiable risk factors that cumulatively are associated with approximately 45% of dementia cases worldwide (Livingston et al., 2024). The factors span the life course and include lower educational attainment, hearing loss, high LDL cholesterol, depression, traumatic brain injury, physical inactivity, diabetes, smoking, hypertension, obesity, excessive alcohol use, social isolation, air pollution, and untreated vision loss. The Commission emphasized that dementia prevention should begin early in life and continue throughout adulthood by improving education, maintaining cardiovascular and metabolic health, staying physically and socially active, avoiding smoking and excessive alcohol, and treating hearing and vision problems. Importantly, the report stresses that reducing these risk factors may benefit people regardless of their genetic susceptibility to dementia. Although not every case of dementia can be prevented, the Lancet report concludes that targeting these potentially modifiable risk factors at individual and population levels could delay or prevent nearly half of dementia cases.

The Lancet Commission report was pivotal in quantifying the proportion of dementia risk that could be reduced by addressing these potentially modifiable risk factors. Prior to the 2024 report, the National Institutes of Health (NIH) commissioned an Agency for Healthcare Research and Quality (AHRQ) systematic evidence review and subsequent National Academies of Sciences, Engineering, and Medicine (NASEM) committee to review the scientific evidence on whether cognitive decline and dementia could be prevented, delayed, or slowed through interventions. The resulting 2017 NASEM report, *Preventing Cognitive Decline and Dementia: A Way Forward*, concluded that, although evidence was still limited and inconclusive, three promising interventions could help maintain brain health as people age. Specifically, the NASEM report identified cognitive training, management of high blood pressure, and increased physical activity as interventions with encouraging evidence of benefit. However, NASEM cautioned that the evidence was not strong enough at the time to support broad public health claims that these interventions definitively prevent dementia. The report therefore emphasized the need for better randomized controlled trials, longer follow-up periods, and improved research methods to determine which interventions truly prevent or delay cognitive impairment and dementia. In addition to three domains with encouraging evidence of benefit, NASEM also identified additional domains—including diet, diabetes management, lipid lowering, depression treatment, sleep, and social engagement—as important areas for further research.

More research was conducted following the 2017 NASEM report, providing rigorous evidence that some domains demonstrate clear and compelling benefits for protecting cognitive health. SPRINT-MIND showed that intensive blood-pressure control reduces the occurrence of mild cognitive impairment, providing evidence that managing a cardiovascular risk factor also can benefit cognitive health (Williamson et al., 2019). Similarly, the ACTIVE trial demonstrated that targeted cognitive training—particularly reasoning and speed-of-processing training—produced improvements in cognitive abilities that could persist for years, with new 20-year follow-up evidence suggesting that speed-of-processing training with booster sessions also may reduce the risk of AD/ADRD (Coe et al., 2026). The I-CONECT trial demonstrated that frequent, cognitively-stimulating social interactions delivered through internet-based video conversations can improve cognitive function, particularly among older adults with MCI, providing further evidence of a strong association between social engagement and cognition (Dodge et al., 2024). Ongoing research is gathering additional evidence about ILIs in broad and distinct populations. For example, the NIH is funding the COMbined Exercise Trial (COMET) to test the combined and independent effects of aerobic and resistance training on cognition, brain structure, and physical function (Szabo-Reed et al., 2022; NCT04848038). Additionally, the NIH is funding a study to test whether a weight loss and dietary intake program slows or delays the progression of AD in individuals with Down syndrome (Ptomey et al., 2025; NCT05985486).

Most powerful have been research evidence from intensive, multi-domain approaches. CMS states that, in other countries, there is randomized controlled trial evidence that multi-domain approaches can slow cognitive decline amongst at-risk older adults, citing the international FINGER trial (Ngandu et al., 2015). This approach has been extended and replicated through U.S. POINTER (Baker et al., 2025), which enrolled 2,111 adults ages 60–79 who were at increased risk for cognitive decline and tested lifestyle interventions addressing multiple

domains—including physical activity, nutrition, cognitive engagement, social engagement, and cardiovascular/health monitoring. Both intervention groups demonstrated cognitive improvement, with greater benefit in the more structured and intensive program. U.S. POINTER's ongoing ancillary studies are examining potential biological pathways through which these interventions may affect brain health, including vascular health, sleep, Alzheimer's-related brain pathology, and the gut microbiome. Complementing this evidence, the SMARRT pilot trial provides support for a more personalized, risk-factor–tailored approach in the U.S. (Yaffe et al., 2024). Rather than providing every participant with the same intervention, SMARRT participants worked with a behavioral coach and nurse to identify and prioritize individual risk factors – including physical inactivity, hypertension, diabetes, poor sleep, depressive symptoms, social isolation, unhealthy diet, smoking, low cognitive stimulation, and potentially harmful medications – and develop personalized goals and strategies. After two years, the multi-domain intervention produced modest but statistically significant improvements in cognition and dementia risk-factor profiles compared with health education alone. Taken together, FINGER, U.S. POINTER, and SMARRT support an emerging model in which well-supported ILIs demonstrate evidence for maintaining brain health.

Recent evidence from the LatAm-FINGERS study demonstrates that these ILIs effectively can be adapted to different community contexts while maintaining core components (Crivelli et al., 2026). Rather than applying the same approach identically everywhere, the program allowed practical elements (i.e., activities, food recommendations) to reflect local traditions, resources, and preferences. Through this research, investigators show that these programs can be adapted for different cultural and linguistic contexts, and that adaptation strengthens program feasibility, participation, and effectiveness.

Critically, these multi-domain ILIs are not focused solely on reducing the risk of or preventing Alzheimer's disease; they support cognitive health and brain health generally as people age. The Alzheimer's Association's 2026 special report on *Brain Health in America: Understanding and Supporting Lifelong Cognitive Health* emphasizes that "brain health is a lifelong priority" and highlights the importance of addressing modifiable factors across the lifespan through interventions such as U.S. POINTER to support cognitive health. The report also highlights the importance of reframing brain health, from an issue of older age to a lifelong priority and a shared responsibility across society. Lasting progress depends on coordinated actions across workplaces, communities, health care systems, and public health institutions to create and sustain the conditions that support cognitive function, brain health, and well-being.

This broader "brain health" perspective is important because the potential value of multi-domain ILIs extends beyond individuals with clinical AD/ADRD, or even those specifically identified as being at elevated risk for Alzheimer's disease. This approach also recognizes the needs of individuals and care partners affected by other progressive neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS), corticobasal degeneration (CBD), multiple system atrophy (MSA), Parkinson's disease (PD), and progressive supranuclear palsy (PSP), for whom accessible supports that promote overall health, function, and caregiver well-being may be

valuable. Ultimately, these interventions represent an approach to maintaining cognitive health, brain resilience, and healthy cognitive aging across the general adult population.

As CMS considers coverage of these interventions, their potential to improve overall health and reduce downstream health care utilization (e.g., hospitalizations, emergency department visits, falls, and management of chronic conditions) should be considered. Broader health benefits make these interventions valuable in improving overall health and reducing costly health outcomes, in addition to significant cognitive benefits.

Eligibility:

Eligibility for ILI services should **not** be restricted to beneficiaries who already have MCI or dementia. Instead, **these interventions should be recognized and treated as important components of protecting brain health throughout the life course**, rather than something initiated only after cognitive symptoms have emerged – when it may be more difficult or possibly too late to impact the disease trajectory. **Participation in an ILI program should be a covered benefit for all Medicare enrollees.**

If CMS determines that eligibility criteria or risk stratification are necessary to target cognitively unimpaired individuals, consideration may be given to a range of factors reflecting an individual's elevated risk for cognitive decline. However, these factors should be used thoughtfully and must not create unnecessary barriers to preventive services. Importantly, these factors should be treated as distinct; meeting any one of them—not necessarily all—could be sufficient for eligibility under the ILI program. Listed in no specific order, potential risk stratification factors may include:

- **Genetic risk.** Genetic factors, including the presence of known genetic risk variants in genes such as APOE for AD, GBA and SNCA for LBD, and C9orf72, GRN, and MAPT for FTD, may help identify individuals who are at elevated risk for AD/ADRD and who would benefit from early risk-reduction interventions.
- **Family history.** Individuals with blood relatives with a history of MCI or dementia may have an increased risk for AD/ADRD, and would be a reasonable consideration when determining who could benefit from ILI.
- **Co-occurring conditions.** Co-occurring conditions (e.g., hypertension, diabetes, hearing and vision loss) as well as modifiable behaviors (e.g., tobacco use) are important risk factors for cognitive decline.
    - *Although this RFI response focuses on ILI, we encourage CMS to integrate brain health education into behavioral intervention programs addressing co-occurring conditions—for example, helping individuals understand that managing hypertension and diabetes, eliminating tobacco use, and addressing hearing and vision loss also may have benefits for cognitive health. This connection will help individuals better understand the importance of these interventions for brain health and may support sustained engagement in and adherence to programs.*

- **Biological evidence of disease pathology.** As biomarkers provide improving opportunities to identify AD/ADRD pathology earlier in the disease continuum, evidence of AD/ADRD pathology could become a reasonable factor for identifying individuals who may benefit from targeted lifestyle interventions. Such an eligibility criterion would need to be aligned with clinical guidelines regarding future circumstances in which biomarker testing in asymptomatic individuals is appropriate.
- **Caregiving responsibilities.** Care partners of individuals with MCI or dementia face significant financial, physical, emotional, and social demands as caregiving responsibilities evolve. Findings from the National Alliance for Caregiving and AARP's *Caregiving in the US* 2025 report underscore the broader burden experienced by family caregivers: Nearly 63 million U.S. adults provide ongoing care for someone with a medical condition or disability, with 44% providing high-intensity care of at least 27 hours per week. Caregiving can affect caregivers' own health and well-being: one in five caregivers report being in fair or poor health, nearly one in four report difficulty caring for their own health because of caregiving responsibilities, and nearly one in four report feeling socially isolated. Furthermore, longitudinal NIH-funded research has found substantially increased dementia risk among spouses who care for a partner with dementia (Norton et al., 2010). Designing and targeting interventions for care partners – and ensuring care partners are offered and have access to programs as Medicare beneficiaries themselves – will aid in supporting their own health and reducing their risk of adverse health outcomes.

We also implore CMS to adapt to the emerging evidence, and make any eligibility criteria aligned with the science, including what may be learned about differences across various forms of AD/ADRD and which interventions are most effective for different populations.

Delivery Models:

We appreciate CMS's consideration of how to create stronger incentives for Medicare to prioritize high-value, preventive care associated with cognitive health and AD/ADRD. Aligning financial incentives with long-term cognitive health outcomes can encourage investment in interventions that improve cognitive and overall health and reduce health care costs over time. Considerations must be made to ensure the right professionals are delivering the programs in an evidence-based manner to broad communities.

- **Team-based model.** A multi-domain ILI requires expertise across multiple areas. At a minimum, this includes an interventionist with expertise in at least one specific domain and a navigator with counseling or coaching expertise. Depending on the program, the care team also may include lifestyle coaches, exercise professionals, registered dietitians, and community health workers. A physician may refer individuals to the program but does not need to be involved in, nor supervise, the delivery. Clinical safety and oversight can be conducted by professionals associated with the community-based entity delivering the intervention.
- **Frequency, duration, and modality.** As the evidence evolves, we will better understand the optimal "dose" of these interventions for different individuals. In the meantime,

programs should be designed around the best available evidence and include regular, ongoing engagement and routine follow-up. At least two years of participation, as demonstrated in the U.S. POINTER study, should be considered. Although evidence suggests that in-person programs may have greater impact, both in-person and virtual options should be offered to ensure broad access and serve rural and other underserved communities. Additionally, a one-size-fits-all approach is unlikely to produce meaningful benefits for all. Programs, services, and supports must tailor the type, intensity, and duration of an intervention to an individual's needs and availability, recognizing that different risk factors may call for different interventions and that programs perceived as overly burdensome may be more difficult for certain individuals to sustain over time. As systems evolve toward precision medicine, they also should evolve toward personalized AD/ADRD ILI programs.

- **Coding and reimbursement.** Entities delivering ILIs often are ineligible for Medicare reimbursement. Accordingly, ensuring all qualified team members are eligible for Medicare reimbursement will be important to supporting effective and accessible delivery of multi-domain interventions. CMS may consider using the *Medicare Diabetes Prevention Program*/*National Diabetes Prevention Program* as a model, working together with the CDC to establish a robust program and Medicare benefit. Additionally, CMS may consider establishing an add-on CPT code to incentivize primary care clinicians to refer individuals to these programs.

Secondary Benefits:

Blaming or shaming people living with AD/ADRD for their condition is harmful and scientifically inaccurate. AD/ADRD is multifactorial, with risk shaped by age, genetics, health conditions, and social and environmental factors—many of which are beyond individual control. While interventions targeting modifiable risk factors can reduce risk at the population level, they cannot prevent AD/ADRD in every individual. For these reasons, we strongly recommend that Medicare program(s) include distinct efforts to reduce stigma and support individuals living with AD/ADRD.

While the primary benefits of a broad and comprehensive national AD/ADRD ILI program would be to promote healthier brain aging and prevent, delay, and/or reduce the intensity of cognitive symptoms, we also encourage CMS to consider the likelihood that such a program would:

- Normalize public discussion of brain health and AD/ADRD;
- Help reduce stigma about AD/ADRD and cognitive changes;
- Heighten public awareness of signs and symptoms of possible cognitive impairment so that people across the country are better prepared to raise cognitive concerns with their health care providers;
- Encourage provider-patient discussions about clinical trial participation (we appreciate CMS's consideration of a new HCPCS G-code); and
- Facilitate adoption of clinically-appropriate treatments to modify disease progression and intensity at a stage when such treatments are most effective.

Early Detection:

In parallel to establishing an ILI program for AD/ADRD risk reduction, CMS should support a comprehensive approach to aggressive early detection of cognitive impairment including, but not limited to:

- Requiring use of validated cognitive assessment tools during the Welcome to Medicare and Medicare Annual Wellness visits;
- Ensuring coverage and reimbursement for the use of validated digital cognitive assessments by qualified providers;
- Expanding coverage and access to validated fluid and imaging biomarker tests;
- Partnering with HRSA, academic health programs, and professional societies to expand the geriatric workforce.
- Collaborating with CDC, state, and local public health departments to establish an enduring, broad, and robust public health campaign.

All of these steps would support greater readiness for, and utilization of, AD/ADRD ILIs and would be all the more important if CMS were to determine that ILI program eligibility should be restricted to individuals living with symptomatic AD/ADRD – **a restriction we would discourage strongly.**

Conclusion:

We commend CMS for its consideration of intensive lifestyle intervention programs as an opportunity to protect the cognitive health of Medicare beneficiaries. We hope the evidence and recommendations presented assist in the development of a new program to reduce risk of AD/ADRD and protect brain health. As the science continues to evolve, we highly encourage CMS to adapt to the emerging evidence, including what we may learn about differences across various forms of AD/ADRD and which interventions are most effective for different populations.

For questions or additional information, please contact Ian Kremer, executive director of the LEAD Coalition (ikremer@leadcoalition.org) or Courtney Wallin, federal policy director of the LEAD Coalition (cwallin@leadcoalition.org).

Sincerely,

Organizations

3 Cheers Respite

Absolute Value Group Consulting, LLC

ACMCRM Arachnoiditis & Chronic Meningitis Collaborative Research Network

ADvancing States (formerly National Association of States United for Aging and Disabilities)

AgeneBio

Aging and Memory Disorder Programs, Howard University

Alliance for Aging Research

Alliance for Patient Access

Alzheimer's Association

Alzheimer's Disease Care, Research and Education Program (AD-CARE) at the University of Rochester School of Medicine

Alzheimer’s Foundation of America

Alzheimer's Impact Movement (AIM)

Alzheimer's Los Angeles

Alzheimer's New Jersey

Alzheimer's Project, Inc.

Alzheimer's San Diego

Alzheimer's Tennessee

Alzheon

AlzInColor

American Brain Coalition

American Medical Women's Association

American Society of Consultant Pharmacists (ASCP)

American Society on Aging

Ann Romney Center for Neurologic Diseases

Argentum | Expanding Senior Living

Association for Frontotemporal Degeneration

Autistic Women & Nonbinary Network — AWN

Beckman Coulter Diagnostics

Benjamin Rose Institute on Aging

Biogen

Biomarker Collaborative

Bone Health and Osteoporosis Foundation

Boston Biotech Forum

Brain Injury Association of Nebraska

BrainCheck Inc.

Bridge Builder Strategies

Brigade Health

BrightFocus Foundation

C2N Diagnostics

Campaign to Prevent Alzheimer’s Disease (PAD 20/20)

Caregiver Action Network

CaringKind, The Heart of Alzheimer's Caregiving

Center for BrainHealth at The University of Texas at Dallas

Coalition of Wisconsin Aging and Health Groups

Cognitive Dynamics Foundation

Cognito Therapeutics

Cognivue

Combined Health Agencies Drive - Nebraska

Creutzfeldt-Jakob Disease (CJD) Foundation

Cure Alzheimer’s Fund

Cure MAPT FTD

Cure VCP Disease

CurePSP

Davos Alzheimer's Collaborative

Dementia Alliance of North Carolina

Disability Rights California

Diverse Elders Coalition

Dyad Health

Eden Alternative

Eisai, Inc.

Eli Lilly and Company

Emory Goizueta Alzheimer’s Disease Research Center

Exon 20 Group

Family Caregiver Alliance

FTD Disorders Registry, LLC

Fujirebio Diagnostics, Inc.

Genentech, Inc.

Genetic Alliance

Genetic ALS & FTD: End the Legacy

Gerontological Advanced Practice Nurses Association (GAPNA)

Gerontological Society of America

Global Alzheimer's Platform Foundation

Global Coalition on Aging

Global Healthy Living Foundation

Hadassah, The Women’s Zionist Organization of America

HealthMatters Program

Healthy Aging Coalition

HealthyWomen

HFC (Hilarity for Charity)

Huffington Center on Aging, Baylor College of Medicine

Huntington's Disease Society of America

Hypertrophic Cardiomyopathy Association

ICAN, International Cancer Advocacy Network

International Association for Indigenous Aging (IA2)

Iona Senior Services

Lantheus

Latino Alzheimer’s and Memory Disorders Alliance

LeadingAge

Lewy Body Dementia Association

Lewy Body Dementia Resource Center

Linus Health, Inc.

Long Term Care Community Coalition

Lorenzo's House

Lundbeck Pharmaceuticals LLC

Lupus and Allied Diseases Association, Inc.

Medicare Rights Center

Memory and Alzheimer's Treatment Center, Johns Hopkins Medicine

Memory Care Home Solutions

MET Crusaders

Michigan State University Alzheimer's Alliance

Milken Institute Alliance to Improve Dementia Care

Minnesota Association of Area Agencies on Aging

Mount Sinai Center for Cognitive Health

National Adult Protective Services Association (NAPSA)

National Alliance for Caregiving

National Asian Pacific Center on Aging

National Association of Activity Professionals

National Association of Social Workers (NASW)

National Association of State Long-Term Care Ombudsman Programs (NASOP)

National Committee to Preserve Social Security and Medicare

National Consumer Voice for Quality Long-Term Care

National Consumers League

National Council for Mental Wellbeing

National Council of Dementia Minds

National Down Syndrome Society

National Hispanic Council On Aging (NHCOA)

National Indian Council on Aging (NICOA)

National Menopause Foundation

National Minority Quality Forum

National Respite Coalition

National Task Group on Intellectual Disabilities and Dementia Practices

NCBA, Inc.

Neurogen Biomarking

Neurotech Network

Nevada Chronic Care Collaborative

New Orleans BioInnovation Center

Noah Homes

NRG1 Energizers

Ohio Council for Cognitive Health

Organic Acidemia Association

Organization for Latino Health Advocacy

Otsuka America Pharmaceutical, Inc.

Partnership to Fight Chronic Disease

Patients Rising

PD-L1 Amplifieds

Pennsylvania State Grange

Pentara Corporation

Positrigo

Prevent Blindness Wisconsin

PrognosUs

PXE International

Roche Diagnostics Corporation

SAGE

Scottish Brain Sciences

Second Wind Dreams, Inc./ Virtual Dementia Tour

Society for Women's Health Research

Synthesis Brain Health

TauRx Pharmaceuticals Ltd.

The Balm In Gilead, Inc.

The Brain Donor Project

The Memory Impairment and Neurodegenerative Dementia (MIND) Center, University of Mississippi Medical Center

The Michael J. Fox Foundation for Parkinson's Research

The Richman Family Precision Medicine Center of Excellence in Alzheimer's Disease, Johns Hopkins Medicine

Toronto Dementia Research Alliance

Toronto Memory Program

UsAgainstAlzheimer's

USAging

Veravas

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