PARTNERSHIP TO FIGHT CHRONIC DISEASE

A VISION FOR A HEALTHIER FUTURE

August 15, 2026

Cynthia Goss
Deputy Assistant Secretary
Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

Re: The National Plan to Adress Alzheimer's, HHS-ASPE-2026-0298

Submitted via regulations.gov

Dear Ms. Goss:

The Partnership to Fight Chronic Disease (PFCD) and the five undersigned organizations representing patients, caregivers, clinicians, public health professionals, and other concerned stakeholders are committed to advancing lifesaving innovations for people living with and at risk of developing Alzheimer's disease. We appreciate the opportunity to comment on the National Plan to Address Alzheimer's that will accelerate innovation and advance health for the more than 7.2 million Americans living with Alzheimer's disease.

In 2026, 7.2 million Americans aged 65 and older are living with Alzheimer's disease, and more than 13.8 million people in America projected to be affected by 2060. The toll is devastating. Between 2000 and 2024, Alzheimer's-related deaths increased by 138%, and one in three older adults will die with the disease. The economic burden is equally staggering, with global dementia-related costs projected to reach $1 trillion annually by 2050. These trends underscore the urgent need to prioritize prevention and early detection, which are critical to improving patient outcomes while reducing long-term costs for the U.S. healthcare system.

The National Alzheimer's Project Act and the National Plan it mandated continue to drive historic research investments to accelerate breakthrough diagnostics and therapies, enable prevention and delayed progression, and build infrastructure that improves the lives of patients and caregivers alike. When the first National Plan was published in 2012, it set one goal above all others: prevent and effectively treat Alzheimer's disease by 2025. Though the disease is not yet entirely preventable or treatable, the progress toward that goal has been meaningful, and the promise has never been greater. We now have two FDA-approved amyloid-targeting therapies shown to modify disease progression in the early stage of the disease with many more promising therapies in the pipeline. We also have two, FDA-cleared minimally invasive blood tests to help diagnose Alzheimer's disease in its early stages. Federal research funding has grown from $448 million in 2011 to more than $3.9 billion. A Medicare

payment model now covers dementia care navigation and caregiver respite. None of this existed in 2012. The 2025 goal worked as a beacon. Its specificity and timeline organized a decade of federal effort. The updated Plan needs a successor of the same character, set to 2035 to match the authorization Congress provided.

We recommend the Plan's leading goal be restated so that **by 2035, every American at elevated risk has access to evidence-based risk reduction; every person with cognitive symptoms receives a timely, accurate diagnosis; and every person diagnosed, along with their caregivers, has access to comprehensive dementia care and the treatments for which they are eligible.** Every element of this can be measured annually, and every shortfall can be linked to a specific policy, program, or payment decision.

We urge HHS to sustain and accelerate progress and set bold new goals that match the urgency felt by the millions of Americans living with Alzheimer's disease and their loved ones. We are at an historic turning point for Alzheimer's disease. Real hope exists thanks to new breakthroughs in the diagnosis and treatment of Alzheimer's, as well as new research demonstrating the power of lifestyle and other interventions that reduce the risk of developing this disease and other forms of dementia.

In the comments below, we share areas in which we feel the National Plan can make the biggest impact to attain this goal, starting with prevention, early diagnosis and treatment, and expanding and supporting the care infrastructure needed to reach more people affected.

Make an early diagnosis routine rather than exceptional. (Question 3)

HHS should recognize the potential of FDA-cleared blood-based biomarkers by establishing Medicare coverage to facilitate diagnosis in both primary and specialty care settings. These innovative blood tests identify biomarkers associated with Alzheimer's pathology, offering a less invasive and more accessible approach to diagnosis. Amyloid plaques can begin to accumulate in the brain in early stages of the disease decades before symptoms appear, making early detection and treatment critical. According to recent a Milken Institute Report, using blood-based biomarkers as a rule-out triage test in the diagnostic pathway could reduce the average cost per confirmed early Alzheimer's diagnosis by 47%, while incorporating a confirmatory test could reduce costs by 86%. These findings underscore the potential of blood-based biomarkers to improve both patient access and healthcare system efficiency. To fully realize this potential, policymakers should support efforts to ensure Medicare covers these tests as preventive screening tools for routine assessments, rather than limiting their use to diagnostic purposes. Congressional action is needed to close this coverage gap, expand access to early detection, and strengthen preventive care for millions of Americans. Also, we encourage the National Plan to recommend that CMS require the use of clinically validated cognitive assessments covered by Medicare in Annual Wellness and Welcome to Medicare visits. In a recent survey of Annual Wellness Visit

participants, only 31% reported that they underwent formal cognitive testing, while 35% were merely asked about memory problems, with just 15% reporting that they received both. Requiring cognitive assessments in wellness visits would increase uptake and enable people at risk to receive the care they need to preserve cognitive function and enhance outcomes. We also welcome further education for Medicare beneficiaries on the availability of these tests and allow patients to request these assessments at their visits.

Treat promoting brain health as chronic disease prevention. (Question 2)

HHS could promote brain health as an explicit goal of existing federal chronic disease programs. U.S. POINTER is the first large-scale, randomized controlled clinical trial in the United States to demonstrate that an accessible and sustainable healthy lifestyle intervention can protect cognitive function. Taking proactive steps in everyday life may meaningfully reduce risks associated with several chronic diseases and help preserve cognitive function and independent living for longer. According to a recent study from *The Lancet*, up to 40% of dementias are caused by 12 modifiable risk factors, including smoking and excessive alcohol consumption. Many of the modifiable risk factors associated with dementia are already addressed in many chronic disease prevention and management programs. Building brain health into those programs could help to expand their reach and uptake. According to the Alzheimer's Association, ninety-nine percent of Americans value brain health, yet only 14% have discussed it with a doctor. The CDC's BOLD (Building Our Largest Dementia Infrastructure) and Health Brain Initiative grants should be sustained and expanded to reach more states and tribes to facilitate efforts to promote brain health and reduce dementia risks.

Remove Medicare coverage with evidence development limitations on FDA-approved therapies for Alzheimer's disease. (Questions 1 and 7)

For four years, Medicare has imposed significant coverage restrictions on FDA-approved Alzheimer's therapies, limiting timely access for many patients with early-stage disease. Innovative therapies such as anti-amyloid medications have the potential to support earlier detection and intervention, but their impact will depend on timely and appropriate patient access. Evidence shows that these therapies meaningfully improved health outcomes in trial participants with early Alzheimer's disease, including amyloid plaque removal, measurably slower disease progression, reduced caregiver burden, and reduced risk of progressing to later stages of disease within a year. The evidence base for anti-amyloid therapies has expanded substantially since CMS first imposed its CED requirement more than four years ago. Since CMS issued the 2022 CED determination, nearly a dozen peer-reviewed studies with over 5,300 participants across 3 continents have documented the safety and efficacy of lecanemab and donanemab, sufficiently answering the questions CMS asked when it initially imposed CED limitations.

Medicare coverage should reflect the current state of the science and avoid unnecessary delays in patient access. Once lifted, Medicare should also confirm that Medicare Advantage plans may not impose coverage conditions more restrictive than traditional Medicare for these therapies.

Make comprehensive dementia care and caregiver support more broadly accessible. (Questions 4 and 5)

We applaud development and dissemination of the groundbreaking GUIDE Model and urge expanding access to the caregiver supports included to reach more people. The GUIDE model provides patients and caregivers with a named navigator, 24/7 access, caregiver training, and respite services.

These critical supports help to address the emotional and financial burden of Alzheimer's disease and related dementias on primary caregivers. In 2024, nearly 12 million unpaid caregivers in the U.S. dedicated around 20 billion hours to providing care for individuals with Alzheimer's. Beyond the financial strain of lost income, the emotional weight of caregiving can be profound. Social isolation is common. Expanding access to services for caregivers would provide significant relief and support to the millions of unpaid caregivers caring for loved ones affected by Alzheimer's disease.

Build the workforce and capacity the National Plan's success depends on. (Question 8)

We simply do not have enough specialists to meet the demand of an aging population and the growth in Alzheimer's disease and other dementias. Among geriatricians and dementia specialists, the U.S. will need to more than double the current number of specialists by 2050. To meet demand, we must do more to support dementia care within primary care practice. Approximately 85% of Alzheimer's diagnoses are initially made by primary care providers, yet two-thirds of primary care doctors receive little to no dementia training in medical school. We need to build capacity across primary care through programs like Project ECHO for dementia. Developing federal programs through legislation such as the ADAAPT Act that train and reimburse nurses, pharmacists, medical social workers, and other qualified providers to deliver cognitive assessments, care navigation, and caregiver training within their scope of practice would significantly expand access.

Sustain the research investment that has made progress possible. (Question 1)

The case for continued investment rests on what the last decade produced. Federal Alzheimer's research funding grew from $448 million in 2011 to more than $3.8 billion today. That public investment accompanied by significant private R&D investments into new therapeutics and diagnostics is why we know more about the disease and why there are disease-modifying therapies, blood-based diagnostics capable of moving detection into primary care, and a pipeline extending beyond amyloid to tau, inflammation, metabolism, and vascular contributors. Momentum of this kind is cumulative. We urge

HHS to build the updated National Plan on a predictable funding trajectory, to continue the professional judgment budget through FY2035 as the Alzheimer's Accountability and Investment Act provides, and to protect the infrastructure that makes the next generation of discovery possible.

By fostering both scientific innovation and timely access to new advances, HHS can help accelerate progress against Alzheimer's disease. Adopting these recommendations will accelerate the progress science is making by ensuring that these innovations reach the people who need them. They will build and support the workforce, coverage policies, and infrastructure we need to prevent dementia, delay its onset and progression, and support people living with Alzheimer's disease and their caregivers at every stage.

We stand ready to work with HHS and CMS to ensure that the millions of Americans living with Alzheimer's disease receive the timely, preventive, and evidence-based care they deserve.

Sincerely,
AlzInColor
Caregiver Action Network
HealthyWomen
National Grange
Voices of Alzheimer's
Partnership to Fight Chronic Disease