TuftsMedicine
Tufts Medical Center

Center for Biomedical System Design & NEWDIGS
Institute for Clinical Research and Health Policy Studies
800 Washington St. Box 63
Boston, MA 02111

NEWDIGS Consortium

Center for Biomedical System Design · Tufts Medical Center

Re: HHS Request for Comment on the Update to the National Plan to Address Alzheimer's Disease

Docket ID HHS-ASPE-2026-0298 · Federal Register Doc. 2026–15045 (published July 24, 2026)

Submitted August 12, 2026

Scope of this response

The NEWDIGS Consortium at Tufts Medical Center's Center for Biomedical System Design appreciates the opportunity to comment on the update to the National Plan to Address Alzheimer's Disease.

We respond to five of the eight questions posed — **Questions 1, 3, 5, 6, and 8** — and confine our comments to the detection, diagnosis, prevention, and treatment of early Alzheimer's disease, most often defined as the stages of mild cognitive impairment (MCI) and mild dementia due to AD. We do not address caregiver supports or late-stage care. Those needs are pressing, but other respondents will speak to them from direct experience, and we would only be repeating them. We comment where we have evidence.

This response was developed through NEWDIGS's early Alzheimer's disease work. NEWDIGS is a pre-competitive collaboration convening over 100 organizations spanning patient advocacy, health care payers, health systems and provider organizations, the biopharmaceutical industry, and diagnostics developers, with program leadership provided by the Center for Biomedical System Design at Tufts Medical Center. A draft was circulated to participating organizations for comment, and this submission reflects our synthesis of that input. It does not constitute endorsement by any individual member organization.

A note on interests

Our membership includes organizations that develop therapeutics and diagnostics for Alzheimer's disease, and we think the Department should read this comment with that in view.

While opinions among our stakeholder group (and in the field at large) still differ regarding the currently available disease modifying therapies and the degree of benefit they offer individual patients, anti-amyloid therapies seem likely to remain an essential option for treatment of early Alzheimer's disease. Moreover, more options for active treatment of early AD seem likely to emerge in coming years, including new forms of anti-amyloid therapy, novel anti-tau therapies, and other agents now in the drug development pipeline.

For many years, active disease modifying treatment of early AD seemed a distant hope but now presents an important, clinically appropriate choice to delay progression of AD for patients who prove eligible. The looming issue is whether the U.S. health care system will adapt itself to make this option available at scale. A delivery system capable of surfacing cognitive concerns early, staging them accurately, and matching individuals to appropriate intervention is valuable whether or not any particular therapeutic class delivers on its promise. The same capability supports risk-factor modification, identification of reversible and non-AD contributors to cognitive impairment — poorly managed polypharmacy prominent among them — accurate prognosis, and advance planning while the individual remains able to fully can still participate in decision-making. System readiness, rather than any single therapy, is the durable object of national strategy.

Overview: the next decade of the National Plan will be governed by a delivery problem

The RFI's questions suggest an expanded remit for the National Plan — one that complements its longstanding focus on care for serious, disabling dementia with a stronger focus on detection, diagnosis, prevention, and treatment. We think this reset is correct and overdue.

The stages of AD most likely to prove amenable to intervention are also the stages least likely to be identified. MCI and mild dementia due to AD are substantially undetected and undiagnosed among U.S. adults, and the detection process as currently constituted is a complex, multi-step pathway that is often triggered only once progression can no longer be meaningfully modified — at which point patients are also more likely to be referred to specialist services that are in short supply across much of the country. This challenge will grow if disease-modifying therapies are approved for individuals with Alzheimer's pathology who are not yet presenting symptoms, a population that advances in biomarker testing and AI-enabled cognitive assessment are making increasingly identifiable.

Our central observation is that these barriers are systemic rather than located in any single actor, and that the U.S. health care system has no reliable mechanism for adopting potentially transformative innovations on an orderly, efficient, and expedited basis. The pattern is not specific to Alzheimer's disease. Evidence-based innovations are typically adopted incrementally over extended periods even when they are transformative. For instance, only about one-third of eligible patients receive direct-acting antiviral treatment for hepatitis C, despite their availability since 2013 with cure rates above 95 percent and studies clearly showing average medical cost savings of $65,841 per treated person. We also found barriers to effective uptake of GLP-1 medications are systemic rather than confined to price, a challenge we addressed in a Roadmap for Transforming Obesity Disease Management.

We define this class of problem as a challenge of **Biomedical System Readiness (BSR)**: the capacity of the delivery system to convert an approved intervention into population-level benefit. Our long-term work is directed at developing system-level metrics and identifying the core capabilities — evidence generation prominent among them — that build readiness in ways that generalize across disease states. **The BSR framework is non-proprietary. We offer it to the Department and to any respondent for use without restriction or attribution requirement.**

We have identified six domains of coordinated action that together determine readiness for early AD care. Several are already reflected in the current National Plan's goal structure, which the Department has indicated they are considering whether to streamline or expand. The crosswalk below is offered as raw material for that decision.

Readiness domain	What it governs	Relevant Question in the Request for Information
Learning	Generating and disseminating the evidence base for early AD detection, diagnosis, prevention, and care — a substantially novel area of practice.	Questions 1, 5
Standards	Authoritative, evidence-based standards for appropriate use and interpretation of blood biomarker tests and digital cognitive assessments; practice guidelines; clinical decision support.	Questions 1, 2
Payment	Clear, adequate, and predictable payment for early AD services — and resolution of the misalignment between who bears cost and who captures return.	Question 2
Health Care Delivery	Care models that make early AD detection and, where appropriate, diagnosis feasible within primary care.	Questions 2, 3
Workforce	Rebalancing tasks across the primary care team and the specialist workforce as diagnostic capability changes.	Questions 2, 3
Access	Removing barriers that are general (coverage, geography, language) and barriers that are specific to early AD care.	Questions 2, 3, 6

Coordinated action across all six is needed. Progress in any one domain alone is generally absorbed by constraints in the others — which is, in our reading, the mechanism behind the incremental adoption pattern described above.

Responses to selected questions

Question 1 — Opportunities and challenges in advancing R&D, including translating scientific progress into effective and scalable treatments and care

The binding constraint in Alzheimer's disease is shifting from scientific discovery to delivery-system readiness, and the National Plan should treat readiness as an explicit object of federal strategy rather than an assumed byproduct of scientific progress.

The Plan's first goal has historically been framed around preventing and effectively treating AD, with translation appearing as a downstream strategy. We would invert the emphasis. The evidence from other therapeutic areas is that discovery outpaces the delivery system's capacity to absorb it by many years, and that the gap is not self-closing. Absent deliberate intervention, scientific advances in Alzheimer's disease will convert to population-level benefit slowly and unevenly, and the resulting shortfall wrongly attributed to the science rather than to the system.

There are two specific implications for the National Plan. First, evidence generation should be treated as delivery infrastructure, not only as research. The questions that would resolve current uncertainty — what early detection yields in routine primary care, how biomarker results perform outside specialty referral populations, which care models are transportable — cannot be answered by trials alone and are not currently anyone's institutional responsibility. Second, readiness should be measured. A national strategy that sets goals for scientific milestones but not for the system's capacity to deliver them has no way of knowing whether it is succeeding. We address measurement under Question 6.

Question 3 — Barriers and challenges affecting early detection and timely diagnosis

Barriers to early detection are systemic and mutually reinforcing, but they converge on a single point in the delivery system: the primary care encounter.

Primary care clinicians are the natural first point of contact for patients with cognitive concerns, and the most promising near-term innovations — blood biomarker testing and brief, increasingly accurate cognitive assessment tools — are well suited to primary care adoption. Yet the barriers begin there: disincentives for patients, care partners, and clinicians to initiate a conversation about brain health at all, compounded by limited capability to follow up with meaningful testing. A detailed elucidation is available in Phares et al., System changes to empower primary care in Alzheimer's disease detection and care (Alzheimer's & Dementia, April 2026), coauthored by our multi-stakeholder team, and in Roadmap 2030: Transforming early Alzheimer's disease care.

Applying the six readiness domains to detection and diagnosis specifically:

Learning. Comprehensive practice for early AD is essentially a new area of clinical medicine. The evidence base for what constitutes appropriate detection, diagnosis, and subsequent management is thin relative to the pace at which the underlying tools are changing, and dissemination lags even that.

Standards. There is no settled, authoritative guidance on appropriate use and interpretation of blood biomarker results or digital cognitive assessment outputs in non-specialty settings, nor on how quality in early AD care should be evaluated. Standards will require continuous refinement given the pace of change, which argues for a mechanism that can update them rather than a one-time issuance. A concrete step within reach now: the Initial Preventive Physical Examination ("Welcome to Medicare" visit) should explicitly require a cognitive assessment using a validated tool, and the Annual Wellness Visit regulations should likewise be updated to require use of a validated cognitive assessment too.

Payment. Payment rates for early AD services are neither clear nor predictable. Two concrete examples: payment policy is unsettled for diagnostic evaluation conducted in primary care following a cognitive concern flagged during the Medicare Annual Wellness Visit; and current time-based codes for comprehensive cognitive assessment, built around a 16-minute-plus evaluation, do not match AI-enabled digital tools designed to run in ten minutes or less. Medicare coverage of blood biomarker testing remains limited, and there is at present no clear pathway for coverage determinations to keep pace with FDA clearances and approvals in this category.

The wrong pocket problem. Beneath the coding and rate issues sits a structural misalignment that adequate payment rates would not resolve. The costs of case-finding, assessment, and diagnostic workup fall on Medicare Part B and on the operating economics of primary care practices. A substantial share of the benefit accrues elsewhere: to Medicaid long-term services and supports, to nursing home admissions that do not occur, and to unpaid family caregiving, which appears on no payer's ledger at all. There is a temporal mismatch as well. The savings accrue over the five to ten years it takes for AD to progress to later stages to progress, while Medicare Advantage plans, which now cover 55% of eligible Medicare beneficiaries, typically retain a member for a shorter period of time.

We characterize this as a wrong pocket problem: the actor best positioned to make the investment is not the actor that captures the return. We raise it here because it is a barrier the federal government is nearly uniquely positioned to address. Individual payers cannot solve a misallocation that runs between payers, and no amount of exhortation to invest in prevention will overcome economics that reward not investing. A national plan that identifies and works to internalize cross-pocket returns — whether through demonstration authority, coverage design, or accounting that makes the Medicaid and caregiving offsets visible — would address a cause rather than a symptom. We would welcome the opportunity to work with the Department on characterizing this for Alzheimer's disease specifically.

Health Care Delivery. Integrating early AD detection, and where appropriate diagnosis, into primary care at scale is a substantial ask of a sector already under well-documented strain. Refining and disseminating efficient care models for this purpose should be a high priority, and lessons from active clinical sites should reach not only health systems but the Medicare program and Medicare Advantage carriers.

Workforce. Neurologists and other specialists currently shoulder most of the diagnostic burden, and national shortages have produced prolonged waits. Expanding the specialist workforce is necessary but insufficient on its own timescale. Many referrals are also avoidable: as biomarker and cognitive assessment tools improve, steps in the detection and diagnosis process can shift to trained members of the primary care team — physicians, nurses, advanced practice clinicians, and medical assistants. Realizing that shift depends on the Standards and Payment domains above; without them, task-shifting transfers liability without transferring capability.

Access. Some barriers are general rather than AD-specific: dementia prevalence is highest among populations that already face limited or uneven access to care, including low-income and uninsured Americans, rural residents, and people with limited English proficiency. Others are specific to early AD and affect everyone. The U.S. Preventive Services Task Force has issued an insufficient-evidence determination on screening for cognitive impairment in older adults — an active finding rather than a mere absence, and one that identifies a concrete evidence gap the Plan could target. Its practical consequence is that structured cognitive assessment is not covered as a preventive service under the ACA preventive mandates. This coexists with, and should be distinguished from, the Annual Wellness Visit's existing requirement to detect cognitive impairment, which creates an obligation to identify concerns without a covered pathway for structured assessment or follow-up.

Question 5 — Models, programs, or practices currently working well, and the factors behind their success

The transferable ingredient in models that are working are not the clinical protocols but the shared infrastructure — common measurement, pre-competitive convening, and analytic tools that let stakeholders navigate challenges to the system together.

Primary care–embedded early AD care models now operating at Davos Alzheimer's Collaborative sites and elsewhere in the U.S. are generating practical knowledge about what makes detection and diagnosis feasible under real conditions. We would encourage the Department to treat systematic capture and dissemination of that knowledge as a Plan activity in its own right, and to route it deliberately toward Medicare and Medicare Advantage as well as toward health systems.

On the analytic side, we have developed an open-access system dynamics model (a working prototype) that allows any user to simulate how discrete interventions and policies propagate through the delivery system as a whole. It is available as the Alzheimer's Disease Scenario Planning Tool. We mention it less as a product than as an instance of a general principle: multi-stakeholder groups converge faster when they are arguing about a shared model than when they are exchanging position statements. Federal support for shared analytic infrastructure of this kind is comparatively inexpensive and disproportionately useful.

Question 6 — Meaningful health outcomes and care goals, and how they should be measured over time

Outcomes that matter to individuals and families need a system-level counterpart, or the delivery system cannot be held accountable for producing them at scale.

We defer to people living with AD/ADRD and their families on what outcomes are meaningful; we do not think that is ours to specify. What we would add is a measurement observation. Person-centered outcome measures capture whether a given individual's care achieved what mattered to them. They do not capture whether the system is delivering those outcomes to everyone who could benefit, or at what resource cost, or whether the answer is improving. Those are different questions, and the National Plan needs them answered in order to track progress under its fifth goal.

NEWDIGS has designed a system-level measurement framework for this purpose, Biomedical Health Efficiency (BHE), with three dimensions: health outcomes achieved, resources consumed in achieving them, and the extent to which those outcomes reach all populations who could benefit. We are currently developing BHE metrics specifically for use with Alzheimer's disease; it is not yet a validated instrument and we would not want the Department to treat it as one. We raise it because the National Plan's 2026–2035 horizon is long enough that a measurement approach maturing now could be shaped to fit the Plan's needs rather than adapted to them afterward. We would welcome the Department's input on that design while it is still open, and BHE, like the broader BSR framework, is non-proprietary.

Question 8 — Workforce and infrastructure challenges

The most consequential workforce constraint is not the absolute number of specialists but the absence of the standards, payment, and training infrastructure that would let diagnostic work move to where patients actually present.

We comment on subparts (a), (c), and (d), and defer on (b) and (e) to respondents with more direct experience.

(a) Research and intervention development. The infrastructure gap we would highlight is in real-world evidence generation. Resolving the USPSTF's insufficient-evidence determination, establishing how biomarker tests perform in unselected primary care populations, and determining which care models transport across settings all require sustained observational infrastructure embedded in routine care. No entity currently owns this, and the trial enterprise is not designed to produce it. A pre-competitive, multi-stakeholder structure with common measurement is well suited to the task and is the model we have pursued in our own work.

(c) Public health initiatives. Public health infrastructure for AD/ADRD is currently oriented toward awareness and toward support for people already diagnosed. The shift toward early detection implies a different infrastructure requirement — population-level capability to identify cognitive concern and route it into a functioning clinical pathway — which will not be effective in advance of that pathway existing. Sequencing matters here: public health efforts to promote early detection will generate demand. It is imperative that the delivery system is able to absorb it reliably and smoothly.

(d) Delivery of health care and long-term care. The core issue is task allocation, not headcount alone. Shifting appropriate steps in detection and diagnosis from specialists to trained primary care teams is the only path we can identify to a workforce capable of operating at the scale early AD prevalence implies. That shift has three prerequisites, all outside the workforce domain proper: standards defining what primary care teams should do with biomarker and assessment results; payment that makes doing it viable; and a training and support infrastructure, including accessible specialist consultation, so that clinicians are not asked to absorb new diagnostic responsibility without backup. Workforce policy pursued in isolation from these will not produce capacity.

Closing

We would offer the Department one thing beyond this comment. The barriers described here span organizations that do not ordinarily convene: payers, health systems, product developers, diagnostics companies, and patient organizations, several of which are competitors. NEWDIGS exists to provide neutral, pre-competitive ground where those conversations can happen, and we have run them for seventeen years across adaptive licensing, cell and gene therapy financing, integrated evidence generation, and now Alzheimer's disease. That capability is available to the Department in support of the National Plan's development or implementation, with no funding request attached and no expectation of a role.

The work referenced here is openly available. The Alzheimer's disease roadmap, the published descriptions of Biomedical System Readiness, and the scenario planning model prototype are open access; the BHE metric specification will be released on the same basis as they are completed. The Department and other organizations working on these problems are welcome to use them, and we ask nothing in return.

About NEWDIGS and the Center for Biomedical System Design

The NEWDIGS (NEW Drug Development ParadIGmS) Consortium, founded at the Massachusetts Institute of Technology in 2009 and now based at Tufts Medical Center, is a global "think-and-do tank" dedicated to improving patient outcomes by accelerating timely, appropriate access to biomedical innovations. NEWDIGS is the flagship program of the Center for Biomedical System Design within Tufts Medical Center's Institute for Clinical Research and

Health Policy Studies. The Center designs, evaluates, and catalyzes solutions that help the health care system keep pace with biomedical science, drawing on leaders from patient advocacy, payers, industry, regulators, clinicians, researchers, and investors. Its prior programs include work on adaptive licensing, which informed the European Medicines Agency's adaptive pathways pilot; FoCUS, on payment models for durable cell and gene therapies; and LEAPS, on integrated evidence generation.