



September 25, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

***by electronic delivery to Seema.verma@cms.hhs.gov and
Brady.Brookes@cms.hhs.gov***

Dear Administrator Verma:

We write to express support for changes the Centers for Medicare & Medicaid Services (CMS) has made to the MedLearn cognitive impairment detection instructionsⁱ for the Initial Preventive Physical Exam (IPPE) and subsequent Annual Wellness Visit(s) (AWVs). Additionally, **we write to encourage CMS to strengthen the IPPE and AWW instructions further by revising them to read “Assess the beneficiary’s cognitive function with a brief validated structured cognitive assessment tool found at the NIA’s Alzheimer’s and Dementia Resources for Professionals website.”**

Timely detection of cognitive impairment is a critical element in patient care that can lead to improved outcomes and better decision making among providers, patients, and their caregivers. The IPPE and AWW instructions should remove as much ambiguity as possible about when and how physician practices should provide cognitive impairment detection services to eligible Medicare beneficiaries.

We appreciate that CMS responded to concerns that the instructions encourage clinicians to rely on direct observation to deliver the cognitive impairment detection benefit. We applaud CMS for directing providers to “use a brief validated structured cognitive assessment tool” and providing a link to the National Institute on Aging’s Alzheimer’s and Dementia Resources for Professionals website. CMS recognition that use of a brief, structured cognitive assessment tool is an important element of the detection benefit is supported by studies demonstrating that these tools correctly classify patients with dementia or mild cognitive impairment (MCI) more often than direct observation by the patients’ own primary care physicians (83% vs 59%, respectively).ⁱⁱ

The AWW provides clinicians and their patients with an important opportunity to overcome barriers to discussing cognitive impairment within the context of overall wellness and preventive care. Clinician awareness of validated tools for cognitive impairment detection may help reduce unrecognized cognitive impairment from its

current high rate of up to 81%. However, CMS use of the prefatory language “if appropriate,” in reference to use of a validated detection tool, may confuse clinicians.

We know of no authoritative source or evidence-based rationale supporting use of direct observation as a means of adequately detecting early cognitive impairment. In fact, direct observation is the least useful and least appropriate tool, resulting in identification of impairment in later stages when decline has progressed beyond mild cognitive impairment. Furthermore, the phrase “if appropriate” injects uncertainty that could all but negate CMS’ well-considered, proactive step to facilitate a meaningful detection benefit. The qualifier “if appropriate” injects counterproductive uncertainty that could undermine the cognitive impairment detection benefit by implying that health professionals should primarily, or even sometimes, use a “tool” known to be ineffective in detecting mild cognitive impairment, a time when detection may be most meaningful to Medicare beneficiaries.

Removing this uncertainty from the CMS MedLearn instructions for the IPPE and AWV would be consistent with Healthy People 2030 (HP2030), including the three dementia-specific national objectives.

Objective DIA-2030-01, Increase the proportion of adults aged 65 years and older with diagnosed Alzheimer’s disease and other dementias, or their caregiver, who are aware of the diagnosis

According to the CDC, “The earlier dementia is diagnosed, the sooner care can be provided. A formal diagnosis allows people living with dementia to have access to available symptomatic treatments and interventions, build a care team, participate in support services, and potentially enroll in clinical trials. They and their caregivers can set systems in place to better manage medications, receive counseling, and address the challenges of other chronic conditions. Additional advantages include planning for future financial and legal needs and end of life choices.”ⁱⁱⁱ Early and accurate diagnosis could save \$7.9 trillion in medical and care costs^{iv} due to improved management of comorbid conditions and other costs of healthcare and caregiving. Clinicians charting a diagnosis is inadequate. The diagnosis must be conveyed in a timely, accurate, compassionate and actionable manner. The earlier in disease progression that the diagnosis is conveyed, the more cognitively able individuals will be to direct or participate in decision-making. Rightly, the DIA-2030-01 phrase “or their caregiver” does not encourage health professionals to withhold information from the patient, but does encourage caregivers to be included so they can better support the patient, particularly in cases where cognitive impairment has reached such an advanced stage as to make the patient unable to receive the diagnosis. **With clarified MedLearn instruction language, the IPPE and AWV begin the process of achieving Objective DIA-2030-01.** The process then can continue with necessary support because CMS provides reimbursement for physicians to engage in meaningful care planning,^v the Health Resources Services Administration (HRSA) has fielded curriculum to educate clinicians on properly making and conveying diagnosis,^{vi} and The Gerontological Society of America makes available a free online toolkit for primary care providers and their care teams to help them initiate conversations about brain health, detect and assess for cognitive impairment, evaluate for dementia, and provide post-diagnostic referrals to community services, educational resources, and information about clinical trials for persons with dementia and their family caregivers.^{vii}

Objective DIA-2030-02, Reduce the proportion of preventable hospitalizations in adults aged 65 years and older with diagnosed Alzheimer’s disease and other

dementias

People with Alzheimer's disease and other forms of dementia have twice as many hospital admissions as those without dementia and at least a quarter of these admissions are preventable.^{viii} This is unsurprising given that diabetes, heart disease and other frequently occurring comorbid and complicating medical conditions require strict medication adherence, and lifestyle improvements made more challenging by dementia (such as exercise, diet and sleep). Guidelines for managing chronic conditions often fail to consider that patients may have dementia, and untrained family members and other informal caregivers are ill-prepared to recognize or address signs of deteriorating health from multiple conditions. Guidelines also rarely consider that "Dementia is one of the major causes of disability and dependency among older people worldwide."^{ix} nor that providing disability supports promote more enduring independence and reduce personal and public costs associated with dementia. **CMS is well positioned to advance Objective DIA-2030-02 by clarifying the MedLearn instructions so more people with cognitive impairment will be detected earlier in the symptomatic progression, thereby heightening opportunities for health professionals and informal caregivers to better manage comorbid conditions** with awareness of the complicating factor of cognitive impairment. This is also consistent with the CDC's Healthy Brain Initiative Roadmap strategic objectives to improve professional care for people living with dementia.^x

Objective DIA-2030-03, Increase the proportion of adults aged 65 years and older with Subjective Cognitive Decline (SCD) who have discussed their confusion or memory loss with a health care professional

As CMS is painfully aware, far too few medical professionals initiate timely discussions with their patients about cognitive health and cognitive impairment for a variety of reasons including time pressure, inadequate training about recognizing signs of impairment, varying degrees of discomfort around the sensitive topic of dementia – particularly in light of the lack of an FDA approved disease modifying therapy – and an over-reliance (read: wishful thinking) that the patient or family member will raise the subject. Patients and their families often lack basic understanding of dementia, labor under stigma and myths such as that these diseases are a "normal part of aging," or expect (for cultural or other reasons) that the health professional should and affirmatively would inquire about possible cognitive impairment. People with undetected mild cognitive impairment also are less likely to be accompanied by a caregiver informant at a medical appointment. In the aggregate, these and other factors result in cognitive impairment detection and diagnosis rates that are unacceptably low among the population at large and particularly among communities with disproportionate prevalence of Alzheimer's disease and other forms of dementia including women,^{xi} people with Down Syndrome and other intellectual disabilities,^{xii} veterans,^{xiii} rural^{xiv} and ethnic minorities.^{xv} Compounding this disease prevalence health disparity is the added burden that detection and diagnosis often come later in disease progression among these populations with profound negative consequences. As noted by a recent Alzheimer's Association report, "African-Americans tend to be diagnosed at a later stage of Alzheimer's disease — limiting the effectiveness of treatments that depend upon early intervention."^{xvi} Diagnoses are delayed because predicate detection is delayed: "African American and Latino patients are often diagnosed at later stages of the disease, with many of them experiencing a delay of up to seven years before their symptoms are evaluated...Delayed diagnosis may result in the patient having reached a greater severity of dementia by the time a diagnosis is made."^{xvii} Because the Veterans Administration does not offer a cognitive impairment detection benefit -- regardless of

age and regardless of risk factors -- for veterans who also are Medicare-eligible, AWWs may provide the best opportunity to detect cognitive impairment in its earliest stages when lifestyle interventions and increased attention to managing comorbidities can have the largest impact in driving more positive health outcomes. The later cognitive impairment is detected, the later affected individuals and their families are able to begin grappling with – and deriving benefits from making -- the full gamut of consequential decisions including participation in clinical trials, use of FDA-approved symptomatic relief therapeutics, caregiver education, and planning involving legal, financial, spiritual and quality-of-life issues. **CMS is well positioned to advance Objective DIA-2030-03 by clarifying the MedLearn instructions so medical professionals will be more likely to initiate discussion with patients and their families about possible SCD and utilize brief validated structured cognitive assessment tools as part of the IPPE and AWW.** Because change over time is among the most important indicators of possible cognitive impairment, using validated tools rather than unreliable direct observation along with removing the uncertainty created by the phrase “if appropriate” would facilitate clinicians’ ability to compare AWW cognitive assessment results against earlier results from the IPPE and previous AWWs to help detect signs of cognitive decline.

Additionally, clarifying the MedLearn instructions would capitalize on recent updates to the Medicare Physician Fee Schedule that encourage dementia diagnosis and care planning (HCPCS 99483), new Medicare Advantage (MA) rules that increase benefits for Alzheimer’s and dementia care along with risk score adjustments for MA Plans caring for people with dementia,^{xviii} the 2017 NIH “National Research Summit on Care, Services, Supports for Persons with Dementia and Their Caregivers”^{xix} and the 2017 CMS “Behavioral Health Payment and Care Delivery Innovation Summit.”^{xx}

Clarifying the MedLearn instructions also would support the National Institutes of Health and its non-governmental partners working to implement the new *National Strategy for Recruitment and Participation in Alzheimer’s and Related Dementias Clinical Research*,^{xxi} which will engage broad segments of the public in the Alzheimer’s and related dementias research enterprise, with a particular focus on underrepresented communities, so that studies with an aim to better understand and eventually cure these disorders can successfully and more quickly enroll and retain individuals. As discussed previously, the later cognitive impairment is detected and diagnosed, the less opportunity individuals have to participate in clinical research trials.

Lastly, clarifying the MedLearn instructions would be consistent with the HHS strategic plan,^{xxii} the Center for Medicare & Medicaid Services (CMS) vision, the Centers for Disease Control and Prevention (CDC) Healthy Brain Initiative Road Map, the Administration of Community Living (ACL) Alzheimer’s Disease Supportive Services Program’s grant funding priorities^{xxiii}, the National Institute on Aging (NIA) goals,^{xxiv} and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) National Plan to Address Alzheimer’s Disease.^{xxv}

Therefore, we encourage CMS to revise its MedLearn instructions to ensure delivery of the meaningful cognitive impairment detection benefit Medicare beneficiaries need to proactively manage their health by issuing revised IPPE and AWW instructions that read “Assess the beneficiary’s cognitive function with a brief validated structured cognitive assessment tool found at the NIA’s Alzheimer’s and Dementia Resources for Professionals website.” This would

make administration of this benefit consistent with the evidence-based approach CMS takes with all other services.

Thank you for considering our views and for your commitment to overcoming Alzheimer's disease and other forms of dementia. For any questions or additional information about this or other policy issues, please contact Ian Kremer, executive director of Leaders Engaged on Alzheimer's Disease (the LEAD Coalition),^{xxvi} ikremer@leadcoalition.org or (571) 383-9916.

Sincerely,

Abe's Garden Alzheimer's Center of Excellence

Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD) Coalition

ActivistsAgainstAlzheimer's Network

African American Network Against Alzheimer's

AgeneBio

Aging Life Care Association®

Paul S. Aisen, MD (Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute*)

Neelum T. Aggarwal, MD (Rush University Medical Center*)

Alliance for Aging Research

Alliance for Patient Access

Alzheimer's & Dementia Alliance of Wisconsin

Alzheimer's Drug Discovery Foundation

Alzheimer's Foundation of America

Alzheimer's Los Angeles

Alzheimer's Mississippi

Alzheimer's New Jersey

Alzheimer's Orange County

Alzheimer's San Diego

Alzheimer's Tennessee

Alzheimer's Texas

American Academy of Neurology

American Association for Geriatric Psychiatry

American Federation for Aging Research (AFAR)

American Medical Women's Association

American Neurological Association

American Society of Consultant Pharmacists (ASCP)

Argentum | Expanding Senior Living

Laura D. Baker, PhD (Wake Forest University Health Sciences*)

Banner Alzheimer's Institute

David M. Bass, PhD (Benjamin Rose Institute on Aging*)

Baylor Scott & White Health

Beating Alzheimer's by Embracing Science

Andrew R. Bender, Ph.D. (Michigan State University)

Benjamin Rose Institute on Aging

Biogen

Boehringer Ingelheim Pharmaceuticals, Inc.

Soo Borson MD (Minnesota Brain Aging Research Collaborative*)

James Brewer, M.D., Ph.D. (UC San Diego and Alzheimer's Disease Cooperative Study*)

Bridge Builder Strategies

BrightFocus Foundation

Christopher M. Callahan, MD (Indiana University Center for Aging Research*)

Caregiver Action Network

Caregiver Voices United

CaringKind, The Heart of Alzheimer's Caregiving

Centene

Center for Alzheimer Research and Treatment, Harvard Medical School

Center for BrainHealth at The University of Texas at Dallas

Center for Memory Health at Hebrew SeniorLife

Center to Advance Palliative Care

Sandra Bond Chapman, PhD (Center for BrainHealth at The University of Texas at Dallas*)

Andrea Bozoki, MD, FAAN (Henry Ford Hospital*)

Joshua Chodosh, MD, MSHS, FACP (New York University*)

ClergyAgainstAlzheimer's Network

Cleveland Clinic Foundation

Coalition of Wisconsin Aging and Health Groups

Cognition Therapeutics

Cognitive Dynamics Foundation

Suzanne Craft, PhD (Wake Forest School of Medicine*)

Creutzfeldt-Jakob Disease Foundation

Jeffrey Cummings, MD, ScD (Cleveland Clinic Lou Ruvo Center for Brain Health*)

Cure Alzheimer's Fund

Walter Dawson, Dphil (Portland State University*)

Dementia Alliance International

Department of Neurology, Washington University School of Medicine

Drexel University College of Nursing and Health Professions

Drexel University Memory and Cognitive Disorder Center

Duke (Alzheimer's) Family Support Program

Eisai Co., Ltd.

Gary Epstein-Lubow, MD (Alpert Medical School of Brown University*)

Faith United Against Alzheimer's Coalition

Fujirebio

Michela Gallagher, PhD (Johns Hopkins University School of Medicine*)

Sam Gandy, MD, PhD (Icahn School of Medicine at Mount Sinai*)

Joseph E. Gaugler, PhD (School of Public Health, University of Minnesota*)

Genentech

Daniel R. George, Ph.D, M.Sc (Penn State College of Medicine*)

Georgetown University Medical Center Memory Disorders Program

Gerontological Society of America

Laura N. Gitlin, PhD (Drexel University, College of Nursing and Health Professions*)

G. Peter Gliebus, MD (Drexel University, College of Medicine*)

Global Alzheimer's Platform Foundation

Global Coalition on Aging

Lisa P. Gwyther, MSW, LCSW (Duke University Medical Center*)

Henry Ford Health System, Center for Cognitive Health

Hilarity for Charity

Nancy A. Hodgson, RN, PhD, FAAN (University of Pennsylvania School of Nursing*)

David P Hoffman DPS CCE (Maria College*)

David M. Holtzman, MD (Washington University School of Medicine, Department of Neurology*)

Home Instead Senior Care

Huffington Center on Aging, Baylor College of Medicine

International Association for Indigenous Aging

Janssen R&D

Kathy Jedrzewski, PhD (University of Pennsylvania*)

Johns Hopkins Memory and Alzheimer's Treatment Center

Katherine S. Judge, PhD (Cleveland State University*)

Nicholas Kanaan, PhD (Michigan State University*)

Keck School of Medicine of USC, Alzheimer's Therapeutic Research Institute

Keep Memory Alive

Theresa Rohr-Kirchgraber, MD, FACP, FAMWA (Indiana University National Center of Excellence of Women's Health*)

Latino Alzheimer's and Memory Disorders Alliance

LatinosAgainstAlzheimer's

Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University

Lewy Body Dementia Association

Life Molecular Imaging

Allison Lindauer, PhD, NP (Layton Aging and Alzheimer's Disease Center, Oregon Health & Science University*)

Linked Senior, Inc

Livpact Inc.

Lou Ruvo Center for Brain Health

LuMind IDSC Foundation

Lundbeck

Kostas Lyketsos, M.D., M.H.S. (Johns Hopkins Memory and Alzheimer's Treatment Center*)

Tabassum Majid, PhD (The Erickson School of Aging, University of Maryland Baltimore County*)

Yannick Marchalant, Ph.D. (Central Michigan University*)

David X. Marquez, PhD (Department of Kinesiology and Nutrition, University of Illinois at Chicago*)

Medicare Rights Center

Michigan State University Alzheimer's Alliance

Milken Institute Center for the Future of Aging

Minnesota Brain Aging Research Collaborative

Mary Mittelman, DrPH (New York University Medical Center*)

David G. Morgan, PhD (Michigan State University*)

Darby Morhardt, PhD, LCSW (Northwestern University Feinberg School of Medicine*)

Mount Sinai Center for Cognitive Health

National Alliance for Caregiving

National Asian Pacific Center on Aging

National Association of Activity Professionals

National Association of Area Agencies on Aging (n4a)

National Association of Nutrition and Aging Services Programs

National Caucus and Center on Black Aged, Inc. (NCBA)

National Certification Council for Activity Professionals

National Down Syndrome Society

National Hispanic Council On Aging (NHCOA)

National Task Group on Intellectual Disabilities and Dementia Practices

NFL Neurological Center

Noah Homes

NYU Alzheimer's Disease Center

NYU Langone Center on Cognitive Neurology

The Ohio Council for Cognitive Health
Otsuka Pharmaceutical Development and Commercialization

Planetree International, Inc.

Daniel C. Potts, MD, FAAN (University of Alabama College of Community Health Sciences*)

Prevent Alzheimer's Disease 2020

Program to Improve Eldercare, Altarum

Peter Reed, PhD (Sanford Center for Aging, University of Nevada Reno*)

Eric Reiman, MD (Banner Alzheimer's Institute*)

ResearchersAgainstAlzheimer's

David B. Reuben, MD (David Geffen School of Medicine at UCLA*)

Second Wind Dreams, Inc./ Virtual Dementia Tour

Amanda G. Smith, M.D. (USF Health Byrd Alzheimer's Institute*)

Reisa A. Sperling, MD, MMSc (Center for Alzheimer Research and Treatment, Harvard Medical School*)

Rudolph Tanzi, PhD (Department of Neurology, MGH/Harvard Medical School*)

The Association for Frontotemporal Degeneration

The Evangelical Lutheran Good Samaritan Society

The Youth Movement Against Alzheimer's

Geoffrey Tremont, Ph.D., ABPP-CN (Alpert Medical School of Brown University*)

John Q. Trojanowski M.D., Ph.D. (Perelman School of Medicine at the University of Pennsylvania*)

R. Scott Turner, MD, PhD (Georgetown University Memory Disorders Program*)

University of Pennsylvania Alzheimer's Disease Core Center

University of Pennsylvania Center for Neurodegenerative Disease Research

University of Pennsylvania Center on Alpha-synuclein Strains in Alzheimer Disease & Related Dementias

UsAgainstAlzheimer's, LEAD Coalition co-convener

USF Health Byrd Alzheimer's Institute, University of South Florida

VeteransAgainstAlzheimer's

Anand Viswanathan, MD, PhD (Massachusetts General Hospital and Alzheimer's Disease Research Center*)

Stella L. Volpe, PhD (Drexel University, Department of Nutrition Sciences*)

Volunteers of America, LEAD Coalition co-convener

Carol J. Whitlatch, PhD (Benjamin Rose Institute on Aging*)

Nancy Wilson, MA LCSW (Baylor College of Medicine*)

WomenAgainstAlzheimer's

Women's Brain Health Initiative

Women's Brain Project

** Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of affiliated institutions.*

-
- ⁱ https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AWV_Chart_ICN905706.pdf
- ⁱⁱ <https://www.ncbi.nlm.nih.gov/pubmed/16534774>
- ⁱⁱⁱ <https://www.cdc.gov/aging/pdf/2018-2023-Road-Map-508.pdf>
- ^{iv} <https://www.alz.org/alzheimers-dementia/facts-figures>
- ^v <https://alzimpact.org/media/serve/id/5ab10bc1a3f3c>
- ^{vi} <https://bhw.hrsa.gov/sites/default/files/bhw/grants/geriatrics/module-2-diagnosing-dementia.pptx>
- ^{vii} <http://www.geron.org/kaer>
- ^{viii} [https://www.alzheimersanddementia.com/article/S1552-5260\(16\)30756-7/fulltext](https://www.alzheimersanddementia.com/article/S1552-5260(16)30756-7/fulltext)
- ^{ix} <https://www.who.int/news-room/fact-sheets/detail/dementia>
- ^x <https://www.cdc.gov/aging/healthybrain/roadmap.htm>
- ^{xi} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6226313/>
- ^{xii} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4184282/>
- ^{xiii} <https://www.aginglifecarejournal.org/dementia-risk-factors-in-veterans/>
- ^{xiv} https://www.rand.org/pubs/external_publications/EP67436.html
- ^{xv} <https://www.sciencedirect.com/science/article/pii/S1552526018332527?via%3Dihub>
- ^{xvi} <https://www.alz.org/media/Documents/african-americans-silent-epidemic-r.pdf>
- ^{xvii} <https://www.questia.com/read/1P3-1862957491/disparities-in-the-diagnosis-and-treatment-of-alzheimer-s>
- ^{xviii} <http://www.milliman.com/insight/2019/Including-dementia-in-the-Part-C-Medicare-risk-adjuster-Health-services-issues/>
- ^{xix} <https://aspe.hhs.gov/national-research-summit-care-services-and-supports-persons-dementia-and-their-caregivers>
- ^{xx} <https://innovation.cms.gov/resources/behavioral-health-paymentcare-summit.html>
- ^{xxi} <https://www.nia.nih.gov/sites/default/files/2018-10/alzheimers-disease-recruitment-strategy-final.pdf>
- ^{xxii} <https://www.hhs.gov/about/strategic-plan/strategic-goal-3/index.html>
- ^{xxiii} <https://acl.gov/programs/support-people-alzheimers-disease/support-people-dementia-including-alzheimers-disease>
- ^{xxiv} <https://www.nia.nih.gov/about/aging-well-21st-century-strategic-directions-research-aging>
- ^{xxv} <https://aspe.hhs.gov/report/national-plan-address-alzheimers-disease-2018-update>
- ^{xxvi} <http://www.leadcoalition.org> Leaders Engaged on Alzheimer's Disease (the LEAD Coalition) is a diverse national coalition of member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and home and residential care providers, large health systems, and biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation's strategic attention on dementia in all its causes -- including Alzheimer's disease, vascular disease, Lewy body dementia, and frontotemporal degeneration -- and to accelerate transformational progress in detection and diagnosis, care and support, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.