AGS Geriatrics Healthcare Professionals
Leading Change. Improving Care for Older Adults.

THE AMERICAN GERIATRICS SOCIETY
40 FULTON STREET, SUITE 809
NEW YORK, NEW YORK 10038
212.308.1414 TEL
www.americangeriatrics.org

July 30, 2024

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

RE: S. 2379, "Concentrating on High-value Alzheimer's Needs to Get to an End Act" ("CHANGE Act")

Dear Chairman Wyden and Ranking Member Crapo:

We are writing to provide feedback on S. 2379, the CHANGE Act, which would revise the Welcome to Medicare Visit (WMV), also known as the initial preventive physical exam (IPPE), and the Annual Wellness Visit (AWV), for which Medicare beneficiaries are eligible after 12 months of enrollment. The House Ways & Means Committee recently included provisions of S. 2379 in H.R. 8816, the "American Medical Innovation and Investment Act," passed by the Committee on June 27, 2024.

The American Geriatrics Society (AGS) is a national non-profit organization of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of all older Americans. Our more than 6,000 members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician associates, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. AGS believes in a just society, one where we all are supported by and able to contribute to our communities and ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. AGS advocates for policies and programs that support the health, independence, and quality of life of all of us as we age.

AGS understands the heavy toll Alzheimer's disease and related dementias (ADRD) take on patients, caregivers, their families, and the country. Geriatricians provide early detection and assessment of cognitive impairment, and work with patients, caregivers, and families to start interventions and care planning when they are most helpful. AGS members also have led much of the relevant research on detecting cognitive impairment in health care settings and serve on national policy boards dedicated to improving the quality of care of individuals with ADRD.

AGS has long advocated for increased attention to cognition in the clinical setting as a key component of older adults' health status. We are encouraged by the Centers for Medicare and Medicaid Innovation (CMMI) pilot of the Guiding an Improved Dementia Experience (GUIDE) model, which aims to support people living with dementia and their caregivers and integrates essential medical and social care services that have historically been siloed. Through this model, patients and their caregivers will have access to a care navigator who will help them access services and supports, including both clinical and non-clinical services such as meals and transportation through community-based organizations. We believe it is critically important that we support older people living with ADRD by ensuring that they receive the right care, in the right setting, in the right amount, and at the right time based on shared decision-making that elicits and is guided by their values and preferences.

The current WMV and subsequent AWV require clinicians to detect cognitive impairment in the following ways.

- ***First Visit**: Check for* cognitive impairment *as part of the first AWV.*
  Assess cognitive function by direct observation or reported observations from the patient, family, friends, caregivers, and others. Consider using brief cognitive tests, health disparities, chronic conditions, and other factors that contribute to increased cognitive impairment risk. Alzheimer's and Related Dementia Resources for Professionals has more information.

- ***Subsequent Visits**: Check for* cognitive impairment *as part of the subsequent AWV.*
  Assess cognitive function by direct observation or reported observations from the patient, family, friends, caregivers, and others. Consider using brief cognitive tests, health disparities, chronic conditions, and other factors that contribute to increased cognitive impairment risk. Alzheimer's and Related Dementia Resources for Professionals has more information.

The CHANGE Act

The bill would require clinicians to complete two specific tasks: (1) use a scientifically validated cognitive test, usually referred to as a "screening test," to detect cognitive impairment, and (2) document any impairment detected in the patient's medical record. Acceptable cognitive tests would be those identified by the National Institute on Aging (NIA), after review of the scientific evidence, as suitable for detecting cognitive impairment in the primary care (i.e., non-specialist) setting.

We understand that many clinicians do not use a validated method to satisfy the requirement for "detection of any cognitive impairment" and that such a requirement is intended to improve validity by standardizing the process. However, detecting cognitive impairment is not like detecting diabetes, which can be done by a routine blood test. It requires distinguishing signs of pathological changes in the brain from symptoms of normal aging, and ruling out potentially reversible cognitive decline due to, for example, psychological conditions such as depression or anxiety, hypo- and hyperthyroidism, polypharmacy, obstructive sleep apnea, delirium, vitamin B12 deficiency, electrolyte imbalances, and sensory deficits.[1] Where evidence exists of neuropathologic changes that may not be reversible, it is crucial that clinicians' discussions with the patient, caregivers, and family members are sensitive to the impact of an ADRD diagnosis and include education and discussion of treatment options and support resources.

We applaud the attention to evidence-based detection tools in the legislative language but are concerned that the bill, as currently written, does not consider patient choice—to accept or decline cognitive testing—or reflect the need for clinician sensitivity as to how to introduce the testing process and engage in a shared decision-making process around testing and evaluation. Further, the bill is silent on the question of how best to proceed to establish the cause once cognitive impairment is detected. It

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[1] Randhawa SS, Varghese D. *Geriatric Evaluation and Treatment of Age-Related Cognitive Decline*. StatPearls; 2024. Accessed July 10, 2024. https://www.ncbi.nlm.nih.gov/books/NBK580536/

does not require an evidence-based process for so doing (either by referral to a specialist or through a valid method for making a diagnosis in primary care).

These concerns and omissions are consequential. Patients with newly discovered cognitive impairment need to be able to understand what is happening, to the best of their ability, and clinicians need to be able to answer their questions and use shared decision-making to establish a plan of care that is meaningful and effective for patients, their families, and caregivers. While we believe that the use of validated screening tests and cognitive assessments are a vital part of good care, we challenge the assumption that requiring specific tests will accomplish the goal of better care for people living with cognitive impairments.

We are also concerned that, in the wake of the recent Supreme Court rulings in *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* overturning the *Chevron* deference, Congress may pass legislation that imposes a legal requirement on clinicians that could undermine the need for discussion with the patient as to what tests patients will undergo and what care and interventions they wish to receive.

Our specific concerns are as follows:

- **Person-Centered Care and Shared Decision-Making**: Person-centered care puts the patient at the center of decision-making about the tests and treatments that they will receive.[2] As currently written, this legislation would impose a requirement on patients that they undergo cognitive testing as a part of the WMV/AWV with no discussion of whether a test is necessary or wanted by the patient. Such a requirement could counteract the welcome uptake in utilization of the AWV that has already helped ensure, for example, that more older adults receive the preventive services they need.

- **Diverse Populations:** While studies have shown that a disproportionate burden of cognitive impairment and dementia falls among older Black and Hispanic adults,[3,4] extensive scientific data indicate that many cognitive screening tests perform differently in diverse populations than in the usually-homogenous populations on which the tests were originally developed.[5] Most affected are historically underserved, particularly non-White populations, and those with limited

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[2] American Geriatrics Society Expert Panel on Person-Centered Care. Person-centered care: a definition and essential elements. *J Am Geriatr Soc.* 2016;64(1):15-18. doi:10.1111/jgs.13866

[3] Matthews KA, Xu W, Gaglioti AH, et al. Racial and ethnic estimates of Alzheimer's disease and related dementias in the United States (2015-2060) in adults aged ≥65 years. *Alzheimer's Dement.* 2018;15(1):17-24. doi:10.1016/j.jalz.2018.06.3063

[4] Manly JJ, Jones RN, Langa KM, et al. Estimating the prevalence of dementia and mild cognitive impairment in the US: the 2016 health and retirement study harmonized cognitive assessment protocol project. *JAMA Neurol.* 2022;79(12):1242-1249. doi:10.1001/jamaneurol.2022.3543

[5] Sabbagh MN, Boada M, Borson S, et al. Early detection of mild cognitive impairment (MCI) in primary care. *J Prev Alzheimer's Dis.* 2020;7(3):165-170. doi:10.14283/jpad.2020.21

English proficiency for whom inequities in detection and diagnosis are already prevalent.[6,7] The most worrisome effect of such socially-determined disparate performance on some otherwise validated screening tests is *overdiagnosis*, finding a cognitive disorder where none exists, merely as a result of using tests that are poorly adapted to the patient's characteristics or known to be biased in specific groups. Ill-adapted screening tests could therefore exacerbate, rather than mitigate, health inequities.

- **Employment Discrimination:** A cognitive impairment diagnosis in a patient's medical record could lead to employment discrimination for older adults. While employers, in general, do not have access to employees' medical records, there are exceptions, such as when the employee is seeking sick leave, workers' compensation, or accommodation for a physical disability. In such cases, the employee may be required to provide medical records to the employer, which could prompt further inquiry into an older employee's cognitive performance. This has the potential to stigmatize some asymptomatic individuals.

- **Difficulty in Obtaining Affordable Long-Term Care Insurance:** Many older adults lack the financial resources to pay out-of-pocket for long-term care services for any extended period and Medicare covers very few such services. A beneficiary with a diagnosis of Alzheimer's disease or another dementia may encounter difficulty in obtaining long-term care insurance.

- **Supplemental Insurance Limitations:** For Medigap policies, Medicare beneficiaries with pre-existing conditions can, under various circumstances, be subject to adverse medical underwriting decisions by Medigap plans.[8] In addition, beneficiaries diagnosed before seeking Medigap coverage will face a six-month waiting period on coverage of expenses related to any care they might need related to a biological diagnosis of Alzheimer's disease.[9]

- **Negative Impact on Clinician Payment and Potential Reduction of Access**: An unintended consequence of this legislation is the potential to reduce access to clinicians providing WMV and AWVs. Because the legislation requires administration of a test and recording of results and does not allow for a Medicare beneficiary to decline cognitive testing, some clinicians may avoid offering WMV/AWVs due to the risk of claim denials. Though the initial AWV is reimbursed at a higher rate ($175.08) than many established patient visits due to inclusion of multiple assessments as part of the AWV, a recent study found that AWVs are not economically beneficial

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[6] Amjad H, Roth DL, Sheehan OC, Lyketsos CG, Wolff JL, Samus QM. Underdiagnosis of dementia: an observational study of patterns in diagnosis and awareness in US older adults. *J Gen Intern Med.* 2018;33(7):1131-1138. doi:10.1007/s11606-018-4377-y

[7] Gianattasio KZ, Prather C, Glymour MM, Ciarleglio A, Power MC. Racial disparities and temporal trends in dementia misdiagnosis risk in the United States. *Alzheimer's Dement: Transl Res Clin Interv*. 2019;5(1):891-898. doi:10.1016/j.trci.2019.11.008

[8] Boccuti C, Jacobson G, Orgera K, Neuman T. Medigap enrollment and consumer protections vary across states. *Kaiser Family Foundation*. July 11, 2018. Accessed July 1, 2024. https://www.kff.org/medicare/issue-brief/medigap-enrollment-and-consumer-protections-vary-across-states/

[9] Hopkins K. Medicare supplement plans and pre-existing conditions. *Medicare FAQ.* Updated March 20, 2023. Accessed July 1, 2024. https://www.medicarefaq.com/faqs/medicare-supplement-plans-and-pre-existing-conditions/

> for all primary care settings, often hampered by administrative challenges, and most often conducted with patients who are healthier and less complex than those at highest risk for dementia.[10] We worry that clinicians will no longer want to offer the AWV due to risk of non-payment for these services if a patient refuses cognitive assessment in the manner described in this legislation.

In summary, we are deeply concerned that this legislation would impose the use of a clinical test, regardless of whether the patient reports symptoms of cognitive impairment or is observed to be impaired, and without shared decision-making. The legislation ignores the potential stigmatizing effects of cognitive screening without preparation of the patient for what may follow. It could also undermine the positive trend toward increased availability of these services, particularly the WMV, should the Centers for Medicare and Medicaid Services (CMS) strictly interpret the legislation post-*Chevron* and deny payment if a patient declines cognitive testing.

We encourage Congress to consider other approaches for increasing detection of cognitive impairment in older adults. For example, Congress could support calling for clinician and team training in the conduct and interpretation of the WMV and AWV, and increasing both the time allotted and payment for WMVs and AWVs given the broad range of services that clinicians are expected to provide.

We strongly encourage you to modify the language to indicate that testing will only be done if clinicians and older adults or their surrogates have had a conversation about the purpose of testing, discussed the risks and benefits of such testing, and explained how knowing about a patient's cognitive status can improve their overall wellbeing and medical care. Much like advance care planning, which is an optional element of the AWV involving a face-to-face discussion with the patient,[11] the decision to conduct specific testing for any condition should be made by the patient in consultation with their clinician and not legislated by Congress. Further, clinicians should be able to refer patients for any necessary additional tests and appropriate treatments.

We appreciate the opportunity to provide these comments. If you have questions or wish to discuss this letter, please do not hesitate to contact Anna Kim (akim@americangeriatrics.org).

Sincerely,

Mark A Supiano

Nancy E. Lundebjerg

Mark A. Supiano, MD, AGSF
President

Nancy E. Lundebjerg, MPA
Chief Executive Officer

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[10] Hamer MK, DeCamp M, Bradley CJ, Nease DE Jr., Perraillon MC. Adoption and value of the Medicare annual wellness visit: a mixed-methods study. *Med Care Res Rev.* 2023;80(4):433-443. doi:10.1177/10775587231166037

[11] Centers for Medicare and Medicaid Services Medicare Learning Network. Advance Care Planning. March 2024. Accessed July 10, 2024. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf