

July 3, 2024

The Honorable Jason Smith
Chair
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

RE: The American Medical Innovation and Investment Act

Dear Chair Smith, Ranking Member Neal, Chair McMorris Rodgers, and Ranking Member Pallone:

We are writing to provide feedback on provisions in the **H.R. 8816, the “American Medical Innovation and Investment Act,”** that would change 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 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. Its 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 communities where 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 of Alzheimer’s disease and related dementias on patients, caregivers, and their families. Our members have conducted much of the relevant research on detection of cognitive impairment in health care settings; they have served on many national policy boards dedicated to improving care of individuals with memory and other cognitive disorders. We are very supportive of increasing attention to cognition as a key component of health status and the need to improve the quality of care provided to patients. We also recognize the critical role primary care clinicians play in detecting cognitive impairment, making a diagnosis, and starting interventions and care planning at a time when they are likely to be most helpful to patients and families. Further, 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. AGS believes it is critically important that we support older people living with dementia by ensuring that they receive the right care, in the right place, in the right amount, at the right time.

The [current WMV and subsequent AWV](#) already 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 proposed legislation would require clinicians to complete two specific tasks: (1) use a scientifically validated cognitive test (screening test) to accomplish detection of 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 valid 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 by a routine blood sugar test; it requires greater sensitivity and a process surrounding detection that makes a difference to the patient's care.

We applaud the attention to evidence in the legislative language, but we find that it does not allow for patient choice—to accept or decline cognitive testing—nor does it require clinician awareness of how to introduce the process or a shared decision-making process around testing and evaluation. Furthermore, it is silent on the question of how best to proceed to establish the cause once cognitive impairment is detected. It does not require an evidence-based process for so doing (either by referral to a specialist or 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 meaningful plan of care. 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.

In the wake of the recent Supreme Court rulings in *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* that overturned the *Chevron* deference, it is critically important that Congress not pass legislation that imposes a legal requirement on clinicians and patients that is the antithesis of an individual's right to choose, in consultation with their clinician, what tests they will undergo and what care 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.¹ 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 also counteract the welcome national growth in utilization of the AWV that has already helped ensure, for example, that more older adults actually receive the preventive services to which they are entitled.
- **Diverse Populations:** While studies have shown that a disproportionate burden of cognitive impairment and dementia falls among older Black and Hispanic adults,^{2,3} 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.⁴ Most affected are historically underserved, particularly non-White populations and those with limited English proficiency for whom inequities in detection and diagnosis are already prevalent.^{5,6} 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 *could* lead to employment discrimination for older adults. While employers generally do not have access to employees' medical records, there are exceptions, such as when the employee is seeking sick leave, workers' compensation, or an accommodation for a physical disability. In such cases the employee may be

¹ 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](https://doi.org/10.1111/jgs.13866)

² 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](https://doi.org/10.1016/j.jalz.2018.06.3063)

³ 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](https://doi.org/10.1001/jamaneurol.2022.3543)

⁴ 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](https://doi.org/10.14283/jpad.2020.21)

⁵ 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](https://doi.org/10.1007/s11606-018-4377-y)

⁶ 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](https://doi.org/10.1016/j.trci.2019.11.008)

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. For Medigap policies, Medicare beneficiaries with pre-existing conditions can, under various circumstances, be subject to adverse medical underwriting decisions by Medigap plans.⁷ 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.⁸
- **Negative Impact on Clinician Payment and Potential Reduction of Access:** Considering the legislation does not allow for a Medicare beneficiary to decline cognitive testing, it could negatively impact payment for the WMV and AWW given that the legislation imposes an absolute requirement in the legislation that a test be administered and results recorded during these visits. An unintended consequence of this legislation is the potential to reduce access to clinicians delivering these services because of the potential that payment will be denied to an already-strained healthcare workforce which could lead to clinicians not offering these visits. Though the initial AWW is reimbursed at a higher rate (\$175.08) than many established patient visits due to inclusion of multiple assessments as part of the AWW, a recent study found that AWWs are not economically beneficial 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.⁹ We worry that clinicians will no longer want to offer the AWW due to risk of non-payment for these services if a patient refuses cognitive assessment in the manner described in the legislation.

In summary, AGS is 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 cognitively impaired, and without shared decision-making. The legislation ignores the potential stigmatizing effects of cognitive screening without preparation of the patient or clinician for what may follow. It would also put clinicians at risk for denial of payment should a patient decline cognitive testing; the likelihood of such declinations only increased with the overturning of *Chevron*. Moreover, the legislation could lead to reversal of the positive trend toward increased availability of these services, particularly the WMV, given heightened risk of payment denials due to strict interpretation of the

⁷ 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/>

⁸ 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/>

⁹ Hamer MK, DeCamp M, Bradley CJ, Nease DE Jr., Perrailon 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](https://doi.org/10.1177/10775587231166037)

legislation by the Centers for Medicare and Medicaid Services (CMS). There are administrative challenges and the services are already not economically viable in some primary care settings; this legislation would add to those challenges for clinicians and the older Americans they care for. 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 increase both the time allotted for and the payment for WMVs and AWVs given the broad range of services that clinicians are expected to provide.

If this bill is to move forward, AGS strongly encourages Congress 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 its intent, 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 requires patient consent, 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, MD, AGSF
President



Nancy E. Lundebjerg, MPA
Chief Executive Officer