



July 18, 2024

The Honorable Jason Smith
Chairman
House Committee on Ways and Means
Washington, DC 20515

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

Dear Chairman Smith and Ranking Member Neal:

On behalf of the Medicare Rights Center, thank you for your bipartisan work to improve Medicare coverage and care. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable and equitable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, we provide services and resources to over three million Medicare beneficiaries, family caregivers, and professionals, including through our national consumer Helpline.¹

Based on this experience, we know that coverage restrictions and affordability challenges can prevent many people with Medicare from obtaining the services and medications they need to build and maintain their health. On June 27, the Committee advanced legislation intended to reduce these barriers.² We applaud this important goal but are concerned that as favorably reported, several of the bills run counter to it. As outlined below, we urge you to correct these misalignments without delay.

Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (H.R. 1691)

This legislation would allow FDA-designated medical breakthrough devices to be temporarily covered under Medicare during a four-year transitional period. In so doing, H.R. 1691 would override Medicare's ability to determine what services are "reasonable and necessary" for beneficiaries. This is an important patient safety and consumer protection in general, and in particular with respect to breakthrough technologies. These devices, by their nature, lack complete evidence of efficacy, safety, or clinical benefit for use among the Medicare population.³

¹ See, e.g., Medicare Rights Center "2022 Medicare Trends and Recommendations: An Analysis of 2022 Call Data from the Medicare Rights Center's National Helpline" (October 2023), <https://www.medicarerights.org/pdf/2022-helpline-trends-report.pdf>.

² U.S. House Committee on Ways & Means, "Markup of H.R. 1691, H.R. 2407, H.R. 8816, and H.R. 4818" (June 27, 2024) <https://waysandmeans.house.gov/event/markup-of-h-r-1619-h-r-2407-h-r-8816-and-h-r-4818/>

³ 86 FR 62944 (November 15, 2021), <https://www.federalregister.gov/documents/2021/11/15/2021-24916/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and>.

We support adhering to the existing reasonable and necessary safeguard. The bill's sharp departure from this standard would undermine CMS's ability to advance evidence-based coverage policies and put beneficiaries at significant risk. We also echo stakeholder requests for better data regarding breakthrough devices as well as more extensive and inclusive clinical trials, clear evidence-based approval and monitoring standards, and robust oversight.⁴

Treat and Reduce Obesity Act of 2023 (H.R. 4818)

As favorably reported, H.R. 4818 would allow Medicare Part D to cover certain weight-loss medications, but only for enrollees whose health insurance continuously covered the drug for the one-year period immediately prior to their Part D enrollment. It is our understanding this limitation is an effort to lower the cost of the bill. We appreciate the Committee's recognition that high prescription drug prices can make medications prohibitively expensive for consumers and insurers, and that increased Part D costs program-wide could increase taxpayer burden. We urge solutions that address the root of that problem—the prices themselves—rather than creating a tiered system that restricts access to earned Medicare benefits and erodes the program's promise of equitable coverage.

This limitation would also cede important decisions about coverage criteria to entities providing a beneficiary's pre-Medicare health insurance, such as private plans, self-insured employers, and state or foreign governments. These payers would not necessarily have consistent criteria or easily transferrable records, further increasing unequal treatment, administrative burden, and potential confusion.

Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act (H.R. 2407)

H.R. 2407 would allow Medicare to cover emerging blood-based cancer screenings that are FDA-approved, shown to have clinical benefit, and determined to be reasonable and necessary for the prevention or early detection of an illness or disability.

We appreciate that unlike H.R. 1691, this bill would maintain Medicare's reasonable and necessary authority, thereby ensuring an evidence-based, beneficiary-centered process for determining coverage parameters. However, like H.R. 4818, this coverage would only reach some Medicare beneficiaries: those who attain a certain age by January 1 of the relevant year or received a test in the prior 11 months. Such a carve out would exclude millions of older adults and people with disabilities of all ages arbitrarily, setting a dangerous precedent and leaving many behind. We support removing this harmful provision from the bill.

⁴ *Id.*

Thank you for your leadership and consideration. Medicare Rights appreciates the Committee's focus on modernizing Medicare benefits and access. We look forward to working together to advance these shared priorities in ways that strengthen the program for all beneficiaries.

Sincerely,

A handwritten signature in cursive script that reads "Fred Riccardi".

Fred Riccardi
President
Medicare Rights Center