June 10, 2025

Centers for Medicare and Medicaid Services
Submitted in abbreviated format via https://www.cms.gov/medicare-regulatory-relief-rfi

Re: Comments in Response to "Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192) -- Request for Information"

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, we write with brief comments on your request for information pertaining to steps that the Medicare program could take to better align with the priorities outlined in Executive Order 14192— an Executive Order whose application and implementation NTU strongly supports across all areas of the federal government.

Introduction

NTU is the nation's oldest taxpayer advocacy organization, founded in 1969. For nearly as long, our experts and advocates have engaged policymakers on important questions surrounding the fiscal impact of federal legislation and regulations on the health care space. We have noted with great concern the decades-long cost spiral in federal health care programs, which has seemed to defy attempts at reducing or at least controlling the burden on current and future taxpayers. According to the Congressional Budget Office (CBO), between 2024 and 2054 the share of federal noninterest outlays consumed by major health care programs is projected to rise from 28% to 39%. By contrast, Social Security, another cost driver in the budget, will see its share of non-interest outlays increase from 26% to 28%.[1]

To NTU, it is abundantly clear that innovative approaches to reducing health care costs must be explored and implemented, to begin shifting this unsustainable trajectory toward a more realistic and affordable direction. We believe that thoughtful deployment of prescription drugs (both branded and generic/biosimilars) and diagnostic tools in more settings, as longer-term alternatives to costlier treatments, can be a vital part of this necessary exercise. There are, in any case, specific matters such as upfront costs, intellectual property rights, and accessibility, that affect the fiscal equation in which taxpayers have an abiding interest.

[1] See the Congressional Budget Office report at: https://www.cbo.gov/publication/60127.

Comments

The format of the public input website for this RFI means that our comments must be narrowly focused. Nonetheless, we wish to note that there are numerous regulatory and tax reform approaches that could "reduce administrative burdens on providers, suppliers, beneficiaries, Medicare Advantage and Part D plans, and other stakeholders participating in the Medicare program." We look forward to working with CMS in implementing more of these approaches, and we encourage CMS to review them on NTU's website.[2]

The following comments concentrate on one emblematic program— Coverage with Evidence Development (CED)— to illustrate common themes for regulatory reform throughout Medicare. Originally conceived more than 20 years ago to encourage innovative treatments and their swift uptake under National Coverage Determinations (NCDs), the CED process provided Medicare coverage for breakthroughs only if eligible patients submitted to clinical studies or other trials.

In theory, CED could help to expedite the introduction of lifesaving diagnostics and treatments, but, in practice, it has sometimes functioned in a contrary manner by effectively stranding therapies in a regulatory limbo. On the diagnostic side, for example, PET scans for early signs of Alzheimer's and dementia underwent CED for ten years before those restrictions as well as the NCD were lifted in 2023. This occurred despite the promulgation of an "Expedited Process to Remove National Coverage Determinations" in 2013 that was finalized in 2015. In fact, most CEDs persist for an average of more than a decade.

History might be repeating itself with CMS's decision to enforce CED as part of a 2022 NCD for Alzheimer's therapies known as anti-amyloid drugs.

NTU is all too familiar with the fiscal impact of Alzheimer's on taxpayer-funded health care programs. As detailed in our extensive 2023 paper, "How Much is Medicine Worth to the American Taxpayer?"[3] the quest for Alzheimer's treatments has been marked by sporadic approvals of new drugs, reversals in government reimbursement for coverage, and controversies over patient affordability. A thorough review of the costs Alzheimer's disease imposes on the American public, and federal regulatory decision-making regarding the approval for and

[2] See, for example, NTU and NTU Foundation's work on reforming the Center for Medicare and Medicaid Innovation's activities at https://www.ntu.org/foundation/detail/resetting-the-scoreboard and https://www.ntu.org/publications/detail/center-for-medicare-and-medicaid-innovation-12-years-into-the-game-taxpayers-still-dont-know-the-score. See also examples of our work on Pharmacy Benefit Manager reforms at https://www.ntu.org/publications/detail/how-pharmacy-benefit-managers-impact-taxpayers-and-government-spending, the 340B program at https://www.ntu.org/publications/detail/ntu-testimony-limit-340b-program-expansion-without-transparency, and other ideas for Medicare regulatory and fiscal reforms at https://www.ntu.org/foundation/detail/medicare-outpatient-payment-reform-could-save-taxpayers-billions and https://www.ntu.org/publications/detail/ntu-comments-on-several-pro-health-transparency-house-bills.

[3] Read the full NTU paper at https://www.ntu.org/publications/detail/how-much-is-medicine-worth-to-the-american-taxpayer-a-cost-benefit-analysis.

coverage of new treatments indicates that, while most of the media focuses on pricing, the question of offsetting financial benefits is often ignored.

The patient group for Alzheimer's patients and caregivers, the Alzheimer's Association, wrote that, in 2022, "the total national cost of caring for people living with Alzheimer' s and other dementias is projected to reach $321 billion," or $41,757 per person living with Alzheimer's or other dementias. That does not account for an additional $35,330 per person, or $271.6 billion, in the Association's estimate for unpaid caregiving costs— $77,087 in total direct and indirect costs per patient.

The Alzheimer's Association estimates that care costs for people with Alzheimer's will more than triple to nearly $1 trillion by 2050. Conversely, a treatment that delays the onset of Alzheimer's by five years, if introduced in 2025, could "reduce total health and long-term care spending for people with Alzheimer's" by a third, according to one study, and by 39% according to another study. That would represent tens of billions of dollars in savings per year in the 2020s, and potentially hundreds of billions of dollars in savings per year decades from now.

An earlier study from the Alzheimer's Association found that a treatment delaying the onset of the disease by five years would save Medicare and Medicaid alone $47 billion in 2030, $105 billion in 2035, $152 billion in 2040, $189 billion in 2045, and $218 billion in 2050— before accounting for treatment costs. Savings in the first ten years (2026– 35) would total $345 billion to Medicare and $189 billion to Medicaid ($534 billion total)— again before accounting for treatment costs.[4]

Even though a CED may be important in providing needed data prior to full non-clinical coverage for anti-amyloid drugs, it could, at the same time, be delaying wider introduction into the Medicare population that could begin chipping away at the daunting programmatic expenses for less-effective Alzheimer's responses. Establishing that balance to which we referred earlier— managing short-term costs to "buy time" for longer-term benefits— is vital.

Such has been our experience in the area of Anti-Obesity Medications (AOMs). In January 2025 comments to CMS,[5] we noted possible policy responses for AOM introduction:

> [W]e are sympathetic to calls among fiscal conservatives, especially those who might be in decision-making positions with the new administration and Congress, that additional measures might be advisable to keep upfront costs under control. In November 2024, NTU Senior Vice President of State Government Affairs, the Hon. Leah Vukmir, spoke of such measures in testimony before the Texas Senate Committee on Health and Human Services, which was considering proposals to expand AOM coverage in state programs:

[4] These hyperlinked studies are also referenced in the NTU paper cited in Note 3.

[5] See the full NTU comments at https://www.ntu.org/publications/detail/ntu-comments-on-medicare-and-medicaid-coverage-of-anti-obesity-medications.

> If judiciously introduced with an eye toward minimizing administrative burdens and managing government's near-term phase-in costs, these medications can offer the promise of greater public and economic health for your state over the long run. As part of a phase-in, you could set limits on a yearly basis for the total amount the state will reimburse, or you could begin with a pilot program limited to the most obese and at-risk patients. As market competition starts to drive down the prices of these drugs, you could always widen their availability as the benefits of reduced comorbidities take hold in the obese community.
>
> Other possible cost-control responses, based upon state-level experiences, would be to establish lifetime per-person coverage of AOM reimbursements, as well as requirements for patients to participate in counseling, thereby encouraging adherence rather than wasting resources on those who drop out of their treatments prematurely.[6]

How should CED be reformed going forward? With due respect to space limitations in the comment form, we offer the following brief recommendations.

- Re-orient CED toward the compact, expedited process it was intended to be. As Drs. Emily P. Zeitler and Lauren G. Gilstrap wrote in the August 2022 edition of the *American Journal of Managed Care:*

  > Making the program more transparent and predictable may improve stakeholder engagement in a process that could ultimately bring promising therapies and services to Medicare beneficiaries in a timely way while offering a mechanism to restrict access to those therapies that are not beneficial. Changes to the CED program to improve transparency and predictability can be applied to future and existing CED NCDs.[7]

- Achieving the transparency and predictability Zeitler and Gilstrap recommend could be facilitated through a "regulatory sandbox." Recently NTUF proposed this framework to the Internal Revenue Service for developing tax regulations governing cryptocurrency. As NTUF Attorney Lindsey Carpenter explained in comments to the IRS:

  > *Under this sandbox method, the IRS would recruit cryptocurrency experts from outside the IRS. These experts should represent all areas of cryptocurrency: Regulatory, taxation, trading platforms, cybersecurity, investors, brokers, sellers, etc. Then, in a controlled environment, the IRS should foster discussion amongst*

[6] See State Senator Vukmir's (R-WI) testimony at: https://www.ntu.org/publications/detail/anti-obesity-medications-can-boost-patient-health-and-lower-expenditures.
[7] See https://pubmed.ncbi.nlm.nih.gov/35981123/.

these individuals, allowing for the free flow of ideas about cryptocurrency and how to properly tax such.[8]

CMS could adapt this proposal, as well as actual sandbox procedures already in place, by calling upon experts from the industry to design the least burdensome methods of coverage determinations and other approvals.

- Evaluate how NCD both comports and conflicts with the goals of the Accelerated Approval Process more recently developed under the auspices of FDA. While created under different circumstances to address distinct parts of the medical development ecosystem, there is potential for holistic thought about these programs that could lead to useful consolidation or streamlining.

- Incorporate useful cross-pollination with other CMS and FDA programs in need of regulatory reform, including the Center for Medicare and Medicaid Innovation (CMMI) and generic/biosimilar approvals. NTU has published extensive analyses of how CMMI demonstrations are falling far short of their promise to deliver taxpayer savings.[9] Equally comprehensive reviews of FDA's often flawed interpretation of the Biologics Price Competition and Innovation Act of 2009 have shown how even streamlined licensure can encounter obstacles.

- Finally, U.S. policy could benefit from more reciprocal paths to coverage and treatment approvals. As far back as 2019, NTU endorsed legislation from Senator Ted Cruz (R-TX) called the RESULT Act, which would have created an "expedited, reciprocal approval process for drugs, biologics, or medical devices that have been authorized to be lawfully marketed in a limited set of other countries."[10] Some of the concepts in this bill could be implemented on a limited basis through executive branch activity.

To conclude:

1) Alzheimer's and obesity are the two biggest current and future cost drivers in taxpayer-funded health care programs. Breakthrough drugs in these areas, brought to market as soon as possible, have at least the prospect of slowing these costs.

2) CED reform can expedite the introduction of these drugs while allowing testing and the patient marketplace to evaluate them simultaneously.

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[8] For further details, see: https://www.ntu.org/foundation/detail/ntufs-comments-on-irs-cryptocurrency-regulations.

[9] See the papers at https://www.ntu.org/foundation/detail/resetting-the-scoreboard and https://www.ntu.org/publications/detail/center-for-medicare-and-medicaid-innovation-12-years-into-the-game-taxpayers-still-dont-know-the-score.

[10] See NTU Thanks Senator Cruz for Introducing the RESULT Act - Publications - National Taxpayers Union

3) Both innovator drugs and generics in the United States face tremendous policy obstacles, such as coercive Inflation Reduction Act prescription drug negotiations, Most Favored Nation reference pricing, and the threat of section 232 tariffs. In this environment, clearing regulatory red tape from contradictory government edicts is more imperative than ever. Space does not permit a lengthy recitation of NTU's concerns over these policies, but we would refer you to materials contained in the hyperlinks above.[11]

4) Accelerating the introduction of new therapies into Medicare must carefully account for near-term costs to taxpayers. Those costs can be managed while long-term fiscal benefits gradually materialize.

Thank you for your consideration of these comments, and should you have any questions on this or any other fiscal or regulatory matter before CMS, we are at your service.

Sincerely and respectfully,

Pete Sepp, President
National Taxpayers Union

[11] See also the three publications referenced in this paragraph at Economic, Legal, Tax, and Health Policy Experts Agree: Scrap the Punitive, Unworkable, and Indefensible Excise Tax on Prescription Drugs - Publications - National Taxpayers Union, Price Controls: How to Make Medicaid Worse Without Really Trying - Publications - National Taxpayers Union, and Section 232 Tariffs on Pharmaceuticals Will Increase Costs and Weaken U.S. National Security .