January 8, 2024

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–9895–P
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Comments on 2025 Notice of Benefit and Payment Parameters (NBPP) Rule

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, we write with brief comments on your notice and request for public comments on the Notice of Benefit and Payment Parameters Rule. We are specifically providing views in relation to Section III.E.4.a. of the document issued by the Centers for Medicare & Medicaid Services (CMS) posted on November 24, 2023, under the document number CMS-2023-0191-0003. This section pertains to potentially updating the drug classification system for the Affordable Care Act's (ACA) marketplace, with the aim of expanding and expediting therapies that would be covered by ACA providers. Our views toward Section III.E.4.a. are further limited to the impact on taxpayers of the CMS's inquiry regarding the "risks and benefits associated with replacing the reference to the USP [United States Pharmacopeia] MMG [Medicare Model Guidelines] with a reference to the USP DC [Drug Classification] as a means of classifying the drugs required to be covered as EHB [Essential Health Benefits] under § 156.122(a)(1)."

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 2023 and 2053 the share of federal noninterest outlays consumed by major health care programs is projected to rise from 27 percent to 38 percent. By contrast, Social Security, another cost driver in the budget, will see its share of noninterest outlays increase from 24 to 28 percent.[1]

[1] See Congressional Budget Office, https://www.cbo.gov/publication/59331#_idTextAnchor019.

To NTU, it is abundantly clear that innovative approaches to reducing health care costs must be explored and implemented, to begin bending this unsustainable curve toward a more realistic and affordable trajectory. We believe that thoughtful deployment of prescription drugs in more settings, as longer-term alternatives to costlier treatments, can be a vital part of this necessary exercise.

Comments

1) Section III.E.4.a., Implemented Carefully with Stakeholder Input, Could Help to Reduce Some Long-Term Systemic Taxpayer Costs for Health Care.

In March of 2023, the National Taxpayers Union Foundation (NTUF), a research-oriented organization affiliated with NTU, published a major paper entitled "How Much Is Medicine Worth to the American Taxpayer? A Cost-Benefit Analysis."[2] This paper summarizes a great deal of research on the economics of prescription drugs, much of which is familiar to CMS, while contextualizing the findings for taxpayer-funded health care programs and making recommendations for fiscally responsible policy going forward. The initially heavy up-front costs to develop drugs (and then for early adopting patients and providers to fund them) is often eventually offset by the lighter costs for non-drug care in the future. As the paper noted:

> Academic literature indicates that advances in medicine have brought trillions of dollars of benefits to the American economy in recent decades, helping people live and work longer, lead healthier and more productive lives, and avoid more expensive medical interventions that occur in hospital or physician settings. This is perhaps one reason why prescription drug spending remains a relatively small portion of overall health spending (less than 10 percent of national health expenditures) and of the nation's economic output (less than two percent of GDP).[3]

Several findings of the paper have relevance to Section III.E.4.a. For example, CMS is no doubt aware of a 2019 *Health Affairs* study which examined per capita Medicare spending from 1999 through 2012. The study determined that Medicare spending growth began to wane in 2005 and that by 2012 "actual spending [per capita] was $2,899 (14 percent) less than the forecasted trend." The authors attributed more than half of the "reduction in cardiovascular disease events" (a major driver of the spending growth slowdown in Medicare) to "increased medication use for hypertension, high cholesterol, and diabetes" – an $824 per capita slowdown in spending.[4]

---

[2] To view the paper, visit https://www.ntu.org/publications/detail/how-much-is-medicine-worth-to-the-american-taxpayer-a-cost-benefit-analysis.
[3] Ibid.
[4] See https://www.google.com/url?q=https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05372&sa=D&source=editors&ust=1679691342023576&usg=AOvVaw2A0UsaAXpAKj74I-YmH8vj.

A major purpose of Section III.E.4.a. is to facilitate greater access to Anti-Obesity Medications (AOMs), which is one of three "case studies" presented in the National Taxpayers Union Foundation paper. Among the studies NTUF reported on:

- A 2021 Journal of Occupational and Environmental Medicine paper estimated that the "annual medical cost of obesity in the United States was $147 billion" (in 2008 dollars).[5]
- A 2017 Johns Hopkins University (JHU) study calculated that "[m]ore than 70 percent of adults in the United States are considered to be overweight or obese, which in direct medical expenses alone costs nearly $210 billion per year."[6]
- A 2015 PharmacoEconomics paper found that "adult obesity raised annual medical care costs by $US3,508 per obese individual, for a nationwide total of $US315.8 billion" (in 2010 dollars).[7]
- A 2019 Journal of Medical Economics (JME) paper reported that the "estimated economic burden of obesity and obesity-related treatment was $427.8 billion in 2014, an amount that has undoubtedly escalated in subsequent years alongside the rising number of people with obesity." JME went so far as to project that "expanding coverage of anti-obesity interventions to eligible individuals could generate $20–$23 billion budgetary savings to Medicare over 10 years," or $6,842 over 10 years for "treated participant" (offset by $1,798 in intervention costs) and $308 over 10 years for each beneficiary (treated or untreated)."[8]

All these figures, adjusted to 2022 dollars, would be much higher, in the latter case exceeding $500 billion. Since the publication of NTUF's paper, subsequent research appears to have reaffirmed and strengthened the case for AOMs' ability to reduce long-term health care expenditures, despite initial short-term costs. An April 2023 USC Schaeffer Center White Paper modeled the fiscal impact of enacting legislation known as the Treat and Reduce Obesity Act (which NTU has endorsed) to provide for access to AOMs in Medicare Part D and projected a 10-year savings to Medicare ranging from $175 billion to $245 billion.[9]

While some have criticized the Schaeffer Center's finding, recently a multi-year SELECT trial of one popular AOM (Wegovy) for more than 17,000 patients across 41 countries provides a more comprehensive view. First publicized in August of 2023, the study reported that the drug's regular use "was associated with a 20% reduction in major adverse cardiac events during a mean exposure

---

[5] See Weight Loss-Associated Decreases in Medical Care Expenditures for Commercially Insured Patients With Chronic Conditions - PMC (nih.gov).
[6] See Weight Loss For Adults at Any Age Leads to Cost Savings, Study Suggests | Johns Hopkins | Bloomberg School of Public Health (jhu.edu).
[7] See Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status | PharmacoEconomics (springer.com).
[8] See https://www.tandfonline.com/doi/full/10.1080/13696998.2019.1652185#:~:text=The%20estimated%20economic%20burden%20of,of%20people%20with%20obesity4.
[9] See 2023.04_Schaeffer_Center_White_Paper_Benefits_of_Medicare_Coverage_for_Weight_Loss_Drugs.pdf (usc.edu).

period of 33 months. This benefit was observed even in the setting of widespread concurrent statin use."[10]

While Section III.E.4.a. pertains to the ACA marketplace rather than Medicare, the SELECT trial reached below Medicare's age cohort to patients as young as 45 years old. It is therefore becoming increasingly difficult to ignore the potential benefit of greater access to AOMs in reducing surgeries, hospital stays, and other costlier interventions in taxpayer-funded health systems.

Indeed, many such systems are already embracing AOMs. As the NTUF paper points out, in addition to the Department of Veterans Affairs and the Federal Employee Health Benefits Program (FEHBP):

> Some states … are already covering AOMs in Medicaid (at least 15, according to a February 2022 report from the Urban Institute) and in State Employee Health Plans (at least 16, according to a 2021 STOP Obesity Alliance report). New Mexico has gone so far as to provide wide coverage of AOMs in its statewide "Essential Health Benefit Benchmark Plan," a concept established under the Affordable Care Act (ACA) to define coverage standards for individual and small group markets. The reason was that health actuaries identified specific beneficial health and fiscal outcomes compared to a cost of increased claims that was statistically insignificant, at 0.03 percent.

Given the necessity of mitigating the enormous impact of government health expenditures on taxpayers, NTU believes that CMS can and should help to facilitate more widespread availability of AOMs to patients, including those in the ACA marketplace. However, will the proposal in Section III.E.4.a. deliver that availability in a manner that minimizes the additional burden on providers? This important question is explored below.

2) Compliance Costs with the Proposal in Section III.E.4.a. Should Not Be Trivialized and Should Be Addressed.

Industry observers who focus on the medical economics of pharmaceutical developments have greeted the results of the SELECT trial with considerable enthusiasm, suggesting that over the longer term, not only taxpayers but also providers (including insurers) may eventually welcome the increased availability of AOMs.

For instance, Markus Manns of Union Investment told Reuters that the SELECT outcome, "[w]ith these numbers," means that "medical insurances should also become more inclined to cover the costs of Wegovy." Presumably, this could be the case with other AOMs reporting similar success. Henrik Laustsen of Jyske Bank added that "The results could improve the willingness to pay for obesity drugs and provide higher incentive to treat obesity at earlier state." Terence McManus of Bellevue Asset Management observed that "Cardiovascular events such as

[10] See https://www.acc.org/Latest-in-Cardiology/Clinical-Trials/2023/11/09/15/04/select.

strokes are expensive for healthcare systems through the increased care such patients need, therefore reducing these events should be supportive of pharmacoeconomic evaluations."[11]

Yet, as several commenters on this rulemaking have noted, in the nearer term, disruptions to existing administrative procedures that those providers employ are certain to occur, especially if Section III.E.4.a. is implemented without care. NTU regards these disruptions quite seriously.

As part of our mission, we have devoted a great deal of effort toward exploring the compliance burdens of various government regulations, chiefly those resulting from tax laws. Since 1999, NTU's research arm (NTUF) has published an annual report on the time, material, and other costs to the public and private sectors associated with administration of the complex tax system. In 2023, NTUF estimated that the federal personal and corporate income tax laws required 6.553 billion hours and $363.8 billion in compliance effort.[12] However, we have also provided analysis and commentary on regulatory burdens in other areas, including rulemakings issued by the Federal Trade Commission, the Department of Energy, the Surface Transportation Board, and the Federal Housing Finance Agency, to name a few.[13]

In our experience, these rulemakings have diverse intentions and mechanics, but can reflect common drawbacks:

- Whether the rulemakings are initially the product of robust stakeholder input or not, they tend to lack ongoing input to help improve their effectiveness over time.
- Paperwork burden and information collection estimates concentrate on the design of products such as forms without also devoting attention to recordkeeping requirements, training, and legitimate private sector concerns over exposure to new enforcement actions.
- Implementation periods and learning curves vary from sector to sector and often among regulated businesses and individuals that appear to be similarly situated to regulators, but actually are quite different.

CMS can at least minimize these problems by adapting solutions that have proven useful to other agencies, or at least instructive to agencies whose rulemaking processes are evolving. This is especially true for tools employed in the tax realm, where regulations, notices, guidance, and

---

[11] See https://www.reuters.com/business/healthcare-pharmaceuticals/view-novos-obesity-drug-cuts-risk-heart-disease-by-20-study-2023-08-08/#:~:text=Aug%208%20(Reuters)%20%2D%20Novo,a%20key%20late%2Dstage%20trial.

[12] See, for example, https://www.ntu.org/foundation/tax-page/complexity-2023-65-billion-hours-260-billion-what-tax-complexity-costs-americans.

[13] See, for example, https://www.ntu.org/publications/detail/ntu-comments-on-irs-proposed-rule-for-supervisory-approval-of-penalties; https://www.ntu.org/publications/detail/ntu-offers-comments-to-the-surface-transportation-board-on-reciprocal-switching; and https://www.ntu.org/publications/detail/ntu-comments-to-the-ftc-on-the-contact-lens-rule.

other pronouncements rival or exceed those confronted by stakeholders in the health care industry. While CMS already has several advisory panels (e.g., the Pharmaceutical and Therapeutics Committee) and other consultation processes at its disposal closely resembling several of the following suggested remedies, we nonetheless believe these are useful starting points:

- Adequate implementation periods, which can be further adjusted as feedback informs the pace of change, should be provided. While seemingly simplistic, the element of time not only affords the private sector adequate planning to institute new systems, but it also allows the public sector to discover and address the "unknowns" while the process is underway rather than attempt to "de-bug" a process that has been hastily completed. Some commenters have suggested implementation of Section III.E.4.a. could realistically need up to two years to complete. CMS should bear these comments in mind to design an acceptable period to reach full compliance.
- Successful rulemakings proposing major changes can still start from a common and familiar knowledge base. In the case of Section III.E.4.a., that knowledge base could already exist for many providers in the ACA marketplace, because systems such as the Federal Employee Health Benefits Plan already allow AOM coverage and may be more familiar with the workings of USP DC. FEHBP will offer more than 150 plans to some 8 million participants in 2024. If CMS is to make a transition to USP DC in the ACA marketplace, it must ensure that the most widely understood version of this system is initially promulgated. This way, some providers in the marketplace will have had prior experience with USP DC. Even so, other safeguards will need to be created.
- Although NBPP is conducted annually, there are still mechanisms available to provide more regular feedback from stakeholders. One technique that NTU would recommend for CMS's study is the Internal Revenue Service's "Job Aid" concept. While they can vary in their composition and operation, Job Aids are generally initiated by the IRS for either members of their own staff or the practitioner community as "how-to" guides for ensuring best practices in carrying out the intent of tax regulations. Some topics have included arcane matters such as "Valuation of Non-Controlling Interests in Business Entities Electing to be Treated as S Corporations for Federal Tax Purposes," and "Discount for Lack of Marketability" as commonly applied in business valuation analyses.
- CMS should also closely examine the "regulatory sandbox" concept, which has already been put to practical use in U.S. states and abroad.[14] 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

[14] See, for example, https://www.ntu.org/foundation/detail/ntuf-comments-to-omb-on-ai-governance.

discussion amongst these individuals, allowing for the free flow of ideas about cryptocurrency and how to properly tax such.[15]

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 method of allowing medications with long-term cost-saving potential to be adopted into the ACA marketplace.

- CMS should design and promulgate "safe harbor" guidance for entities that would confront USP DC in the ACA marketplaces. Safe harbors are employed throughout the federal government, including those in the health care area, to give a level of legal reassurance to regulated entities that they are compliant with regulations by following specific government guidance. While safe harbors appear in many parts of tax regulations, the Department of Health and Human Services (HHS) also issues such guidance. For example, HHS's Office of Inspector General has published safe harbor regulations that "describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute."[16]

All these concepts deserve CMS's consideration to provide a policy framework that is flexible, responsive, transparent, and less onerous for the entities who must comply with it. Those entities are, after all, taxpayers as well.

3) CMS Should Shape Policy with an Awareness of ACA's Future.

It should be noted here that National Taxpayers Union strenuously opposed Congressional passage of the Affordable Care Act, due to its creation of punitive tax increases on many Americans, large subsidies, and heavy regulations of a health care sector already straining under the weight of government mandates. An additional element that merited NTU's concern was the system of premium subsidies through tax credits that were widely refundable, i.e., claimable by taxpayers well in excess of their actual tax liability. The proliferation of refundable tax credits of all kinds – also known as "spending in the Tax Code" – will present serious policy challenges in the near term. In addition to ACA's creation of premium tax credits, the American Rescue Plan Act of 2021 expanded those credits well past 400 percent of the federal poverty level for a two-year period, while the Inflation Reduction Act extended those generous provisions through the 2025 plan year.

The Congressional Budget Office is continuing to revise its estimates of the premium tax credit's fiscal impact. Worst, in our view, is the fact that the portion of that impact attributable to the spending side of the federal ledger is growing. According to its May 2023 "Update of the Budget Outlook," "CBO and the staff of the Joint Committee on Taxation increased their projections of

[15] See https://www.ntu.org/foundation/detail/ntufs-comments-on-irs-cryptocurrency-regulations.
[16] See https://oig.hhs.gov/compliance/safe-harbor-regulations/.

outlays for premium tax credits for health insurance purchased through the marketplaces established under the Affordable Care Act and related spending by $7 billion for 2023 and by $160 billion (or 18 percent) for the 2024–2033 period."[17] CBO noted that the shift toward higher outlays versus lower revenues of premium tax credit projections resulted in no net change to federal deficit forecasts. For taxpayers, however, this change in "mix" remains problematic – in our experience, it is more difficult over time to restrain the growth of spending programs than tax relief programs.

As alarming as NTU finds this trend, the political environment in Washington will make major reforms to ACA spending less likely to occur in the near term. This means that a gradualist approach may be taxpayers' best hope for cost control in the ACA marketplace. As with the introduction of breakthrough prescription drugs in other parts of the health care system, the initial fiscal impact will be higher spending as innovators recover their massive development costs and patient utilization rates increase. Over time, however, the offsetting effect described earlier can begin to yield net systemic savings as patient outcomes from drug utilization obviate more expensive therapies and the drugs become more widely available. CMS's challenge is to manage this process for the ACA marketplace in a way that gets out ahead of long-term unsustainability, especially as the premium tax credit expansion nears its next legislative "cliff" in less than two years.

Conclusion

Taxpayers have a deep and abiding interest in ensuring both access and affordability of prescription drugs. Yet, a variety of recent policies – ranging from the extortionary drug price "negotiation" process created by the Inflation Reduction Act to the state of Florida's ill-advised drug importation plan – threaten to undermine these unique attributes of the American health care system. Whatever other flaws may exist in the ACA marketplace model, the introduction of certain new prescription drug therapies such as AOMs can, if thoughtfully planned with an eye toward minimizing administrative burdens, offer the prospect of longer term economic and fiscal benefits. Thank you for your consideration of these comments.

Sincerely,

Pete Sepp, President

[17] See https://www.cbo.gov/publication/59159.