



ASSOCIATION CHAIR OF THE BOARD

Everett E. Vokes, MD, FASCO

ASSOCIATION TREASURER

Brian Edward Persing, MD

ASSOCIATION DIRECTORS

Lisa A. Carey, MD, FASCO

Tara O. Henderson, MD, MPH, FASCO

Elizabeth R. Plimack, MD, MS

Lynn M. Schuchter, MD, FASCO

Enrique Soto Pérez de Celis, MD, MSc, PhD, FASCO

Piyush Srivastava, MD, FASCO

Eric P. Winer, MD, FASCO

Robin T. Zon, MD, FACP, FASCO

NON-VOTING DIRECTOR

Chief Executive Officer

Clifford A. Hudis, MD, FACP, FASCO

December 20, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted Electronically at www.regulations.gov

Re: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program (CMS–9895–P)

Dear Administrator Brooks-LaSure,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the 2025 Notice of Benefit and Payment Parameters proposed rule (CMS–9895–P) that was published in the Federal Register on November 24, 2023.

ASCO is a national organization representing nearly 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

We are pleased to offer our comments on select provisions below.

* * * * *

Coverage of Prescription Drugs as Essential Health Benefits

CMS proposes to codify essential health benefit (EHB) policy related to prescription drugs in excess of the benchmark plan. If a health plan covers drugs beyond what are included in the benchmark plan, these drugs would still be considered EHB and would be required to count towards the annual cost sharing and out of pocket limits. ASCO strongly supports this proposal.

Our physician members continue to express concern over “specialty carve-out” schemes and “alternative funding programs”, which are sometimes referred to as the “EHB loophole” affecting patients in self-funded and large employer

group plans. These are an emerging trend among payers seeking to reduce their drug spending¹ by excluding coverage for high-cost branded specialty drugs from an enrollee’s prescription drug benefit and directing patients to Patient Assistance Programs (PAP) to access the drug.

Under an alternative funding program, a plan sponsor contracts with a third-party entity which develops a list of specialty medications which are specifically excluded (or “carved-out”) from coverage under the health plan’s prescription drug benefit. When a plan member is prescribed one or more of these carved-out drugs, the claim is automatically denied by the PBM, rendering a patient functionally uninsured for those drugs. The member is then moved into a process with a third-party “alternative funding vendor” that facilitates a search for financial coverage from another source, such as a PAP offered by a pharmaceutical manufacturer or from patient assistance or charitable foundations; some vendors may use foreign sources of drugs. Once the patient is enrolled with the third-party vendor, the vendor handles all aspects of payment and fulfillment of their prescription.² Vendors have different payment arrangements with plan sponsors including a percent of “savings” charge or an administrative fee approach.^{3,4} Patient groups have also noted a variation on this process, which involves a utilization management company simply denying a claim for a high-cost specialty drug—even if it is on formulary for that patient—and funneling the patient into a PAP.

It is important to note the coercive nature of these programs and the financial burdens they can impose on patients. A third-party vendor may ask for extremely personal financial and medical information from the patient, and many patients have been asked to sign powers of attorney. If the patient agrees to enroll in the PAP and they qualify for free or reduced cost drug, resources intended for truly uninsured or under-insured patients are being drained from the system. If the patient refuses to enroll, not only are they responsible for paying completely out of pocket for their needed high-cost drug, but none of these payments count toward the patient’s out of pocket expenses. There are no “winners” in this scenario except for the third-party vendors who collect a fee for their “services,” which may be a percentage of the drug cost.

Moreover, alternative funding is not guaranteed. Needs-based funding requires income verification, and the enrollee may exceed the maximum income threshold. Additionally, PAPs are not endless, and assistance will exhaust. If resources are not available through a PAP, an enrollee may find themselves without affordable access to the necessary cancer therapy. Finally, PAPs are designed to provide access to brand-name medications at little or no cost to low-income individuals who do not have insurance or are underinsured. Alternative funding programs are diverting limited resources away from those who

¹ <https://khn.org/news/article/employers-patient-assistance-programs-offset-drug-costs/view/republish/>

² Some of our members report that the presence of this vendor adversely complicates their own efforts to guide patients through the complex web of coverage and assistance programs.

³ [Understanding Alternative Funding for Specialty Medications – RxBenefits](#)

⁴ [The Shady Business of Specialty Carve-Outs – Drug Channels](#)

rely on PAPs and giving them to otherwise-fully insured individuals, increasing inequities in the health care system.

When prescription drug coverage is carved-out and alternative funding arrangements are pursued, care is less streamlined and more fragmented. Enrollees that unexpectedly find themselves in such an arrangement must seek coverage from third parties unrelated to their plan and employer, and each additional process step can potentially delay initiating treatment. Patients with comorbidities may also be served by both a PBM and an alternative funding vendor with their medications in two different places—some with the PBM, some with the alternative funding vendor. This fragmented service may make it more difficult for the patient to adhere to their treatments.⁵

ASCO is concerned both that these practices can delay and complicate treatment for patients prescribed specialty medications and that they divert resources from the most truly needy patients. Many of these alternative funding programs remain opaque, with little available public information. We understand that CMS is looking for information about how widespread these programs are; however, because of the secretive nature of them, little published evidence is available to share with CMS. To date, we have identified only two analyses on the prevalence of these programs. In one analysis, the share of employers currently using an alternative funding program grew, from 6% in 2021 to 14% in 2022. According to the report, 17% of large employers currently use an alternative funding program.⁶ A separate survey found that up to 10% of self-insured plans with at least 5,000 employees were using one of these programs, with another 27% considering the use of one in the next 2-5 years.⁷

In addition, legal challenges have emerged and are currently before the courts. We continue to object to any practices that delay or deny care to patients with cancer and increase inequities already present in the health care system and urge CMS to finalize this proposal.

Copay Accumulator Programs

ASCO is extremely disappointed with the Administration's decision to file an appeal with the United States Court of Appeals for the D.C. Circuit in *HIV and Hepatitis Policy Institute et al v. HHS* and its subsequent notice that it will not enforce the 2020 NBPP. This case was brought by patient advocacy groups who challenged the 2021 Notice of Benefit and Payment Parameters rule that permitted insurers to impose copay accumulator policies. Plaintiffs opposed the accumulator program, asserting that **manufacturer copay support should count towards calculating patients' cost sharing obligations** and should not be excluded from such calculations.

In ruling in favor of the plaintiffs on their motion for summary judgment, in September 2023 the U.S. District Court set aside the 2021 NBPP, largely supporting plaintiffs' challenges that the 2021 NBPP rule's

⁵ [Better together: PBM and Integrated Specialty Management Strategies – OptumRx](#)

⁶ [Employers Expand Use of Alternative Funding Programs—But Sustainability in Doubt as Loopholes Close – Drug Channels](#)

⁷ [Alternative funding: Real savings or real problems? – OptumRx](#)

language is internally contradictory, that it runs counter to the statutory definition of “cost sharing” found in the Affordable Care Act, and that it runs counter to the agencies’ pre-existing regulatory definition of “cost sharing.”

As a result of the District Court’s ruling, the government should use an earlier 2020 version of the rule which allowed insurers to exclude from cost-sharing caps only copay support coupons for branded drugs that have available generic equivalents; if there is no generic equivalent, under the 2020 version of the rule, manufacturer copay support must be counted toward cost sharing. ASCO is very disappointed to learn that the Agency does not intend to enforce the 2020 NBPP rule prohibiting copay accumulator programs. ASCO strongly urges the Agency to reconsider and subsequently to issue guidance for insurers and enforce the 2020 copay accumulator program prohibitions.

ASCO has addressed the devastating effects copay accumulator programs have on patient access to needed care and life-saving prescription drugs in the last three rule cycles, 2022-2024. We continue to urge CMS to reverse course and prohibit copay accumulator programs to align with the improved access to coverage updates in this rule.

Copay assistance is generally available for high-cost brands and specialty medications without a medically equivalent generic alternative and is used by people with serious and complex chronic illnesses.⁸ People with low incomes and people of color are more likely to be living with a chronic illness.⁹ Such utilization management tactics negate the intended benefit of patient assistance programs—and remove a safety net for patients who need specialty medications but cannot afford them. ASCO strongly opposes the use of copay accumulator and copay maximizer programs for patients with cancer. We strongly urge CMS to reverse the current policy and eliminate copay accumulator programs. To learn more, please read our position [statement](#).

Special Enrollment Periods

ASCO supports CMS’ proposal to align the effective dates of coverage after selecting a plan during certain special enrollment periods (SEPs) across all Exchanges, including State Exchanges. CMS would require all State Exchanges to provide coverage that is effective on the first day of the month following plan selection, if a consumer enrolls in a qualified health plan during certain SEPs.

Consistent coverage without disenrollment or a gap in benefits is essential for beneficiaries with a cancer diagnosis or for those who have recently finished treatment. Even one day without coverage can halt cancer treatment or stop treatment altogether. Patients that have recently finished treatment must remain covered to access follow-up visits with their physicians for on-going monitoring. ASCO agrees

⁸ K. Van Nuys, G. Joyce, R. Ribero, D.P. Goldman, *A Perspective on Prescription Drug Copayment Coupons*. Leonard D Schaeffer Center for Health Policy & Economics. (February 2018),

<https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/>

⁹ The Center for American Progress, Fact Sheet: *Health Disparities by Race and Ethnicity*. (May 7, 2020),

<https://www.americanprogress.org/article/health-disparities-race-ethnicity/>

with CMS that this proposal would prevent coverage gaps, particularly for consumers transitioning between different Exchanges or from other insurance coverage, and we urge CMS to finalize this proposal.

ASCO also supports CMS' proposal to revise the parameters around the availability of a special enrollment period for advance premium tax credit for qualified individuals with a projected household income less than 150 percent of the Federal Poverty Level.

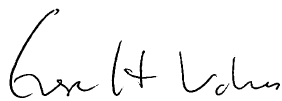
ASCO is committed to supporting policies that allow individuals to access affordable insurance without interruption¹⁰, and we agree with CMS that this proposal would make affordable coverage available to more uninsured people and provide additional enrollment opportunities to low-income beneficiaries.

ASCO believes that all eligible individuals should be able to apply, enroll in, and receive Medicare coverage benefits in a timely and streamlined manner that promotes equitable coverage, especially for individuals with a cancer diagnosis, or who are at increased cancer risk. Efforts to preserve access to health insurance, given the integral link to health care access, can improve cancer health outcomes.¹¹ Enrollment delays or restrictions result in disruptions in care, unanticipated treatment delays, and delays in screening and care, all of which are linked to worse cancer care outcomes. When patients are no longer able to access screening or other preventative care services, they may (knowingly or not) delay seeking treatment until their disease is at an advanced stage.¹² We urge CMS to finalize both proposals.

* * * * *

We appreciate the opportunity to comment on the 2025 Notice of Benefit and Payment Parameters proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Everett Vokes, MD, FASCO
Chair of the Board
Association for Clinical Oncology

¹⁰ <https://www.asco.org/sites/new-www.asco.org/files/content-files/2017-ASCO-Principles-Healthcare-Reform.pdf>

¹¹ Yabroff KR, Reeder-Hayes K, Zhao J, et al: Health insurance coverage disruptions and cancer care and outcomes: Systematic review of published research. J Natl Cancer Inst 112:671-687, 2020

¹² Amini A, Jones BL, Yeh N, et al: Disparities in disease presentation in the four screenable cancers according to health insurance status. Public Health, 138, 50-56, 2016