September 12, 2025

Submitted electronically via *https://www.regulations.gov*

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Oz,

We, the undersigned organizations, collectively represent community-based organizations and nonprofits with deep expertise and experience providing navigation services to patients, survivors, and caregivers impacted by cancer and other complex conditions. We recognize the Centers for Medicare & Medicaid Services' (CMS) commitment to ensuring that Medicare and Medicaid programs reflect the values and needs of patients. As community-based organizations, our work with patients and their loved ones provides us with an understanding of how principal illness navigation (PIN) codes provide necessary support. Our insight is formed by our experiences, which are used to create recommendations throughout our comments.

We are pleased to offer our comments in response to the principal illness navigation (PIN) provisions of the CY 2026 Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule (MPFS) proposed rule.

PIN Codes and Mental Health Services

We appreciate CMS' emphasis on encompassing a broader approach to preventative care, including mental health. We commend CMS for clarifying that Principal Illness Navigation services may be provided through additional mental health professionals. The clarification of the definition of "certified or trained auxiliary personnel" to include Certified Social Workers (CSWs), Marriage and Family Therapists (MFTs), and Mental Health Counselors (MHCs) increases the ability for more patients to receive diagnosis or treatment of a mental health service through Community Health Integration (CHI) and PIN services.

PIN Code Use for Holistic Navigation Services

The definition of Principal Illness Navigation (PIN) services, which focuses on individuals that the CY 2026 MPFS proposed rule defines as being diagnosed with "one serious, high-risk condition expected to last at least 3 months," does not account for important navigation services integral to helping at-risk patients avoid secondary cancer or other diagnoses or recurrences often part of the illness trajectory. We would be pleased to work with you to enhance PIN and other reimbursement approaches to ensure more

holistic, essential services are provided throughout all phases of care for cancer and other conditions. By providing comprehensive, person-centered services that guide patients through the complexities of our health care system, CBOs improve both the effectiveness and efficiency of patient care. Similarly, the comprehensive psychosocial care CBOs provide to patients before, during, and after "active" treatment is essential to secure the consistency in care adherence needed throughout the entirety of the patient's care and treatment, which may include long-term adjuvant treatment to help deter diagnoses of cancer recurrence. These scenarios highlight significant gaps in the current framework that need to be addressed to ensure comprehensive and continuous care for patients.

Patient Cost Sharing

A key concern, shared in response to the CY 2025 MPFS proposed rule and reiterated by the undersigned organizations, is whether accepting contractual payments from providers who use PIN codes and charge patients a copay conflicts with CBOs' mission to provide free navigation and support services to all patients and caregivers, regardless of their ability to pay. Our organizations have seen firsthand the challenges and negative consequences resulting from cost sharing imposed on patients for PIN code utilization. Financial hardship is a rising reality for most patients diagnosed with cancer and other serious illnesses. This is true even for individuals with health insurance. Costs of medical and other care escalate fast and often overwhelm even the best planned household budgets. This hurts individuals' economies, health, and quality of life.

National Patient Advocate Foundation partnered with the Patient Insight Institute at its sister organization, Patient Advocate Foundation, to capture patient data on the prevalence of financial hardship across disease diagnoses earlier this year. This national survey of 2510 patients revealed that 82% experienced financial difficulties in the past year because of expenditures related to medical care, insurance, cost of living challenges, lost wages, and more. Notably, 77% of these patients identified financial distress as their top worry in healthcare – ranked above the possibility of dying,[1]

In the context of cancer, about 50 percent of cancer patients experience financial distress as a consequence of their diagnosis, which has a direct association with psychosocial outcomes like stress, anxiety, and social function. Evidence shows that cancer patients experiencing financial distress are 3-5 times more likely to postpone care and experience poorer outcomes.[2] Survivors with financial hardship have a higher adjusted mortality risk and report experiencing ongoing challenges that also hurt their

[1] Patient Insight Institute 2025 national survey synthesis of financial hardship findings: NPAF Issue Brief accessed August 29, 2025 at https://www.npaf.org/resources/needs-navigation-issue-brief-2/.

[2] Mollica, M. A., Zaleta, A. K., Gallicchio, L., Brick, R., Jacobsen, P. B., Tonorezos, E., Castro, K. M., & Miller, M. F. (2024). Financial toxicity among people with metastatic cancer: findings from the Cancer Experience Registry. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*, *32*(2), 137. https://doi.org/10.1007/s00520-024-08328-2

future financial health.[3] Requiring a copayment for patients with cancer and other serious illnesses or conditions, particularly those with limited financial resources, compounds an already delicate situation for many patients and can threaten access to and utilization of principal navigation services.

To address these concerns in the near term, barring a statutory requirement waiving beneficiary cost-sharing, we recommend the Center for Medicare and Medicaid Innovation (CMMI) develop a demonstration project or model focused on principal navigation that waives beneficiary cost sharing for Medicare beneficiaries to test how PIN services improve outcomes, reduce or maintain costs, and improve or maintain quality of care for Medicare beneficiaries. This recommendation is consistent with CMS' overarching goal of lowering costs and improving care while addressing causes of poor health such as behavioral risk factors. If adopted, this model or demonstration could provide technical assistance and resources to physicians and other eligible providers about the benefits of PIN and how to have these conversations with their patients. The development of this model would also assess whether utilization of PIN services increases if patients do not have a copay responsibility, providing valuable data on the financial implications of current policies and the long-term sustainability and success of principal navigation services under Medicare.

Telehealth Services

Medicare beneficiaries, both rural and urban, would benefit from increased Medicare coverage of telehealth services by reducing geographic, physical, and financial barriers to accessing quality and timely healthcare.

Although PIN services may be delivered via direct in-person contact between the auxiliary personnel and the patient, most, if not all, PIN services may be effectively provided via two-way audio or audio-visual methodologies with the added benefit of receiving such services without patients having to overcome often insurmountable barriers such as transportation means/costs and the physical/emotional challenges of travel. While these concerns cut across the Medicare population, they are most acute for individuals in under-resourced and rural communities.

Therefore, to ensure broad access, delivery, and receipt of PIN services, sites must be permitted the flexibility of offering patients PIN services via the modality – whether in-person, two-way audio, or audio-visual – that is most effective and least burdensome for each individual. Therefore, it is critical that all PIN services be accessible via telehealth (including audio-only options) and across state lines in accordance with applicable accreditation licensure laws.

Training Requirements, Cross-State Licensure

To ensure patient-centered care is consistently of high quality, it is essential that all entities and individuals providing PIN services meet standardized, comprehensive educational requirements

[3] Yabroff KR, Han X, Song W, Zhao J, Nogueira L, Pollack CE, Jemal A, Zheng Z. Association of Medical Financial Hardship and Mortality Among Cancer Survivors in the United States. J Natl Cancer Inst. 2022 Jun 13;114(6):863-870. doi: 10.1093/jnci/djac044. PMID: 35442439; PMCID: PMC9194618.

delivered through accredited institutions or programs. Additionally, standards, such as the Oncology Navigation Standards of Professional Practice, should be based on expert input and evidence-based studies, with a requirement for timely updates and the incorporation of new, verified data as it becomes available.

Patients navigating cancer may need to travel to receive cancer-related care or assistance from a loved one. This travel may occur within a single state or across state lines. For PIN services to be truly effective, they must meet patients where they are – both physically and emotionally. Given the unique needs and experiences of each individual diagnosed with cancer, there should be no artificially imposed barriers limiting where or how patients receive the PIN services they need and value.

We welcome the opportunity to collaborate with CMS on approaches that reflect opportunities for improving quality care and promoting cross-state access for patients.

Community-Based Organization (CBO) Billing Considerations: "Incident To" Billing

We appreciate CMS' ongoing encouragement that CBOs engage in contracts with qualified providers to deliver principal navigation services as well as the incorporation of CBOs into PIN code payment through "incident to" billing. In practice, funding for these services only goes directly to the billing provider and not the collaborating CBOs. Mandating reimbursement for PIN services within the MPFS code structure, with payments directed to CBOs "incident to" a practitioner's services, creates many operational barriers.

Whether the "incident to" structure is an effective method of delivering these services remains uncertain. In addition to developing a CMMI model without patient cost sharing, another potential comparator to the new PIN "incident to" billing codes is to monitor and measure Medicare patient utilization, outcomes, costs, and quality of care when physician practices incorporate and receive reimbursement for internally providing PIN services. This approach could reveal differences, if any, in uptake and patient satisfaction between the different pathways, ultimately empowering patients to choose how they prefer to receive these vital services.

Conclusion

The undersigned organizations appreciate the opportunity to comment on the CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies.

We look forward to continuing our strong partnership with CMS to ensure that all Medicare beneficiaries, including patients and caregivers impacted by cancer and other serious, high-risk chronic conditions or illnesses, have access to affordable principal navigation services and other life-enhancing care. Please consider our organizations a resource as the agency continues to implement and build upon these efforts to improve Medicare beneficiaries' outcomes and quality of life by addressing unmet social

needs that impact healthcare access. We stand ready to assist and work with CMS to mitigate any barriers to widespread access and adoption of these critical services.

If you have any questions or need additional information, please contact Daneen Sekoni, Vice President, Policy and Advocacy at Cancer Support Community, at dsekoni@cancersupportcommunity.org.

Sincerely,

Cancer Support Community
Cancer*Care*
National Patient Advocate Foundation
Academy of Oncology Nurse & Patient Navigators
Colorectal Cancer Alliance
GO2 for Lung Cancer
HealthTree Foundation
Native American Cancer Research Corporation
National Minority Quality Forum
Smith Center for Healing and the Arts
Susan G. Komen
The Sheri and Les Biller Family Foundation
Together for Supportive Cancer Care
ZERO Prostate Cancer