

September 9, 2024

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Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1807-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Dear Administrator Chiquita Brooks-LaSure,

We, the undersigned organizations, 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 appreciate the Centers for Medicare & Medicaid Services' (CMS) commitment to finding policy solutions aimed at providing whole person care by addressing factors and providing support related to social drivers of health and psychosocial and emotional health.

We enthusiastically support the intent behind the creation of these PIN codes as a critical step to offering patient navigation services to all patients who may benefit. As community-based organizations, we are acutely aware of the value patient navigation services can provide to patients impacted by a serious, high-risk condition or illness.

We are pleased to offer our comments in response to the principal illness navigation (PIN) provisions of the CY 2025 Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule (PFS) proposed rule.

Our comments focus on the following provisions discussed in the Request for Information for Services Addressing Health-Related Social Needs (Community Health Integration Services, Principal Illness Navigation Services, Principal Illness Navigation-Peer Support and Social Determinants of Health Risk Assessment).

Questions to Consider

First, there is a need to assess whether the practitioner's definition of "treatment", outlined by Physician Fee Schedule (PFS) Codes for addressing serious, high-risk conditions or illnesses, aligns with the broader understanding of treatment held by community-based organizations (CBOs), which often includes psychosocial support, financial toxicity management, and other non-clinical aspects of care.

Additionally, it is crucial to determine if CBOs receipt of payments and referrals from providers raises anti-kickback or other billing concerns for CBOs. This leads to further questions regarding the specific data and documentation that CBOs should collect, retain, and report (to whom and when), for patients referred under “incident to” services. Similarly, it is important to consider whether there are additional HIPAA considerations that may come into play for these referred patients, beyond the standard requirement for other patients.

PIN Code Frequency, Overlap, and Intensity of Service

In reviewing the proposed changes to the CY 2024 physician fee schedule (PFS), the undersigned organizations have concerns regarding the sufficiency of the allotted 60 minutes per month, with an additional 30 minutes as an add-on, for CBO services, particularly when additional time is needed to meet the complex needs of different patients. Ethical obligations of CBOs require that patient care be prioritized regardless of source of funds for services. This raises questions about how such additional time would be documented and accounted for outside of the contractual amount provided.

PIN Code Use for Prevention, Screening, and Survivorship

The definition of PIN services, which focuses on individuals “diagnosed with a high-risk condition,” appears to exclude reimbursement for prevention and screening as well as survivorship services. In our experience, PIN services are equally valuable throughout the continuum of a patient’s journey, including prevention, screening, and survivorship. Excluding reimbursement for services provided during these phases of care leaves patients without the anchor necessary to guide them through the complexities of our health care system, a critical person-centered service provided by CBOs. Similarly, the comprehensive psychosocial care CBOs provide to patients before, during, and after “active” treatment is essential to secure the anchor throughout the entirety of the patient’s care and treatment, which may include long-term adjuvant treatment to help prevent 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 arises when considering whether receiving contractual payments from providers who use PIN codes and charge patients a copay contradicts CBOs’ mission to provide free navigation and support services to all patients and caregivers who may benefit regardless of their ability to pay. Charging patients to navigate the complexities of a fractured and often confusing healthcare system – complexities that patients neither created nor can control – raises questions of appropriateness and possibly even ethicalness of such fees. Our concern is that PIN code utilization with a cost sharing requirement will have the unintended consequence of discouraging uptake by Medicare beneficiaries most likely to benefit thereby widening health disparities. Specifically, Medicare beneficiaries eligible for PIN services will have a cost sharing obligation while non-Medicare beneficiaries eligible for PIN services may not.

Moreover, we know that about 50 percent of cancer patients experience financial toxicity, which has a direct association with psychosocial outcomes like stress, anxiety, and social function. Evidence shows that cancer patients experiencing financial toxicity are 3-5 times more likely to postpone care and that financial toxicity is associated with poorer outcomes. Survivors with financial hardship have a higher adjusted mortality risk and report experiencing financial hardship after their diagnosis. Requiring a copayment for patients with cancer and other serious illness or conditions, particularly those with limited financial resources, compounds an already delicate situation for many patients and can threaten access to and utilization of patient 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) consider developing a demonstration project or model focused on patient 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 to Medicare beneficiaries. This recommendation is consistent with CMS' overarching goal to continue moving Medicare beneficiaries to value-based care models. If adopted, this model or demonstration could also 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 and ethical implications of current policies and the long-term success of patient navigation services under Medicare.

Community Based Organization (CBO) Billing Considerations: “Incident To” Billing

We appreciate CMS' ongoing encouragement that CBOs engage in contracts with qualified providers to deliver patient 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. Including reimbursement for PIN services within the PFS 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 that waives 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 model could reveal differences, if any, in uptake and patient satisfaction between the three different pathways, ultimately empowering patients to choose how they prefer to receive these vital services.

A more viable, long-term solution, and patient-centered approach to CBO funding for PIN services would be to follow a similar grant model as the one recently announced by the Biden-Harris Administration, providing \$100 million in grants for insurance navigators to assist patients

enrolling in Affordable Care Act (ACA) plans. This type of model would be more fitting for CBOs, like the undersigned organizations, who provide essential PIN services outside of the “clinical care” setting. We recommend that CMS explore the feasibility of adopting a reimbursement structure that supports the sustainability of CBOs providing navigation services to under-resourced communities, similar to the ACA resource navigator program. Importantly, such a program could, ideally, be designed to include reimbursement for services sought by and provided to caregivers of patients.

Training Requirements, Cross-State Licensure

To ensure patient-centered care, it is essential that all entities and individuals providing PIN services meet standardized, comprehensive educational requirements 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, there should be no artificial barriers regarding where or how patients receive the PIN services they need and value.

Telehealth Services

Telehealth greatly enhanced patient access to care during the COVID-19 public health emergency and allowed for providers and CBOs to deliver critical healthcare to patients. 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 underserved and rural communities. Therefore, to ensure equitable 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 the established standardized and comprehensive educational requirements.

Conclusion

The undersigned organizations appreciate the opportunity to comment on CMS' proposed rule on the CY 2025 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 patient 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 social and psycho/emotional drivers of health. We stand ready to assist and work with CMS to mitigate any barriers to widespread and equal 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 (CSC)
CancerCare
National Patient Advocate Foundation (NPAF)
Center to Advance Palliative Care (CAPC)
Colorectal Cancer Alliance
Digital Medicine Society (DiME)
Georgia Center for Oncology Research and Education
HealthTree Foundation
Lupus and Allied Diseases Association, Inc.
National Minority Quality Forum (NMQF)
Smith Center for Healing and the Arts
Susan G. Komen for the Cure
Ulman Foundation