

September 9, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1784-P – Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Coverage Policies

89 Fed. Reg. 61596 (July 31, 2024)

Dear Secretary Becerra and Administrator Brooks-LaSure:

On behalf of the American Cancer Society (ACS), the American Cancer Society Cancer Action Network (ACS CAN), and other leading patient advocacy organizations, we appreciate the opportunity 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. Each of the **XX** signatories is committed to continuing to increase access to patient navigation services and building upon the meaningful step of the PIN codes in providing critical services for patients with cancer and other serious illnesses.

Navigating the healthcare system can be confusing and complicated, and making decisions after receiving a complex medical diagnosis such as cancer is challenging for anyone but particularly for populations that have been historically marginalized. Patient navigation programs in oncology, first established in the 1990s, have been developed to make healthcare systems more manageable, to provide additional support to cancer patients and their families, and to help lessen the cancer burden across the care continuum, from connecting individuals to screening and prevention services as well as care during and after treatment. For cancer patients there are several benefits of oncology patient navigation including improved access to tailored patient-centered care and services like care coordination, and symptom management. Furthermore, evidence supports that oncology patient navigation addresses health-related social needs and ultimately, reduces disparities in health outcomes. All of these benefits ultimately help to improve care and reduce costs for patients, providers and the larger health care system.¹ Long term financial sustainability and reimbursement of evidence-based patient navigation services is critical to ensuring access to these important services and for addressing health disparities across the cancer continuum.

In the CY 2024 Medicare Physician Fee Schedule final rule, CMS finalized the creation of four new PIN codes, including (1) G0023 for PIN services by a certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a patient navigator or certified peer specialist, for 60 minutes per calendar month per beneficiary; (2) G0024 for an additional 30 minutes of PIN services per calendar month per beneficiary as well as (3) G0140 for PIN Peer Support by a certified or trained auxiliary personnel under the direction of a physician or other practitioner, including a certified peer specialist, for 60 minutes per calendar month per beneficiary; and (4) G0146 for an additional 30 minutes of PIN Peer Support services per calendar month per beneficiary.

We applauded the creation of these PIN codes as an important first step to help ensure that every cancer patient everywhere will have access to the navigation services needed for a better care experience and improved health

¹ Dwyer AJ, Wender RC, Weltzien ES, Dean MS, Sharpe K, Fleisher L, Burhansstipanov L, Johnson W, Martinez L, Wiatrek DE, Calhoun E, Battaglia TA; National Navigation Roundtable. Collective pursuit for equity in cancer care: The National Navigation Roundtable. *Cancer*. 2022 Jul 1;128 Suppl 13:2561-2567. doi: 10.1002/cncr.34162. PMID: 35699616.

outcomes. We remain encouraged that CMS continues to build upon last year's progress to increase access to patient navigation services by reimbursing for these services under Medicare – laying the foundation for all types of patient navigation services to be sustainable, scalable, and broadly accessible in the future.

The American Cancer Society National Navigation Roundtable (ACS NNRT) fielded a survey to 175 organizations with patient navigation programs to gather information about the use of the CMS PIN codes since the codes went into effect January 1, 2024. The ACS NNRT will continue to collect this survey data over the coming months to elucidate readiness of uptake, current use, and any challenges in utilizing the PIN codes. We want to use these data as a resource to CMS to continue to build upon the progress to date. Survey respondents are geographically distributed across the US and represent a wide range of institutions including NCI-designated cancer centers, NCCN member institutions, academic institutions, large and small clinical settings, and community-based or non-profit organizations. A variety of professional perspectives are represented as well, with administrators of navigation programs comprising the largest segment (38%), followed by navigation supervisors (30%), patient navigators (27%), and others (22%).

Early data is revealing that 59% of those surveyed are either implementing the CMS PIN and/or CPT PCM codes or are working toward implementing them. Their reported experiences clearly demonstrate a positive impact on access to patient navigation services: 78% anticipate expanding an existing program or creating a new navigation program, and institutions plan to use the codes to support a variety of roles including nurse navigators (81%), patient navigators (64%), and social work navigators (41%). Furthermore, while there is a clear need for navigation services in oncology, over one-quarter (29%) report plans to implement the codes for other disease states/departments.

The institutions working toward implementing the codes anticipate several benefits, including a return on investment (69%), improved patient outcomes (68%), increased patient and provider satisfaction (60%), income generation (59%), and improved treatment adherence (52%). A number of additional key benefits are observed by institutions that have not yet begun implementing the new codes as well as by those that have. Over a third (39%) say the development of the new codes has increased buy-in or support of a navigation program from leadership, 30% say it has expanded knowledge through regional/national workshops, 25% say it has increased job satisfaction for navigators, and 24% report the development of the new codes resulting in the approval of new patient navigation positions.

The survey also identified challenges to implementing the new codes that suggest opportunities to enhance utilization. These can be categorized into three main themes: administrative and workforce burden, a need for education/information about how to use or implement the codes, and concerns about out-of-pocket patient costs and organizational reimbursement. The administrative and workforce challenges are the most frequently cited, both among organizations working toward implementing the codes and as a reason why some institutions have yet to implement the codes. Chief among these are the burden of documentation/billing, challenges integrating with the electronic health record, and training/staffing/workforce issues. As we continue as a community to collect further data and analyze the results, we look forward to meeting with you and your team to discuss the findings.

Our groups offer specific comments on the following policies:

II. PROVISIONS OF THE PROPOSED RULE

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)

Telehealth List: In the CY 2024 final Physician Fee Schedule, CMS did not finalize PIN services on the Medicare Telehealth Services List but noted the agency would consider the issues for future rulemaking.

Telehealth provides cancer patients and survivors with a convenient means of accessing both cancer care and primary care. The importance of adaptable policies around telehealth that allow patients to reap the optimal benefits of telehealth were demonstrated during COVID-19 pandemic and many of the telehealth flexibilities enacted during the COVID-19 Public Health Emergency improved access to care for cancer patients.

Although many elements of PIN services involve direct in-person contact between the auxiliary personnel and the patient, some PIN services might be performed via two-way audio. For instance, for many underserved and rural areas, direct contact via two-way audio and audio-video may be more common than in-person given the patient burden and arranging services to support their care (e.g. transportation), and therefore it would be important to allow sites to provide PIN in the most impactful and efficient direct contact modalities. Additionally, patients benefit from follow-up phone calls to coordinate access to resources, assess additional needs, and provide emotional support between in-person appointments.

We ask CMS to confirm that synchronous virtual communication like telephone calls count towards reimbursable minutes, in addition to asynchronous virtual communication and in-person interactions. We also appreciate CMS' clarifying that the PIN codes were not added to the Medicare Telehealth List because these services are ordinarily furnished outside of an in-person, face-to-face visit, and so are outside the scope of Medicare telehealth services and therefore are not necessary to add to the Medicare Telehealth Services List. Still, we encourage CMS to continue to monitor whether excluding PIN services from the telehealth list creates any limitation on providing these services and revisit the decision, if needed.

Barriers to furnishing the service addressing health-related social needs: CMS is requesting feedback regarding any barriers to furnishing the services addressing health-related social needs, and if the service described by the current PIN codes allow practitioners to better address unmet social needs that interfere with the practitioners' ability to diagnose and treat the patient.

Waiver of beneficiary cost sharing obligations: Patient navigation has become increasingly recognized for improving patient outcomes, reducing unnecessary treatment costs and increasing patient experience. Cost is a proven barrier to getting care ² and can lead to delays in follow-up testing and treatment, which will ultimately impact a person's survival. For example, research shows that being required to pay for cost-sharing – including co-pays, co-insurance and deductibles – can be a significant barrier for individuals who need preventive services.³ This is especially true for people with limited incomes, for whom these payments can represent a significant percentage of their income. Removing cost-sharing for preventive services has proven to increase the use of those services. For instance, following the removal of cost-sharing for preventive services in Medicare, there was a statistically

² The Clinical Practice Guideline Treating Tobacco Use and Dependence 2008 Update Panel, Liaisons, and Staff. (2008). A Clinical Practice Guideline for Treating Tobacco Use and Dependence: 2008 Update: A U.S. Public Health Service Report. *American Journal of Preventive Medicine*, 35(2), 158–176.

<http://doi.org/10.1016/j.amepre.2008.04.009>.

³ Han X, Robin Yabroff K, Guy GP, Zheng Z, Jemal A. Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States? *Prev Med*. 2015 Sep;78:85-91. doi: 10.1016/j.ympmed.2015.07.012.

significant uptake in mammography screenings among Medicare enrollees.⁴

We encourage CMS to work with Congress to allow them statutory authority to waive cost sharing for valuable coordination of care services such as PIN services, since the additional cost could prevent people who most need these services from benefitting from them. In the recent ACS NNRT survey, nearly half of the institutions surveyed that are not yet implementing the codes report concerns about patient costs as a contributing factor.

Allow multiple providers to bill for PIN codes: As CMS noted in the CY 2024 Physician Fee Schedule final rule, PIN services “is perhaps most critical when a patient is first undergoing treatment for such conditions, due to the extensive need to access and coordinate care from a number of different specialties or service-providers for different aspects of the diagnosis or treatment, and in some cases, related social services (for example, surgery, imaging and radiation therapy, and chemotherapy for cancer).” Thus, CMS recognizes that multiple specialties can be contributing to the patient’s care, even for a single condition, with navigators housed within each of these specialties. While CMS currently allows for one billing practitioner for each condition if there are multiple conditions present the CY 2024 PFS final rule did not allow for multiple practitioners per condition.

As patients progress along their treatment journey, they often do have times of appropriate overlapping care among various providers. This overlap can lead to multiple billing practitioners in the same month with multiple navigators appropriately involved in the patient’s care. For example, a patient’s treatment plan may include surgery, chemotherapy, and radiation within short succession or concurrently, or they may receive chemotherapy at one facility due to distance from the facility and then radiation at another. Concurrent palliative care is another example. In each of these examples, the patient could benefit from navigation, and coordination across specialties and facilities is expected, but each billing practitioner with auxiliary personnel providing PIN services should be eligible for reimbursement of their services.

We recommend that CMS allow more than one billing practitioner per month per eligible condition with the additional requirement that the concurrent care be documented by both billing practitioners as necessary for the patient’s treatment plan.

Certification of auxiliary personnel in PIN services: CMS is also requesting information on whether there are other certifications, and/or training requirements that are not adequately captured in current coding and payment for these services.

If someone is certified, regardless of the certification entity, the rule assumes the person has been trained in the PIN training requirements; however, not all certifications require the PIN training requirements. We recommend that CMS clarify that PIN training requirements apply to both certified and non-certified auxiliary personnel to demonstrate that they are providing PIN services that are eligible for reimbursement.

Under the leadership of the ACS, several of the undersigned organizations have committed to playing a leading role in training and establishing certification standards that comport with the requirements provided in the FY2024 PFS. In 2022, the Professional Oncology Navigation Task Force developed the Oncology Navigation Standards for Professional Practice, a set of oncology patient navigation standards intended to provide guidance on the knowledge and skills that all professional navigators should possess. The task force includes several leading oncology focused professional organizations as well as patient advocacy groups. The development of these standards ultimately built upon the foundational steps laid by the Biden Administration's Cancer Initiative Working

⁴ Cooper GS, et al. Changes in Receipt of Cancer Screening in Medicare Beneficiaries Following the Affordable Care Act JNCI J Natl Cancer Inst (2016) 108 (5): djv374 doi:10.1093/jnci/djv374.

Group on Patient Navigation as part of the initial 2016 White House Cancer Moonshot initiative.

The Oncology Navigation Standards of Professional Practice define the knowledge and skills all professional navigators should possess to deliver high-quality, culturally competent, and ethical services to people impacted by cancer and should serve as a critical source document and the backbone for certification and training efforts. These standards establish benchmarks for healthcare employers and provide information for policy and decision makers, healthcare professionals, and the public to understand the role of professional oncology navigators. The standards are intended to guide PIN service providers and may be applied differently, as appropriate, in diverse cancer care settings. As such, there are numerous existing evidence-based certifications and trainings that could help to inform CMS' decisions regarding certification.

Community Based Organization (CBO) collaboration with billing practitioners: CMS is interested in how CBOs are collaborating with billing practitioners, including current or planned contracting arrangements, and if there is anything else CMS should do to clarify services where auxiliary personnel can be employed by CBOs.

For many underserved patients, community-based and cultural navigators provide essential links to accessing timely and quality care. For example, the Native American Cancer Research Corporation (NACR) based in Colorado is a non-profit organization attempting to create a formal Memorandum of Agreements with the University of Colorado Cancer Center, National Jewish Health, Rose Medical Center, Rocky Mountain Cancer Center, Saint Joseph Hospital, Presbyterian-St. Luke's Medical Center and others to reimburse NACR for cultural oncology patient navigation services. Nationally, American Indian and Alaska Native (AIAN) people have the highest incidence of and mortality from cancers of the colorectum, kidney, liver, and lung and bronchus than any population. AIAN people also have the highest incidence rates for cervical cancer and the highest cervical cancer mortality rates alongside Black individuals.⁵ Providing cultural oncology patient navigation services like those provided by the NACR's patient navigators are essential in assisting the AIAN population access quality, timely and appropriate care.

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 but recognize this means that funding for these services only goes directly to the billing provider and not the collaborating CBO(s). CMS should continue to encourage subcontracting with CBOs to ensure funding includes CBOs, which can be underfunded or under-resourced organizations. We recommend that CMS encourage Medicare to take advantage of the opportunity to engage CBOs to ensure these critical providers remain sustainable and make these services more accessible to the communities that need these services most.

Related services not described by the current coding: CMS is seeking comment on any related services that may not be described by the current coding CMS finalized in the CY 2024 PFS final rule and that are medically reasonable and necessary "for the diagnosis or treatment of illness or injury" under section 1862(a)(1)(A) of the Act.

The proposed rule also currently limits PIN services to services that practitioners would only provide during active cancer treatment (i.e., services for a serious, high-risk condition expected to last at least 3 months that places the patient at significant risk of hospitalization, acute exacerbation, functional decline or death). Although PIN services

⁵ American Cancer Society Cancer Action Network. *Just the Facts: Cancer Screening Disparities Among American Indian and Alaska Native People; 2024.*
https://www.fightcancer.org/sites/default/files/just_the_facts_aian_cancer_screening_disparities_fact_sheet_fina_4.25.24.pdf

during active cancer treatment are vital, PIN services can also be instrumental throughout a patient's cancer journey starting with prevention, early detection, diagnosis and into survivorship.

Early detection of cancer through screening can improve survival and reduce mortality by detecting cancer at an early stage when treatment is more effective. For instance, patient navigators have been shown to help increase cancer screening rates among historically marginalized racial and ethnic populations by providing access to disease prevention education, conducting community outreach, and facilitating public education campaigns.^{6,7,8,9,10} One study showed that women in the patient navigation intervention group had significantly higher likelihood of being up to date on their mammography screening at the end of the follow-up period compared to women in the control group who did not receive these services, with the largest impact among African American Medicare beneficiaries living in urban areas who were previously not up to date on their breast cancer screenings.¹¹

Additionally, AIAN men and women have reported increased screening participation and follow-up once cultural navigation services are provided, both within urban and reservation settings.^{12,13} This is especially important as the most recent data show breast and lung cancer screening rates were lowest among American Indian and Alaska Native people compared to other race and ethnicities, and below all race and ethnicities combined for cervical, colorectal, and prostate cancer screening.¹⁴ Prevention programs conducted and evaluated by qualified cultural oncology patient navigators that emphasize daily physical activity, healthy eating, reducing exposure to environmental contaminants have resulted in significant healthier behaviors among AIAN community members. We encourage CMS to explore reimbursement pathways for PIN services that also provide prevention and

⁶ Natale-Pereira, A., Enard, K., Nevarez, L., Jones, L. (2011) "The Role of Patient Navigators in Eliminating Health Disparities", *Cancer*, p. 3543-3552 <https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.26264>.

⁷ Guide to Community Preventive Services. Cancer Screening: Patient Navigation Services to Increase Cervical Cancer Screening and Advance Health Equity. <https://www.thecommunityguide.org/findings/cancer-screening-patient-navigation-services-to-increase-cervical-cancer-screening.html>. Page last updated: January 24, 2023.

⁸ Nelson HD, Cantor A, Wagner J, et al. Effectiveness of patient navigation to increase cancer screening in populations adversely affected by health disparities: a meta-analysis. *J Gen Intern Med*. 2020;35(10):3026-3035. doi:10.1007/s11606-020-06020-9.

⁹ Marshall, J.K., Mbah, O.M., Ford, J.G. et al. (2016) "Effect of Patient Navigation on Breast Cancer Screening Among African American Medicare Beneficiaries: A Randomized Controlled Trial". *Journal of General Internal Medicine*, 31, p. 68–76. <https://doi.org/10.1007/s11606-015-3484-2>.

¹⁰ Natale-Pereira, A., Enard, K., Nevarez, L., Jones, L. (2011) "The Role of Patient Navigators in Eliminating Health Disparities", *Cancer*, p. 3543-3552, <https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.26264>.

¹¹ Marshall, J.K., Mbah, O.M., Ford, J.G. et al. (2016) Effect of Patient Navigation on Breast Cancer Screening Among African American Medicare Beneficiaries: A Randomized Controlled Trial. *Journal of General Internal Medicine*, 31, p. 68–76. <https://doi.org/10.1007/s11606-015-3484-2>.

¹² Batai K, Sanderson PR, Joshweseoma L, Burhansstipanov L, Russell D, Joshweseoma LL, Hsu CH. Formative Assessment to Improve Cancer Screenings in American Indian Men: Native Patient Navigator and mHealth Texting. *Int J Environ Res Public Health*. 2022 May 27;19(11):6546. doi: 10.3390/ijerph19116546. PMID: 35682130; PMCID: PMC9180909.

¹³ Batai K, Sanderson PR, Hsu CH, Joshweseoma L, Russell D, Joshweseoma L, Ojeda J, Burhansstipanov L, Brown SR, Ami D, Saboda K, Harris RB. Factors Associated with Cancer Screening Among Hopi Men. *J Cancer Educ*. 2022 Aug;37(4):915-923. doi: 10.1007/s13187-020-01900-4. Epub 2020 Oct 20. PMID: 33083892

¹⁴ American Cancer Society Cancer Action Network. *Just the Facts: Cancer Screening Disparities Among American Indian and Alaska Native People; 2024*. https://www.fightcancer.org/sites/default/files/just_the_facts_aian_cancer_screening_disparities_fact_sheet_fina_4.25.24.pdf

screening services, if these services are not covered under any proposed changes to the Community Health Integration (CHI)

Navigation services are also critical in survivorship care. We urge CMS to consider extending eligibility for navigation services for up to one year following the period when a patient meets the current eligibility criteria. For example, a person with a new cancer diagnosis may have 6 months of cancer treatment, and benefit from navigation services during this time. Then, that patient enters a survivorship phase of care in which they are not receiving active cancer treatment but may continue to have intense needs as a result of the cancer or its treatment. Research shows that cancer survivors can experience significant psychosocial, financial and lifestyle impacts during years after completing treatment. While expenditures for cancer treatment tend to be highest in the active/initial treatment and end-of-life phases of care^{15,16}, cancer survivors who have finished their active treatment also experience higher out-of-pocket costs compared to individuals who have never been diagnosed with cancer.¹⁷ Cancer survivors continue to have higher health care costs after active treatment for several reasons, including monitoring for disease progression or recurrence, ongoing side effects from cancer treatment, mental health treatment and other late and long-term effects.¹⁸

While a survivor could benefit from CHI services if social determinant of health (SDOH) needs are present, if the survivor does not have SDOH needs but their needs warrant the intensity of navigation time required to bill for PIN services, CMS should reimburse for this care. Doing so will improve the health and wellbeing of beneficiaries. Additionally, many primary care physicians do not fully understand the post-cancer treatment needs of their returning patients. Patient navigators can be that important link to successfully guiding recovering cancer patients into survivorship and through the transition back to their primary care provider. We urge CMS to ensure the PIN services are included as part of survivorship care.

Conclusion

Thank you for your leadership on behalf of individuals with cancer. ACS CAN, ACS, and the ACS National Navigation Roundtable, a coalition of over 100 organizations with the goal of achieving health equity and access to quality care across the cancer continuum through effective patient navigation, stand ready to assist with ongoing implementation and consideration of next steps to build on the progress of this work. As the ACS NNRT continues fielding our previously mentioned and cited survey, we welcome the opportunity to share those findings with CMS to help the agency increasingly understand the current uptake of the PIN codes as well as any barriers or challenges to utilizing the PIN codes. Should you have any questions or need additional information, please contact Gladys Arias, Principal for Health Equity Policy Analysis and Legislative Support at ACS CAN and Co-Chair of the ACS NNRT Policy Task Group at gladys.arias@cancer.org.

¹⁵ Cited source defines these terms as follows: “the initial phase, defined as the first 12 months after each diagnosis; the end-of-life (EOL) phase, defined as the 12 months before death among survivors who died, and the continuing phase, the months in-between the initial and the EOL phases.”

¹⁶ Angela B. Mariotto, K. Robin Yabroff, Yongwu Shao, Eric J. Feuer, Martin L. Brown, Projections of the Cost of Cancer Care in the United States: 2010–2020, JNCI: Journal of the National Cancer Institute, Volume 103, Issue 2, 19 January 2011, Pages 117–128, <https://doi.org/10.1093/jnci/djq495>.

¹⁷ Ekwueme DU, Zhao J, Rim SH, de Moor JS, Zheng Z, Khushalani JS, Han X, Kent EE, Yabroff KR. Annual Out-of-Pocket Expenditures and Financial Hardship Among Cancer Survivors Aged 18-64 Years - United States, 2011-2016. MMWR Morb Mortal Wkly Rep. 2019 Jun 7;68(22):494-499. doi: 10.15585/mmwr.mm6822a2. PMID: 31170127; PMCID: PMC6553808.

¹⁸ American Cancer Society Cancer Action Network. The Cost of Cancer Survivorship 2022. <https://www.fightcancer.org/policy-resources/costs-cancer-survivorship-2022>

Sincerely,

American Cancer Society

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