



September 8, 2023

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 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Coverage Policies
88 Fed. Reg. 52262 (August 7, 2023)

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 patient advocacy organizations, we appreciate the opportunity to offer our comments in response to the patient illness navigation (PIN) and community health integration (CHI) provisions of the CY2024 Centers for Medicare and Medicaid Services (CMS) Physician Fee Schedule proposed rule. Each of the 59 signatories is committed to advancing navigation services for patients with serious illness.

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 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 both ensuring access to these important services and for addressing health disparities across the cancer continuum.

We are encouraged by this important first step CMS has proposed 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. Our groups offer specific comments on the following policies:

II. PROVISIONS OF THE PROPOSED RULE

Services Addressing Health-Related Social Needs (Community Health Integration Services and Principal Illness Navigation Services)

CMS is exploring ways to remove health-related social barriers that interfere with practitioners' ability to deliver a medically necessary plan of care to help patients with serious illnesses like cancer navigate the health care system.

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

CMS notes that while work is currently being done, to the extent it is reimbursed it is often included in payment for other services, such as evaluation and management (E/M) visits. CMS also notes that because this work is not specifically identified in the current coding system it is often underutilized and undervalued. As such, CMS proposes to create new coding to identify these services and distinguish them from current care management services. We support this provision as the expansion and sustainability of patient navigation services will only be achieved through a reimbursement strategy that helps increase access to patient navigation services needed to ensure better patient care experiences and outcomes following a cancer diagnosis. Furthermore, the billing code can be identified in claims data and used for quality improvement efforts which aim to better understand how providers are delivering services and their association with patient outcomes.

Principal Illness Navigation (PIN) Services: CMS acknowledges the mounting evidence supporting the use of patient navigation services, particularly for individuals who are undergoing high-risk serious illnesses such as cancer. CMS notes that while it currently provides reimbursement of care management services, this code tends to be more focused on clinical – rather than social aspects – of care. To address this, CMS proposes that beginning in CY2024, it will use a new G code (GXXX3) to reimburse PIN services that are focused on patients with a serious, high-risk illness who may not have Social Determinants of Health (SDOH) needs. For individuals who may have SDOH needs, CMS also proposes to establish a new code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit through a new G Code (GXXXX5), for the administration of a standardized, evidence-based SDOH risk assessment of 5 to 15 minutes not more often than every 6 months.

We applaud CMS for recognizing that individuals with serious, high-risk illnesses such as cancer often need additional support to coordinate and access timely, appropriate care. The use of patient navigation services has been shown to improve patient outcomes, reduce unnecessary treatment costs and increase patient satisfaction.²

Certification or training of auxiliary personnel in PIN services: Several studies demonstrate that the fidelity to principles of high-quality navigation is key to achieving improved outcomes.³ Like other healthcare fields, professional navigation requires a set of skills and competencies that must be instilled, reviewed, and assured. Previous demonstrations of professional navigation have been successful when they included robust training/curriculum with frequent audits of performance, certification of proficiencies with commitment to ongoing education, and facilitation of training/certification through a centralized, credible body. Furthermore, as professional navigation is an evolving role with a continuously updating evidence base, a commitment to longitudinal training and certification is crucial to ensuring that navigation delivery is aligned with the most recent evidence. We agree with the CMS proposal to require that all auxiliary personnel who provide PIN services must be certified or trained to provide all PIN service elements and that such personnel must be authorized to perform these services under applicable State law or regulations. In States that do not have applicable licensure, certification or other laws, CMS proposes auxiliary personnel be trained to provide these services.

We strongly support this requirement. While we recognize that PIN services will differ depending on the individual needs of the patient and their informal caregivers, as well as the communities in which they live, we believe there must be baseline cancer-specific training and education of auxiliary personnel on how to address the holistic needs of the patient. For example, successful navigation of patients with cancer undergoing treatment involves the deployment of skills and care plans different from other diseases like heart failure and chronic respiratory disease. Patients with cancer face unique challenges related to accessing multidisciplinary care (e.g., medical oncologist,

² Kline, R. et al., (2019). "Patient Navigation in Cancer: The Business Case to Support Clinical Needs", JCO Oncology Practice, <https://ascopubs.org/doi/full/10.1200/JOP.19.00230>

³ American Cancer Society. "A Decade Later: The State of Patient Navigation in Cancer Care." *Cancer*, July 2022, <https://acsjournals.onlinelibrary.wiley.com/toc/10970142/2022/128/S13%20>

radiation oncologist, surgical oncologist, and interventional radiologist), enrollment in clinical trials, and a rapidly-evolving standard of care. Thus, training must be high-quality, evidence-based, and timely. It should also be culturally informed, patient-centered, and solution-oriented (in terms of addressing barriers to access and care).

Under the leadership of the ACS, several of the undersigned organizations have committed to playing a leading role in training and establishing standards of practice that comport with the requirements provided in the proposed rule. 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 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. There are numerous other existing evidence-based training and/or certification programs that could help to inform CMS's decisions regarding certification. 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.

We believe that entities that provide continuous training and certification of cancer-specific navigation should have the breadth and depth that reflects the complexity and variety of cancers that patients face. For example, we believe such entities should have expertise in all cancers, including solid tumors, hematologic malignancies, and transplantation. Furthermore, we believe that ideally these entities would have a national footprint alongside close relationships with navigation-providing bodies (e.g., health systems, provider groups, cancer centers) so that uptake of training and certification can commence in early 2024. Lastly, training and certification entities must have credibility, recognizability, and long-term experience in the cancer space so as to encourage uptake among the professional navigation workforce.

Time and duration of PIN services: CMS is seeking comment on what is the typical amount of time practitioners spend per month providing PIN services as well as the typical duration, in terms of the number of months. CMS is proposing that PIN services include 60 minutes per calendar month and that only one practitioner per beneficiary per calendar month can bill for PIN services, and that each additional 30 minutes per calendar month is then billed separately under a different billing code.

We caution that this time frame could be limiting for cancer patients — particularly those at the beginning of their treatment — who may need a variety of PIN services over the course of one month or may need multiple visits involving PIN services. In both cases, one PIN related visit a month does not suffice. PIN services, particularly for a complex chronic illness like cancer, often encompass a spectrum of services across a large medical team — potentially requiring more frequent use of PIN services.

Our groups also encourage CMS to consider whether the one hour per month could be increased and broken down into other time increments to accommodate more visits per month. For instance, rather than limiting PIN services to one 60 minutes per month, PIN services could be increased to 120 minutes per month and be broken down into 30-minute increments, and additional 30 minutes per calendar month could still be added. Or perhaps allow for eight 15-minute increments over the course of one month when a patient may require several consultations that take less time than anticipated. Allowing for greater time and flexibility in how the time and duration of PIN services can be billed over the course of one month would allow practitioners to prioritize patient-centered care,

better assess a patient's SDOH related needs and ensure that all the necessary PIN services can be provided to the patient.

Patient consent for PIN services: CMS is seeking comment on whether it should require patient consent for PIN services. CMS also notes that statutory constraints prohibit the Agency from waiving patient cost sharing for PIN services.

We urge CMS to require that PIN services require advance patient consent before services can be provided, but without setting consent requirements in a manner that would be overly burdensome to the patient or provider and thereby become a barrier to care. Proper consent in this context should be a flexible process designed to meaningfully inform the patient of the benefit of PIN services, the limitation of those services, and the patient cost-sharing responsibilities. Moving forward, we also urge 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.

Documentation in the medical record: CMS proposes that the time spent furnishing PIN services be documented in the medical record in its relationship with the serious, high-risk illness.

We support this requirement. The undersigned groups believe that documentation in the medical record is an important requirement to better facilitate coordination among providers who are responsible for an individual's care. This is particularly important for cancer patients who are living with a complex disease and may also have comorbid conditions which necessitate the services of multiple specialists (e.g., oncologist, cardiologist, endocrinologist). Documentation in the medical record ensures that providers who may not be directly providing patient navigation services are made aware of the needs of the individual patient and what is being done to address those needs.

Service elements in the proposed PIN services code: CMS is requesting comments on whether there are other elements that should be included in the proposed PIN services code. We strongly support the creation of a new code to better allow CMS to track the use of PIN services and encourage the Agency to finalize this proposal effective January 1, 2024.

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 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. 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.^{4,5,6,7,8} We encourage CMS to explore reimbursement pathways for PIN services that also provide prevention and screening services, if these services are not covered under the proposed CHI codes. Navigation services are also critical in survivorship care. Many patients who complete their treatment do not know what steps to take next. Some may need physical or occupational therapy. Others require nutritional counseling. And all need clear direction in terms of the steps to take to prevent their cancer from returning and to treat any lasting effects resulting from cancer treatment. Unfortunately, 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 PIN services are included as part of survivorship care.

Where and how PIN services will be provided: CMS believes that many of the elements of PIN would involve direct contact between the auxiliary personnel and the patient and that some services may not necessarily be in-person but some portion of services might be performed via two-way audio.

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. 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 the COVID-19 pandemic and many of the telehealth flexibilities enacted during the COVID-19 Public Health Emergency improved access to care for cancer patients. Therefore—similar to SDOH Risk Assessment codes—we encourage CMS to include PIN services on the telehealth list and urge Congress to take up permanent telehealth legislation to ensure Medicare beneficiaries continue to have the option to see their providers in a manner that is most convenient to them.

Community Health Integration Services

CMS also proposes to create two new G codes describing community health integration (CHI) services performed by certified or trained auxiliary personnel, including patient navigators, to address SDOH needs that are significantly limiting the ability to diagnose or treat problems addressed in an initiating E/M visit. CMS proposes that SDOH(s) may include, but are not limited to, food insecurity, transportation insecurity, housing insecurity, and unreliable access to public utilities to the extent these issues limit a practitioner's ability to diagnose or treat a medical issue.

The undersigned groups support CMS' proposal to add two new G codes (GXXX1 and GXXX2) to help address

⁴ 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>.

⁵ 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.

⁶ 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.

⁷ 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>

⁸ 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>

Medicare beneficiaries whose health-related social needs impact their ability to access care needed for effective diagnosis and treatment. Thirty-six percent of Medicare beneficiaries have incomes at or below 200% of the federal poverty level,⁹ many of whom can benefit from facilitating access to community-based services to address SDOH. Research also shows how differences in SDOH — specifically housing, transportation, and food insecurity among patients with cancer — are associated with profound inequities in cancer incidence, care delivery, and patient outcomes, including stark disparities in survival.¹⁰ People who do not have access to resources that protect, improve, and maintain a good quality of life can cause them to experience unfair and unjust cancer disparities. Further, addressing SDOH can have a critical impact in improving cancer prevention and early diagnosis.

As with our comments on PIN services above, we would strongly urge CMS to require flexible, but meaningful patient consent to receive CHI services, particularly in light of the cost-sharing obligations as CMS is statutorily prohibited from waiving cost sharing. Additionally, similar to PIN services, we encourage that CMS consider whether the one hour per month time and duration limitations for CHI services could be broken down into other time increments to accommodate more visits per month. Finally, given the proposed limitation of PIN services to active treatment, we also urge CMS to monitor and seek future comment on whether CHI codes are effective in supporting navigation services across other parts of the care journey, such as access to screening and early detection as well as survivorship care and to adjust the codes accordingly if they do not reach this critical aspect of care.

Conclusion

Thank you for your leadership on behalf of individuals with cancer. ACS, ACS CAN and the 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 implementation and consideration of next steps to build on the progress of this work. 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.

Sincerely,

American Cancer Society / American Cancer Society Cancer Action Network
Academy of Oncology Nurse & Patient Navigators
Adventist Health White Memorial
Alliance for Women's Health and Prevention
American Sexual Health Association & National Cervical Cancer Coalition
American Society for Clinical Pathology
Amorvard Development Foundation
Association of American Cancer Institutes
Association of Community Cancer Centers
Association of Oncology Social Work
Association of Physician Associates in Obstetrics and Gynecology (APAOG)
Azra AI
Boston Medical Center

⁹ Medicare Payment Advisory Commission. https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_SEC.pdf (chart 2-5).

¹⁰ Bona, K., & Keating, N. (2022). Addressing Social Determinants of Health: Now Is the Time. JNCI: Journal of the National Cancer Institute, Volume 114, Issue 12, December 2022, Pages 1561–1563, <https://doi.org/10.1093/jnci/djac137>

Brem Foundation to Defeat Breast Cancer
California Colorectal Cancer Coalition
Cancer Support Community
CancerCare
Carrum Health
Center for Health Law and Policy Innovation of Harvard Law School
Cervivor, Inc.
Colon Cancer Prevention Project
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Fox Chase Cancer Center/Temple University Health System
Guardant Health
Latino Research and Policy Center at the Colorado School of Public Health, University of Colorado Anschutz Medical Campus
Lobular Breast Cancer Alliance, Inc.
Medical Oncology Association of Southern California, Inc.
Mount Sinai Tisch Cancer Center
National Association of Chronic Disease Directors
National Association of Nurse Practitioners in Women's Health (NPWH)
National Association of Social Workers
National Consortium of Breast Centers
National Patient Advocate Foundation
National Rural Health Association
New Mexico HPV Pap Registry
North Carolina Colorectal Cancer Roundtable
North Carolina Oncology Navigator Association
OSF Healthcare Saint Francis Medical Center
Patient Access Network (PAN) Foundation
Prevent Cancer Foundation
Sarah Cannon Cancer Institute
Sisters Network Inc.
Susan G. Komen
Texas Health Resources
The American Society for Clinical Pathology
The George Washington University Cancer Center
The Ohio State Comprehensive Cancer Center
The University of Texas MD Anderson Cancer Center
Triage Cancer
University Of Alabama at Birmingham
University of Illinois at Chicago
University of Illinois Cancer Center
University of North Carolina Hospitals healthcare system (UNC Health)
University of Texas Southwestern Medical Center
Virginia Commonwealth University (VCU) Massey Cancer Center
Washington Colon Cancer Stars
Women Veterans Interactive Foundation