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:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the calendar year (CY) 2024 Medicare Physician Fee Schedule proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society’s (ACS) nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN offers comments on the following policies:

- Principal Illness Navigation Services
- Community Health Integration Services
- Social Determinants of Health (SDOH) – Proposal to establish a stand-alone G Code
- Telehealth Provisions
- Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services
- A Social Determinants of Health Risk Assessment in the Annual Wellness Visit

II. PROVISIONS OF THE PROPOSED RULE

Services Addressing Health-Related Social Needs (Community Health Integration CHI Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

CMS is exploring ways to remove health-related social barriers that interfere with practitioners’ ability to execute a medically necessary plan of care to help patients with serious illnesses navigate the health care system. CMS notes that while this 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 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. ACS CAN strongly supports 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 notes 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 aspects – 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 for PIN services that are focused on patients with a serious, high-risk illness who may not have Social Determinants of Health (SDOH) needs.

ACS CAN applauds CMS for recognizing that individuals with serious, high-risk illnesses such as cancer often need additional support to address the social aspects of their care. ACS and ACS CAN have a long-standing commitment to ensuring that individuals have access to patient navigators, professionally trained individuals who offer assistance to patients, families and caregivers to help them overcome health care system barriers and facilitate timely access to quality health care.1 The use of patient navigation services has been shown to improve patient outcomes, reduce unnecessary treatment costs and increase patient satisfaction.2

In 2005, ACS established its own Patient Navigation program by directly hiring Patient Navigators that reached over 700,000 patients at hospital sites across the country over 15 years. In 2017, ACS established the National Navigation Roundtable (NNRT), a nationwide coalition of over 100 organizations organized around the goal of achieving health equity and access to quality care across the cancer continuum through effective patient navigation services. We offer the following comments on the provisions of the proposed rule:

**Certification 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. ACS CAN agrees with CMS proposal to require that all auxiliary personnel who provide PIN services must be certified or

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1 ACS and ACS CAN are joining other groups in the submission of comments solely in response to the inclusion of the PIN services provision of the CY2024 Medicare Physician Fee Schedule proposed rule.


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.

ACS and ACS CAN support this requirement. While we recognize that PIN services will differ depending on the individual needs of the patient and their caregivers, as well as the communities in which they live, we believe there should 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, 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 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).

ACS, ACS CAN, and the American Cancer Society’s National Navigation Roundtable have committed to playing a leading role in training and establishing certification standards that comport with the certification 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 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.

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 certifications training 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.

ACS CAN believes 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

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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.

ACS CAN cautions 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.

ACS CAN encourages 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-minute service per month, PIN services could be increased to 120 minutes per month and broken down to 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 consultants 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 of 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.

ACS CAN urges CMS to require that PIN services require advance patient consent before services can be provided. We believe that proper consent must meaningfully inform the patient of the benefit of PIN services, the limitation of those services, and the patient cost-sharing responsibilities. 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.

**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.
ACS CAN supports this requirement. We 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 may 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 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. One study showed that women with access to patient navigation services had significantly higher likelihood of being up to date on their mammography screening compared to women 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. Additionally, given that many cancer screening guidelines are based on family history and personal risk factors, patient navigators can offer individualized advice and help patients assess individual eligibility, improving treatment adherence by increasing a patient’s cancer knowledge and understanding their unique health risks.

We encourage CMS to explore reimbursement pathways for PIN services that also provide prevention education, conducting community outreach, and facilitating public education campaigns.

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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 the 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 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 COVID-19 pandemic and many of the telehealth flexibilities enacted during the COVID-19 Public Health Emergency improved access to care for cancer patients. We encourage Congress 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 proposes to create two new G codes describing community health integration (CHI) services performed by certified or trained auxiliary personnel 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.

ACS CAN supports CMS’ proposal to add two new G codes (GXXX1 and GXXX2) to help address Medicare beneficiaries whose SDOH impact their ability to access care. Thirty-six percent of Medicare beneficiaries have incomes at or below 200% of the federal poverty level, many of whom can benefit from facilitating access to community-based services to address SDOH. Research from ACS 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

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outcomes, including stark disparities in survival. 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.

As with our comments on PIN services above, we would strongly urge CMS to require 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.

**Social Determinants of Health (SDOH) – Proposal to establish a stand-alone G Code**

In furtherance of HHS’ Strategic Approach to Addressing SDOH to Advance Health Equity, CMS 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. CMS proposes 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.

ACS CAN supports CMS’ proposal to create a new G code to encourage practitioners to learn more about their patients’ SDOH needs. Identifying the SDOH needs of an individual is only the first step in addressing those needs. If the practitioner is unable (or lacks the capacity) to connect the patient with resources and services to address those SDOH needs, the collection of information related to the patient’s SDOH needs can be seen by the patient as an unwelcomed intrusion into their private life. Therefore, we urge CMS to require that as a condition of payment for SDOH risk assessment practitioners certify they have the capacity to furnish CHI, PIN, or other care management services or be able to refer to the patient to community-based organization that has the capability to provide assistance. We would further encourage CMS to ensure that furnishing such services and/or referral to an external entity is conducted in a manner that will provide meaningful assistance to the individual. For example, providing a patient with a list of organizations and then connecting patient to these organizational resources that can offer assistance to address food insecurity is only meaningful if practitioners can help patients utilize one of the resources on the list, which contains accurate information (including hours of operation) of those organizations and rigorous confirmation that the list of organizations remains open and has the capacity to provide assistance to individuals.

Practitioner capacity is also important in the likelihood that a patient may have multiple SDOH related barriers that need to be addressed. In which case, an SDOH assessment may require multiple referrals across different community-based organizations. This referral process is likely to be better tailored to address a patient’s unique SDOH needs when a practitioner or facility is already aware of and currently

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has existing partnerships with various local community-based organizations.

CMS is also seeking comments on how these services would typically be provided and similar to the comments on the time and duration of PIN services above, ACS CAN encourages CMS to consider whether the 5 to 15 minutes per 6 months could be increased to at least 30 minutes but remain broken down in 5-to-15-minute increments to more visits in a 6 month timeframe. CMS should also consider increasing the frequency of when SDOH assessments should be conducted to more than only once per 6 months, particularly for individuals with cancer who may have multiple and/or simultaneous SDOH related needs. The current time and duration proposed does not provide enough time to adequately assess SDOH needs as well as create an action plan to address those identified needs.

**Payment for Medicare Telehealth Services Under Section 1834(m) of the Act**

CMS proposes to permanently add HCPSC code GXXX5 (administration of a standardized, evidence-based Social Determinants of Health Risk Assessment (SDOH) tool, 5-15 minutes) to the telehealth list (assuming CMS finalizes the proposed SDOH code).

As discussed in more detail above, ACS CAN supports the creation of the new code GXXX5, which will help identify an individual’s SDOH needs which may impair their ability to access health care services. We also support CMS’ proposal to permanently add this code to the list of telehealth codes to better ensure access to this tool for individuals – particularly those in rural and remote areas – who may rely on telehealth services for their health care. These individuals may be more likely to have SDOH barriers to care (e.g., transportation issues) and thus it is important for their provider to be aware of any concerns.

**Proposal to Implement Telehealth Provisions as Enacted by the Consolidated Appropriations Act, 2023**

CMS proposes to make policy changes to implement certain provisions of the Consolidated Appropriations Act of 2023 (CAA 2023), including provisions that extend certain Medicare telehealth flexibilities adopted during the COVID-19 Public Health Emergency (PHE), through December 31, 2024. These policy changes include:

- Removing restrictions on telehealth originating sites to allow telehealth services to patients located in any site in the U.S., including their home;
- Expanding the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech pathologists, qualified audiologists, federally-qualified health centers, and rural health clinics; and,
- Allowing the use of certain audio-only telehealth services.

ACS CAN was supportive of these flexibilities during the legislative process and applauds CMS for proposing to implement the necessary regulatory changes as enacted in the CAA, 2023. We urge the Agency to adopt these proposals.
Telehealth provides cancer patients and survivors with a convenient means of accessing both cancer care and primary care. A particular benefit of telehealth emerged during the COVID-19 PHE - cancer patients vulnerable to COVID-19 could conduct a video or audio visit with their providers from the safety of their home without risking additional exposure to the virus. The pandemic demonstrated the importance of adaptable policies around telehealth that allow patients to reap the optimal benefits of telehealth.

According to one survey of cancer patients and survivors about their experience with and interest in telehealth, an overwhelming majority that had telehealth visits believed their issues and questions were well-addressed.\textsuperscript{14} Fifty-five percent of respondents had a phone visit and 43% had a video visit with a telehealth provider about an issue related to their cancer care that otherwise would have been an in-person office visit (not a prescription refill or appointment booking). In both cases, 94% said their issues and questions were addressed well.

Many of the telehealth flexibilities enacted during the COVID-19 PHE improved access to care for cancer patients. Continuing these flexibilities for a temporary period is a positive step toward ensuring that people with cancer can continue to have the option to receive care via telehealth services and aligns FFS Medicare with benefits commonly offered by private insurance, including Medicare Advantage, that allow enrollees to access telehealth services in their own homes and services provided outside of rural areas. However, we encourage Congress take up permanent telehealth legislation to ensure FFS Medicare beneficiaries continue to have the option to see their providers in a manner that is most convenient to them.

\textbf{Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services}

Medicare pays for dental services if they are an integral part of a covered procedure. In the CY2023 Medicare Physician Fee Schedule final rule CMS identified certain clinical scenarios where payment is permitted under Medicare Part A or Part B for certain dental services. CMS is proposing to provide additional clarification of Medicare-covered dental services. Specifically, CMS is proposing that Medicare may cover dental services that are inextricably linked to other Medicare-covered medical services in the following situations: chemotherapy when used in treatment of cancer; CAR T cell therapy, when used in the treatment of cancer; and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer. In these circumstances CMS would pay for the following: dental or oral examination performed as part of a comprehensive workup (either inpatient or outpatient setting); medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with any of the services noted above; and services that are ancillary to these dental services (e.g., x-rays, the administration of anesthesia; and the use of the operating room). CMS also proposes to clarify that with respect to head and neck cancers, that Medicare payments may be made for covered dental services whether the cancer is primary or metastatic, regardless of site of origin, and regardless of initial modality of treatment.

ACS CAN supports CMS’ clarification of medically necessary dental services to be covered under the Medicare program. We are particularly pleased with CMS’ recognition that dental services are actually a part of certain cancer treatments. As CMS finalizes its policy to expand access to medically necessary dental services, we urge the Agency to conduct significant education and outreach to providers, Medicare Administrative Contractors (MACs), and enrollees to better educate stakeholders about the changed policy. This education and outreach will help to minimize confusion and unnecessary appeals.

**A Social Determinants of Health Risk Assessment in the Annual Wellness Visit**

CMS proposes to add other elements to the annual wellness visit (AWV) by adding a new SDOH Risk Assessment as an optional, additional element with an additional payment.

ACS CAN supports this proposal. As noted above, and as CMS notes in the proposed rule, SDOH have a major impact on an individual’s health care. We believe that allowing practitioners the option to provide a SDOH risk assessment as part of the AWV is critical to ensure that individuals with specific needs can be identified, informed and matched to services to address those needs. We are also particularly pleased that this assessment would not result in any additional cost-sharing for the individual provided that the service is furnished on the same day as the AWV.

CMS encourages clinicians to choose from several widely adopted evidence-based SDOH risk assessment tools in their AWV but does not restrict the proposal to a specific list of approved assessments. ACS CAN supports this recommendation to encourage practitioners use evidence-based tools informed by best practices and clinical expertise, while also allowing practitioners to determine which specific evidence-based tool will best assist in determining and addressing the unique SDOH needs and barriers of their patient population. By using existing evidence-based tools, practitioners also avoid the potentially time consuming and costly process of developing entirely new assessment tools and instead can focus on the implementation process and/or how to best customize the existing tool for the needs of their patients.

**CONCLUSION**

Thank you for the opportunity to comment on the CY2024 Medicare Physician Fee Schedule proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA  
President  
American Cancer Society Cancer Action Network