

CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS
ADDRESSING PUBLIC POLICY ISSUES IN CANCER

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-1784-P, Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies

Dear Administrator Brooks-LaSure:

The undersigned organizations represent cancer patients, health care professionals, researchers, and caregivers. We are pleased to offer comments on the Medicare physician fee schedule proposed rule for calendar year 2024.

We commend the proposals related to principal illness navigation (PIN) and community health integration (CHI) and offer recommendations for strengthening the proposals to ensure smooth implementation and robust utilization to improve the cancer care experience for Medicare beneficiaries. We also comment below on telehealth proposals and dental services proposals included in the rule. We express concerns about the adverse impact of the proposed rule on payment for radiation oncology services and the potential adverse impact on patient access to care.

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

The Centers for Medicare & Medicaid Services (CMS) describes the proposals to establish codes for community health integration (CHI) services, social determinants of health (SDOH) risk assessment, and principal illness navigation (PIN) services as part of the agency's ongoing, incremental effort to improve coding and payment for care management and coordination. CMS also notes that the new codes will support the agency's pillars for equity, inclusion, and access and will support the White House's Cancer Moonshot Initiative. We commend the agency for these proposals, which have the potential to improve access to quality cancer care and enhance the overall cancer care experience for Medicare beneficiaries.

We have in past years in connection with other PFS proposed rules offered our advice regarding CMS efforts related to care coordination codes. For example, we have recommended changes to the chronic care coordination codes that would clarify standards for billing and make the utilization of the codes a more straightforward proposition for those providing cancer treatment. We have also consistently and persistently recommended establishment of a cancer care planning code, which we see as an initial and critical step toward better coordination of care.¹ We offer below advice about community health integration, SDOH assessment, and principal illness navigation, to ensure these codes are utilized and that the services supported have a positive impact on cancer patients.

Community Health Integration Services

The agency acknowledges that it has received broad-based feedback and notes the increased recognition within the medical community regarding the ways in which social needs can interfere with the ability to diagnose and treat patients. In response, the agency proposes two new G codes that describe community health integration, or CHI, services performed by certified or trained auxiliary personnel. CHI services could be furnished monthly, as medically necessary, following an initiating evaluation and management (E/M) visit and under the general supervision of the billing practitioner.

CMS suggests that CHI services could be provided by community health workers. According to the proposed rule, all auxiliary workers who provide CHI services must be “certified or trained to perform all included service elements, and authorized to perform them under applicable State laws and regulations.” The agency outlines the core competencies that auxiliary personnel performing CHI services must have but also asks for public comment on the number of hours of required training, the training content, and who should provide the training.

We urge the agency to offer specific advice about the training required for community health workers in the CY 2024 PFS final rule. In order for billing practitioners to feel comfortable about utilizing community health workers or others outside their practice to provide CHI services to their patients, billing for those services, and receiving reimbursement, they must have clear standards for the personnel that they may hire to provide their patients CHI services. We offer more specific advice below about the training standards for navigators, and we suggest that those standards may be applicable to those offering CHI services.

We agree with the proposed rule on the importance of “direct contact” between the auxiliary personnel providing PIN and CHI services. However, we do not agree with the requirement that a substantial portion of CHI services be provided in-person. Instead, we suggest that most of the elements of CHI services would involve direct contact between the auxiliary personnel and the patient, but those services need not be in-person and a portion of them could be performed via two-way audio. The Medicare beneficiaries who have SDOH needs are exactly those who may have difficulty traveling to receive services in-person but who would on the other hand benefit from audio services.

¹ We note that the Oncology Care Model (OCM), which was tested from July 1, 2016, to June 30, 2022, included a requirement that participating practices supply patients a cancer care plan developed according to the standards identified by the Institute of Medicine. The Enhancing Oncology Model (EOM), which has just launched, includes a comparable planning standard for participating practices.

Social Determinants of Health Risk Assessment

CMS suggests that assessment of health-related social needs, or SDOH needs, is occurring in the context of providers taking patient histories, assessing patient risk, and through medical decision making, diagnosis, care, and treatment. The agency concludes that the resources involved in the activities above are not appropriately reflected in current coding and payment policies. The proposed rule includes a new code to separately identify and value a SDOH risk assessment that is furnished in conjunction with an E/M visit.

The proposed rule would require providers billing for the SDOH risk assessment to use an evidence-based risk assessment tool.

We support this effort by CMS to properly value SDOH risk assessment. We recommend below that the initiating visit for both community health integration services and principal illness navigation services might be a cancer care planning service. In those situations where a cancer care planning service is the initiating visit for CHI services, the SDOH risk assessment might be conducted in conjunction with cancer care planning.

Principal Illness Navigation Services

For CY 2024, CMS proposes to:

“[B]etter recognize through coding and payment policies when certified or trained auxiliary personnel under the direction of a billing practitioner, which may include a patient navigator or certified peer specialist, are involved in the patient’s health care navigation as part of the treatment plan for a serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, function decline, or death.”

In proposing two codes for Principal Illness Navigation (PIN) services, the agency acknowledges the advice from experts about the benefits of navigation for individuals with serious, high-risk diseases. We would like to underscore the evidence to support navigation for cancer patients, including a recent umbrella review of 61 systematic reviews published between 2012 and 2022 and a review of 53 primary studies published worldwide since 2021. This review highlighted “patient navigation as effective for improving uptake of cancer screening programs for breast, cervical, and colorectal cancer as well as shortening time frames from screening to diagnosis and from diagnosis to treatment initiation. There is also some emerging evidence suggesting that

patient navigation has positive effects on patients' quality of life, satisfaction with care in the survivorship phase, and hospital use from active treatment to survivorship."²

In an editorial accompanying the systematic review of cancer navigation, the authors commented on the review, "This report solidifies the evidence – when can we all agree that enough evidence is enough and that PN needs to be an integral part of usual clinical care with reimbursement?"³ We agree with this assessment and commend the PIN proposal in the PFS for CY 2024 as a step toward paying for navigation services and making them an integral part of cancer care.

We would also note that the agency has seen the benefits of navigation to patients, through the Oncology Care Model that included navigation as a critical element of the delivery/payment model. The ongoing Enhancing Oncology Model (EOM) will also include navigation as an element of care. The PFS proposal will improve access to navigation for those beneficiaries who are not cared for in EOM practices.

We offer advice about the implementation of the PIN codes. The proposed rule suggests that Medicare providers should consider auxiliary personnel with a wide range of perspectives and experience, even stressing that navigators with "lived experience" may be especially well-qualified to serve as navigators. The proposed rule specifies that navigators should meet the applicable licensure, certification or other laws and regulations of the states in which they practice, or in states without such standards the auxiliary personnel serving as navigators should be trained to provide these services. We agree that navigators should meet state licensure or certification standards or should be trained.⁴ These standards are critical for ensuring that patients receive navigation services of high quality.

It is also critical that Medicare providers can retain or contract with navigators with an assurance that they have met coding and billing standards; that will require clarity about training requirements. We offered the same advice about clarity of training requirements for those performing CHI services. We repeat our recommendation in connection with PIN services.

We also believe that defining navigation services is another step in ensuring patient access to quality navigation services. The authors of the recent review article on cancer navigation services admit the lack of a definitive definition of cancer navigation but offer a framework for navigation that reflects general consensus regarding the elements of navigation. The PFS proposed rule identifies the activities of navigation:

- Person-centered assessment, performed to better understand the individual context of serious, high-risk condition.

² Chan RJ, Milch VE, Crawford-Williams F, et al. Patient navigation across the cancer care continuum: An overview of systematic reviews and emerging literature. *CA: A Cancer Journal for Clinicians*. 10.3322/cacc.21788. 8.23.2023.

³ Paskett ED, Battaglia T, Calhoun EA, et al. Isn't there enough evidence on the benefits of patient navigation? *CA: A Cancer Journal for Clinicians*. 10.3322/caac.21805. 8.23.2023.

⁴ There are options for certification of navigators, including the certification examinations led by the Academy of Oncology Nurse and Patient Navigators Foundation and the certification process available through the ANSI National Accreditation Board.

- Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.
- Practitioner, home, and community-based care coordination.
- Health education.
- Building patient self-advocacy skills.
- Health care access/health system navigation.
- Facilitating behavioral change as necessary for meeting diagnosis and treatment goals.
- Facilitating and providing social and emotional support to help the patient cope with the condition, SDOH need(s), and adjust daily routines to better meet diagnosis and treatment goals.
- Leverage knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

We believe that there are advantages to the definition above, for guiding the work of navigators and ensuring patient access to quality navigation services. However, we caution that the documentation requirements for billing GXXX3 and GXXX4 should not be so detailed and onerous that they discourage Medicare practitioners from offering navigation services provided by auxiliary personnel. In the implementation of the new codes, we urge CMS to be mindful of documentation requirements that might undermine utilization of the codes and as a result adversely affect any benefits of the new services to Medicare patients.

We offered strong advice above regarding flexibility in the provision of CHI services, recommending that audio services may be appropriate for portion of those services. We echo that advice with regard to PIN services, suggesting flexibility in how the services are provided.

The Relationship between Community Health Integration and Principal Illness Navigation Services

We have separately offered advice regarding CHI and PIN services. However, we have questions regarding the relationship of CHI and PIN services. The agency describes PIN services and community health integration (CHI) services as services existing in parallel. CMS describes the services in this way:

The navigation services such patients need are similar to CHI services (as discussed previously in this section), but SDOH need(s) may be fewer or not present; and there are specific service elements that are more relevant for the subset of patients with serious illness. Accordingly, we are proposing for PIN services a parallel set of services to the proposed CHI services, but focused on patients with a serious, high-risk illness who may not necessarily have SDOH needs; and adding service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed.

Although the agency does not definitively state that a patient could receive CHI services OR PIN services but not both, we conclude that is the determination of the agency. We suggest instead that there will be patients who DO have significant SDOH needs and who would benefit from CHI services in addition to PIN services. We understand that CMS anticipates that navigators will address SDOH that might affect the diagnosis or treatment of disease, and in this way it acknowledges that a cancer patient who needs a navigator might also have SDOH needs. We suggest that there will be cancer patients who have significant SDOH needs and would benefit from receipt of CHI services provided in conjunction with PIN services. We note that PIN and CHI services may only be provided monthly, and we certainly believe that there are patients who would benefit from both services in a single month. We see no reason that a navigator could not also provide patients CHI services.⁵

Proposal to Establish a Cancer Care Planning Code

The proposed rule explains that PIN and CHI services will have a prerequisite of an initiating visit that is an E/M visit (other than a low-level E/M visit that can be performed by clinical staff) performed by the billing practitioner who will be providing the PIN and CHI services during subsequent calendar month(s).

We recommend that a new service and code be established for cancer care planning, which might be the initiating visit for PIN and CHI services for cancer patients. Such a service, functioning as the initiating visit for PIN and CHI services, would address the issues identified above related to whether a patient might appropriately be provided both PIN and CHI services. Initiating PIN and CHI services for cancer patients with a cancer care planning services would also ensure that the services are well tailored to the patient. The proposed rule says that the initiating visit for PIN services should include a plan that will guide the provision of PIN services. We suggest that this standard could be honored by establishing a cancer care planning service and identifying it as a potential initiating visit for PIN and CHI services.

CMS has acknowledged the importance of cancer care planning by including it as an element of the Oncology Care Model (OCM) and the Enhancing Oncology Model (EOM), both alternative delivery models intended to improve the delivery of cancer care. The Enhancing Oncology Model requires that participating practices provide patients a “detailed care plan that involves your engagement and preferences on discussions surrounding prognosis, treatment options, symptom management, quality of life, and psychosocial needs, among other topics.”⁶

We propose the same service – a cancer care planning service – as a possible initiating visit for PIN and CHI services for cancer patients. The standards for care planning should be those of the OCM and EOM initiatives. We think that a cancer care plan, as described above, will facilitate

⁵ CMS states that other care management codes could be billed alongside PIN or CHI services. We ask for clarification that, for certain cancer patients, PIN and CHI services may both be appropriate.

⁶ Description of Enhancing Oncology Model, accessed online on August 27, 2023: <https://innovation.cms.gov/innovation-models/enhancing-oncology-model>.

the delivery of effective PIN and CHI services. A plan will guide the delivery of these services, improve the cancer care experience for patients, and help with addressing SDOH needs.⁷

We realize that establishing a cancer care planning visit as the initiating visit for cancer patients would set a different standard than for other beneficiaries who might receive CHI or PIN services. We cannot comment on whether a care planning visit should be the initiating visit for any beneficiaries other than cancer patients. However, because of the potential significant benefits of a cancer care planning visit as a possible PIN and CHI initiating visit, we make the recommendation for beneficiaries with cancer. We also note again that the agency has itself seen cancer care planning as an element of quality cancer care through inclusion of the service in OCM and EOM.

Telehealth Services

We support the proposal to implement several telehealth-related provisions of the Consolidated Appropriations Act, 2023 (CAA 2023). Among these provisions are the expansion of the scope of telehealth originating sites for services provided by telehealth to include any site in the United States where the beneficiary is located at the time of the telehealth services. Extending the originating site protections is important for cancer patients, and we support the agency decision to do so. CMS also proposes to continue to define direct supervision to permit the presence and immediate availability of the supervising practitioner through real-time audio and video communications through 2024. Before the end of the direct supervision flexibility, oncology professionals will weigh in with CMS regarding any safety concerns about virtual presence and whether they can be answered to permit extension of this flexibility beyond 2024.

Dental and Oral Health Services

We commend the actions of CMS to improve coverage for dental services for certain cancer patients and other beneficiaries. The agency proposes to codify for CY 2024 the previously finalized payment policy for dental services prior to, or during, head and neck cancer treatments, whether primary or metastatic. Moreover, the agency proposes payment for certain dental services that are linked to other services used to treat cancer. These services include chemotherapy services, Chimeric Antigen Receptor T-cell therapy (CAR-T cell therapy), and the use of high-dose bone modifying agents (antiresorptive therapy). These are important steps to improving cancer patients' access to dental services that are inextricably linked to their cancer therapy.

⁷⁷ Concerns have been expressed about the fact that an E/M code may not be reported for a patient who has begun a course of radiation therapy; some have suggested that the PIN and CHI services might be tried instead to the Weekly Treatment Management code. We urge that the issues confronting the patient in the midst of radiation therapy be considered. We also suggest that the cancer care planning code that we have identified, if well-defined, effectively implemented, and embraced by practitioners, might be the initiating visit for cancer patients beginning any therapy.

Payment Rates for Radiation Oncology Services

The CY 2024 PFS would reduce payments for radiation oncology services. At a time when operating costs for radiation oncology practices are up and staff shortages, including key clinical staff shortages, are adversely affecting radiation oncology practices, the PFS would cut payments for radiation oncology services by approximately 2%. Our coalition of patients and providers wishes to highlight the potential negative impact on patient access to radiation oncology services as a result of the payment cuts. We understand that the solution to radiation oncology payment cuts may be legislative and not achieved through changes to the proposed rule, but we nonetheless wish to highlight this shortcoming of the PFS and its potential negative impact on cancer patients.

We appreciate the opportunity to comment on the Medicare PFS for 2024 and offer advice about ways the PFS might protect patient access to quality cancer care.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
American Society for Radiation Oncology
Association of Oncology Social Work
CancerCare
Cancer Support Community
Children's Cancer Cause
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
LUNgevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation
Susan G. Komen