C-TAC
COALITION TO TRANSFORM ADVANCED CARE

September 11, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure,

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule regarding its effect on those living with serious illness.

C-TAC is a national non-partisan, not-for-profit coalition dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high-quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC comprises more than 200 national and regional organizations including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

C-TAC defines serious illness as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their family caregivers. This definition has been widely adopted, including by the National Committee for Quality Assurance (NCQA) and the National Quality Forum (NQF).

Serious illness is also a health equity issue. A history of disenfranchisement has led to healthcare gaps across the country. Per a 2021 Commonwealth report on racial and ethnic health equity, communities of color live fewer years, on average, than white people do, are more

likely to die from treatable conditions, and are also at higher risk for many chronic health conditions. For serious illness, the lack of access to health insurance and primary care mean many are diagnosed only at a late or end stage of illness, when disease-modifying treatment is typically no longer effective. Those from historically under-resourced communities who also have serious illness experience poorer care and access, making improving their care a health equity opportunity.

Payment for Caregiver Training Services (CTS)
We strongly support the inclusion of payment for these important services. Caregivers are often instrumental in the lives of those with serious illness, as the proposed rule correctly notes. Our suggestions for this area are:

- Definition of a caregiver- We appreciate the proposed comprehensive definition of caregiver. We particularly note the definition is not restricted to just family as some patients have friends or neighbors who help them with their care. We do however recommend the following:

  Removing the categories "proxy" and "guardian" from the definition- Patients may have a legal proxy or guardian but that is not always the same person as the one helping with their practical care and, therefore, the one needing training. Often the legal guardian or proxy is not even located near the patient or is nearby but does not have a role in their day-to-day care. Excluding these designations from the definition will help ensure CTS is only for those caregivers directly involved in the patient's care. If a guardian or proxy is also a caregiver, that person could qualify for CTS.

  Considering adding payment for paid caregiver training- Some patients hire paid caregivers as home health aides or caretakers. These may be the only such resources in these patients' lives and often accompany them to medical appointments. Furthermore, they may have no relevant training. Therefore, it would be appropriate to pay to provide training to them as well as unpaid caregivers in such circumstances.

- Training clarification- It would be helpful to clarify the CTS specifics by providing a basic outline for what training needs to entail in order to qualify for the payment. Having such guidance would clarify what is expected and what constitutes "training" and would likely help to prevent inappropriate CTS billing. We recommend balancing the current CTS description's flexibility with some clarification so as to help providers to deliver CTS appropriately.

  As part of such clarification, we also suggest that CMS clarify how "caregiver understanding and competence in assisting and implementing these interventions" (page 183) will be gauged. Our experience is that without requiring providers to check

for understanding, via the use of teach-back methods or other techniques, some CTS may not be fully effective.

- Patients who benefit from care involving caregivers- We appreciate that the proposal includes patients with both physical and behavioral health conditions as both can be challenging to manage and therefore would benefit from caregiver training.

- Caregiver training in strategies and techniques to facilitate the patient's functional performance (CPT codes 9X015, 9X016, and 9X017) – We would note that not all training should be solely for facilitating the patient's functional performance. There are situations where caregiver training could help helping to alleviate a person's pain or other symptoms. These are opportunities to help improve the patient's quality of life, regardless of their functional performance.

- Assessing for caregiver burden- We recommend that part of assessing for the need for CTS is also assessing caregiver capability, stress, or burden. This should be done upfront as it would be important to know before providing any caregiver training since that may affect caregiver understanding and ability to provide help to the patient.

Services Addressing Health-Related Social Needs

We are delighted to see these additions in this proposed rule, thank you. While we will comment below on the specific elements later, here are some comments that go across them:

- Comprehensive assessment- We appreciate that the new codes and processes require providers to assess for the need for community health integration services, social determinants of health (SDOH), caregiver training, and principal illness navigation services. These components represent almost all of the kind of comprehensive assessment that C-TAC recommends for all with serious illness. By comprehensive we mean going beyond just a thorough medical or physical assessment to also assess for social risk factors and needs, emotional, psychological, and spiritual issues, family caregiver concerns or burdens, financial concerns, and whatever else is of importance to the patient and family. Advance care planning (ACP) and discussion of the person's and family's values and goals are also a key component of such an assessment. We are excited that with this proposed rule, all those components, with the exception of assessing caregiver burden, now have payment associated with them.

- Duplicative services- While we understand the risk of potentially duplicative services, there are situations where providers in community hospitals or skilled nursing facilities, for instance, might be the most appropriate ones to assess for CTS, CHI, or PIN as part of ongoing care. In these situations, the provider treating the patient may have the ability and intention to follow them back into the community and, therefore, could provide helpful continuity in care there. We therefore recommend that such duplication be allowed for these new services. For CTS, the dually eligible population may also be

exactly the kind of patients who would benefit from caregiver training, and so we encourage CMS to work with the states to clarify how this new payment opportunity could be coordinated across Medicare and Medicaid. We also believe that CMS should also allow caregiver training to occur for those patients enrolled in home health services. The home health team may identify training needs outside of what a provider may see in a clinical setting. We also support including CHI as part of the Medicare Annual Wellness Visit (AWV).

- Patient consent for these services- We agree that patient consent should be required given that there will be patient copays, outside of an AWV, for these services. Patients should be made aware of and agree to services and copays in advance. We suggest, however, that confirmation of patient consent be via the provider's charting, rather than an additional or potentially burdensome process for patients, providers, and practices. Beyond this, C-TAC is concerned about the impact of such copays on patient acceptance of these services and believe that providers may not offer them in anticipation of the copay being unaffordable for patients, as some evidence suggests is already the case with the ACP billing codes. C-TAC helped introduce a federal bill last year to remove the ACP cost-sharing and is working on similar legislation this session. Copays are problematic as they disproportionately affect communities of color, which is surely not what CMS intends by introducing these new services or payment codes. It would be unfortunate if those struggling with social issues, including financial ones, would not be offered SDOH screening out of concern for their personal financial cost, or would accept it and be burdened with the associated costs.
- Telehealth- We further support the use of audio-only telehealth for CHI and PIN services, as many of the elements of these services could involve direct contact between the auxiliary personnel and the patient and may not necessarily be in-person and a portion might be performed via two-way audio. Two-way audio is also important for those patients lacking access to broadband or cellphone services. And older patients are familiar and comfortable with talking on the phone, so this helps them as well.

Our comments on the specific areas are:

- Community Heath Integration (CHI) Services- We commented in support of the role of community health workers (CHWs) in the previous RFI, as they are important to help support patients and help access available services given the CHW's local knowledge and ties to the community. We therefore support the proposal here to add new G codes for CHI services and feel that, as stated above, this is part of providers doing a more comprehensive assessment of patients' needs and helping them to better access needed community services.

- Social Determinants of Health (SDOH) –Proposal to establish a stand-alone G code- We support the proposal to add this new SDOH G code as we agree that additional payment is necessary to add this important activity to providers' already busy clinical workflow. This also provides payment for a key part of the comprehensive assessment C-TAC is

promoting. We hope that future rulemaking will also require providers to address any identified SDOH needs and, ultimately, make and track referrals to ensure patients get the services they were referred to.

We also recommend that CMS develop ways to collect and analyze the gathered SDOH data from these assessments. We salute the agency for laying the foundation for more equitable care by requiring, and now paying, providers to identify SDOH issues. Analysis of this data will then help us all to better understand what is really going on at the patient or population level. There are already Z codes for SDOH but we suspect those are not widely used. Perhaps adding diagnostic codes for common or key social risk factors could identify their prevalence. Coding for nutritional or housing insecurity, for instance, could be some of the new diagnostic codes that could also be used to risk adjust payment for these factors.

- Proposed Principal Illness Navigation (PIN) Services- We strongly support the addition of these new services as well and appreciate the holistic view this proposed rule takes as to what these should include. We also agree that these new services are needed as there are gaps in coding for patient navigation services for treatment of serious illness, and that that they are not already included in current care management services such as advance care planning services, chronic care management services, general behavioral health integration care management services, home health and hospice supervision, monthly ESRD-related services, principal care management services), psychiatric collaborative care management services, and transitional care management services. All these current services are done by a provider and generally do not involve addressing any social or other needs on the part of the patient.

  Encouraging elements that will truly promote whole person-center care in the PIN proposal include:

  > Conducting a person-centered assessment to understand the patient's life story, strengths, needs, goals, preferences, and desired outcomes, including understanding cultural and linguistic factors.
  >
  > Facilitating patient-driven goal setting and establishing an action plan.
  >
  > Providing tailored support as needed to accomplish the practitioner's treatment plan.
  >
  > Identifying or referring patient (and caregiver or family, if applicable) to appropriate supportive services.
  >
  > Facilitating behavioral change as necessary for meeting diagnosis and treatment goals, including promoting patient motivation to participate in care and reach person-centered diagnosis or 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.

Leveraging knowledge of the serious, high-risk condition and/or lived experience when applicable to provide support, mentorship, or inspiration to meet treatment goals.

We also strongly support the language on page 213 about "addressing a serious high-risk condition/illness/disease, with the following characteristics: one serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death," as it is very close to C-TAC's definition of serious illness per page 1 of this letter.

This definition and the list of example illnesses also aligns very strongly with the kinds of serious illnesses that benefit from the addition of palliative care services. (By palliative care, we mean the CMS definition of "*Patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice"* and not just care at the end of life or hospice.) It would be wonderful if future rulemaking could promote better access to these services for this population.

We have long advocated for more community-based service and resource involvement and so agree with the proposal that a billing practitioner may arrange to have PIN services provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through a community-based organization (CBO) that employs CHWs, if all of the "incident to" and other requirements and conditions for payment of PIN services are met.

Finally, we also agree that the navigators involved should have training or certification, although this is a potential equity issue as such training or certification carries a cost that may be hard for those from lower socioeconomic levels to afford. Some of our payer members provide in-house training but this supplements, rather than supplants, the initial training requirements. We encourage CMS to work with those organizations providing training and certification to ensure both their quality and affordability.

Advancing Access to Behavioral Health Services

As strong supporters of interdisciplinary patient care, we were in agreement with the CAA 2023 legislation that requires marriage and family therapists, mental health counselors, and addiction counselors who meet the requirements to be billable providers for Medicare part B in-person and telehealth services. We therefore support the proposed regulatory language here

to include them in Medicare programs and look forward to their contribution to improving access to much needed behavioral health services going forward.

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

Per our previous comments above, we are also in favor of adding an optional SDOH risk assessment to the AWV. We share CMS's concern, however, that these can be sensitive conversations and wonder if provider training for this kind of communication should be a requirement. Then, as stated earlier, we encourage future rulemaking to contemplate requiring referrals to community services and that identified services are actually available and delivered, since assessment is only the first step in meeting these patient needs.

Hospice: Changes to the Hospice Conditions of Participation

Again, as supporters of interdisciplinary patient care we are pleased to see that marriage and family therapists, mental health counselors, and addiction counselors can now be added to the hospice team as their contribution, when available, could be significant. However, it is our belief that these roles should be added to hospice *as optional not mandatory ones*. CMS is well aware of the challenges smaller and/or rural hospice face these days and requiring them to have all three of these new roles on every hospice team is not feasible given workforce shortages and costs. Please revise the final rule to clarify that these roles are optional, versus mandatory, as some interim CMS guidance seemed to suggest.

A.2. Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

C-TAC was supportive of this measure's development and are pleased to see its addition here to the family medicine, internal medicine, and hematology/oncology specialty sets. Our hope is that even though it was developed and endorsed for home-based palliative care programs, it should be considered for all specialties, as it focuses on communication between the person and their medical provider, a foundation of good and trustworthy medical care.

Palliative Care Exclusions

We have concerns about the exclusions of those receiving palliative care services from the Preventive Care and Wellness (composite), page 1446, and D.49 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, page 1835. While those with an end-stage serious illness getting palliative care would not benefit from these services, others earlier in an illness getting palliative care might.

We also continue to be concerned that proposed rules and other CMS communication seems to use palliative care synonymously with end-of-life or hospice care. *That is not the case* per CMS's own definition, cited on page 6 of this letter. Using the terms interchangeably contributes to this misunderstanding contributing to what evidence shows is public and health care providers thinking palliative care as only appropriate for the end of life when in actuality it can be

delivered throughout a serious illness. Such misconceptions have contributed to low enrollment in CMMI models featuring palliative care, per a 2022 evaluation, and the cancellation of a PCORI palliative care trial.

We have separately had discussions with CMS leadership about this issue as perpetuating the misconception that palliative care is only for dying people limits its access and appeal, which unfortunately denies many its multiple evidence-based benefits. They have encouraged us to continue calling this out thorough the public regulatory comment process, hence these comments. Therefore, we urge the agency to be clearer when using the term palliative care and, when truly meaning just end-of-life care, to use the term "hospice" instead.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Marian Grant, Senior Regulatory Advisor, C-TAC, at mgrant@thectac.org.

Sincerely,

Marian Grant

Marian Grant, DNP, ACNP-BC, ACHPN, FPCN, FAAN, RN
Senior Regulatory Advisor
Coalition to Transform Advanced Care (C-TAC)