



June 17, 2021

David Meyers, MD  
Acting Director  
Agency for Healthcare Research and Quality  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Meyers:

On behalf of Children's Cancer Cause, please see our comments regarding the Agency for Healthcare Research and Quality (AHRQ) draft report entitled, *Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer: A Realist Review*. Children's Cancer Cause (CCC) is the leading national advocacy organization working to achieve access to less toxic and more effective pediatric cancer therapies; to expand resources for research and specialized care; and to address the unique needs and challenges of childhood cancer survivors and their families. We have organized our comments into specific areas with recommendations for how the report can be used to identify and overcome the challenges faced by childhood cancer survivors.

#### **Utilizing The Children's Oncology Group (COG) Guidelines**

The Children's Oncology Group (COG) **Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent and Young Adult Cancers** are the only evidence-based guidelines available to determine late effects risk and recommended surveillance for younger survivors. This resource was developed as a collaborative effort of the Nursing Discipline and the Late Effects Committee of COG and is now routinely maintained and updated by the Long-Term Follow-Up Guidelines Core Committee and its associated Task Forces. The COG Guidelines are harmonized with late effects guidelines that are available across the globe. Importantly, the Guidelines include access to Health Links that briefly detail anticipated late effects in lay language, serving as key educational material for survivors and their families (and fully translated into Spanish, Chinese, and French). We believe the report gives minimal attention to the unique role of the guidelines as the current standard of care. Further education and awareness efforts to achieve greater uptake and utilization of the COG guidelines is needed.

- According to the report, a survey of US general internal medicine and family practice providers found that 93 percent reported never using the COG late effects guidelines and only 40 percent of providers were aware of the guidelines. However, another study reported substantial improvements in adherence to the COG guidelines between 2003 and 2016 and speculated that physician awareness of COG guidelines may be growing.

- Regardless of increased uptake, the current COG guidelines are lengthy and complex and would benefit from further study about barriers and whether a shorter version is needed for easy primary care use. The final report should recommend this action.

### **Incorporating a Summary of Care and Survivorship Care Plan**

The report notes that if care for adult survivors of childhood cancer is to be delivered outside of the specialty setting, there needs to be communication of knowledge to both survivors and primary care providers. CCC agrees with this conclusion; however, multiple steps are necessary to achieve this goal. Our thoughts:

- First, a summary of care and survivorship care plan (SCP) must be delivered to both patients and families and primary care providers. The optimal time for delivery is likely at the first long-term follow-up visit, so that ample time can be offered to review the document and answer questions. Both items should conform with Children's Oncology Group guidelines.
- Finally, multiple delivery mechanisms and formats are needed to address geographic disparities, survivor population differences, and provider capacity. A printout of the SCP is helpful during the visit as a tangible resource that can be explained point by point. But the SCP must also be documented in the medical record, sent to the PCP, and sent to the survivor. Survivors need an online version of the SCP, preferably one that can be viewed on a handheld device or from home (if they have a computer) and shared easily with other health care providers. There are multiple tools that assist with this, including Survivor Link and Passport for Care. New tools need to be specifically adapted for use in medically underserved, lower-income communities with limited access to WIFI, home computers, and smart phones.

The report found that developing and delivering a SCP is a uniformly good practice. However, use of the SCP by primary care providers, even when it is in the medical record, can be limited. The report found that the timing and type of intervention (tailored and specific) was relevant. Future demonstrations should include and evaluate how best to flag SCPs for providers considering mechanisms such as quality measures, use of electronic medical records, or other mechanisms. The report recommendations should highlight this issue.

### **Knowledge Transfer**

The report found that if care is delivered outside of the specialty setting, there must be an **effective** knowledge transfer to survivors and PCPs. This report identified several ways this knowledge could be shared, including a range of resources (e.g., guidelines, SCPs) and contexts (e.g., survivor confidence in PCPs, shared care with oncologists). The report identified studies showing that knowledge transfer did not always result in survivorship care planning and that more work is needed to make sure the knowledge is available, accessible and the provider is reminded about it and knows where to get it. The report found, and we agree, that further research is required to evaluate the above knowledge transfer mediums and contexts for effective actualization.

### **Recommendation of a Passport Model**

The report found improved knowledge for survivors “who were given a passport card describing diagnosis, treatment, risks, and recommended follow up. . . were more likely to demonstrate improved knowledge versus survivors without a passport.” We feel the report should include further information about successful passport models, including mobile access to the personalized SCP.

### **Develop and Test New Healthcare Payment and Service Delivery Models**

The need for improved survivorship care is well documented and, in recent years, studies have proliferated. However, they are often descriptive with no outcome data. The report highlights that there are an infinite number of models of survivorship care developed by circumstance rather than by design. This reality highlights the need to develop and test new healthcare payment and service delivery models that have a real-world application.

The report supports a major goal of CCC – the authorization of a Center for Medicare and Medicaid (CMMI) demonstration program to develop standards of care for survivors of childhood cancer with a focus on scalable models based on the COG guidelines across the United States. Attached is a CCC proposal for such a demonstration entitled the Child and Adolescent Cancer Survivorship Transition (CAST) Model. We recommend that the report include the proposal as a strategy to overcome barriers to survivorship care.

The CCC’s legislative and regulatory proposal would serve children and adolescents under a Medicaid demonstration program, providing care for at least a six-month period following their active cancer treatment.

As a main component, every childhood cancer survivor would have a care summary and follow up plan in the survivor’s native language to assure consistency and accessibility of information. The plan would specify their treatment history and address individual post-treatment needs based on Children’s Oncology Group recommendations. The goal is to develop multiple models that are accessible in different geographic regions, and that consider unique regional barriers. As the CAST model develops, we will build on some of the key findings of the AHRQ report. IT will assess evolving ideas about telemedicine, how low risk patients might receive quality care in the community and draw from real-world evidence.

A major report finding was the “lack of clarity regarding the appropriate models of survivorship care. There are multiple barriers that preclude many childhood cancer survivors from receiving specialized long-term follow up care, but there are also barriers that preclude those survivors from receiving quality survivorship care in primary care.” Thus, we believe a CMMI demonstration program would further our understanding of how best to address barriers identified in the report by evaluating real world interventions.

In conclusion, the report notes that real world evidence documenting the quality of the care adult survivors of childhood cancer receive is limited. The report also found a lack of formal evaluations of outcome data for the models of care, particularly mortality. Specifically, the report states, “There is no consistent taxonomy for survivorship models of care, and models of care are rarely specifically selected

in practice. The literature identified in this review generally provided evidence regarding who gets seen where and what care they receive (patterns of care) rather than formal evaluations of specific models of care.” CCC believes that real world evidence is the next step in improving survivorship care for childhood cancer survivors.

Not surprisingly, the report found few major studies focused on childhood cancer survivors and were forced to supplement with evidence from adult survivors of adult-onset cancers. The final draft should indicate where a study included survivors who were diagnosed with cancer as a child vs. diagnosed as an adult. Additionally, the final draft should note where studies include both pediatric and adult-onset cancers (if the childhood cancer survivor population composes <20% of the overall study population). The report should address this issue both broadly and study by study. Reported studies regarding childhood cancer survivors are lacking, however survivorship needs vary based on cancer onset by age. Thus, the report should clearly identify the study cohorts since the objective is to describe access to care barriers experienced by childhood cancer survivors.

Thank you for this important report and the opportunity to comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Wosahla". The signature is fluid and cursive, with the first name "Steve" being more prominent than the last name "Wosahla".

Steve Wosahla  
Chief Executive Officer  
Children's Cancer Cause



## Childhood Cancer Survivorship Proposal

### **Overview**

Authorize the Center for Medicare and Medicaid Innovation Center to create a new demonstration program under the authority of section 1115A of the Social Security Act – the Child and Survivorship Transition CAST Model (CAST). The model is a local service delivery and state payment model for children and young adults up to age 21<sup>1</sup> diagnosed with cancer who are in the survivorship phase of their treatment, for children covered by Medicaid through the testing of models that create a survivorship plan for these individuals and disseminate the plan to individuals, families and their providers. The model will offer states and local providers support to develop and implement different survivorship care planning models.

### **Why develop a model?**

Americans are living longer with cancer, resulting in larger numbers of cancer survivors in the United States. Pediatric survivors of cancer are uniquely affected because of long-term and late effects of cancer treatment. Today there are over 500,000 childhood cancer survivors in the U.S. Over 80% of childhood cancer survivors will have at least one severe, disabling, or life-threatening late effect of their disease or treatment by the time they reach 45 years of age. Over one third of these individuals will suffer severe and chronic health impairments.

Despite the increase in survivors, however primary care physicians (pediatricians, internists, family medicine physicians, osteopaths, etc.) often are not familiar with the consequences of cancer and its treatment. Survivors seldom receive explicit guidance – a survivorship care plan – from oncologists on how to treat cancer survivors. Patients are generally not educated about ongoing and future needs and thus lack the information to anticipate and manage their survivorship care. Often there is no formal transition from the oncologist to a primary care physician, and there is minimal care coordination where follow up occurs. Establishing best practices in caring for patients with a history of cancer will minimize wide variation in care. Finally, lack of reimbursement for the transition from active cancer care to survivorship care is a major barrier to care delivery. Reimbursement limits exist around provider communications, treatment plan development, and information transfers to the primary care setting.

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<sup>1</sup>According to the National Cancer Institute children are 0 – 14 years and adolescents are 15 – 19 years. Children and adolescents up to age 19 are categorically eligible for Medicaid at certain income levels. Some state programs cover adolescents up to age 21.

The proposed model would establish survivorship care planning delivered both in a hand-off from an oncologist and over a 6-month period, delivered in both a survivorship clinic and a primary care setting. Plans will summarize information critical to the individual's long-term care, such as the cancer diagnosis, treatment, and potential consequences; the timing and content of follow-up visits; tips on maintaining a healthy lifestyle and preventing recurrent or new cancers; and the availability of psychological and support services.

### **What are the goals of the model?**

The goals of the CAST model are to educate childhood cancer survivors and their families, primary care providers and others on survivors' unique and specific clinical and non-clinical needs at the time their immediate cancer care ends. The CAST model creates a six-month survivorship care plan benefit with payment to providers dependent on where the patient is treated. The model will provide survivors with a care transition visit, which includes survivorship care planning, a concrete plan to follow and the tools to receive appropriate care in the survivorship care phase using a Center for Medicare and Medicaid Innovation (CMMI) demonstration approach.

The CAST Model will support providers to conduct identification and treatment of pediatric survivors across care settings. Through the APM developed through this model, providers will use a shared care approach which will allot payments where the patients are during a given 6-month period following the end of active cancer care.

The model will attempt to address the current gaps in care for pediatric cancer survivors. It will:

- Start survivorship care planning once active cancer treatment ends and encourage communication between the oncologist, pediatrician and primary care provider.
- Develop a survivorship care plan document that is helpful and accessible to both the patient and provider.
- Develop and reimburse a survivorship care planning/transition/handoff visit during which primary care providers can review the plan and update the record about cancer history and recommended follow up care.
- Educate patients, families, and providers regarding the unique needs of survivors.
- Create a standard of care where all childhood cancer patients receive a transition care visit analogous to a hospital discharge summary, which leads to a post admission primary care visit.
- Determine whether different levels of survivorship care planning are appropriate for patients based on stratification of risk of severity of late effects following active cancer treatment.
- Utilize electronic health records to assist the survivorship care transition process.

### **Areas of Special Interest/Barriers**

All model participants will address areas of special interest to establishing comprehensive survivorship models. These areas represent components which are considered burdensome, present

a barrier to entry, are costly or vary by region. Therefore, CMS will consider models favorably that address these issues.

- Staff capacity. Models will explore whether adequately providing survivorship care to childhood cancer patients requires a team of providers such as nurses, physician assistants, patient navigators, or scribes.
- EHR. Models must utilize electronic health care records including how to populate treatment plans and roadmaps early.
- Methods to obtain medical records from different providers and institutions.
- Legal issues involving confidentiality.

### **What are the key elements of the survivorship care model?**

Every childhood cancer survivor should have a comprehensive care summary and follow-up plan once they complete their primary cancer care. The plan should specify their treatment history and address various individual post-treatment needs to improve their health and quality of life. The model will include reference to and incorporation of, as appropriate, the Children's Oncology Group *Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent, and Young Adult Cancers* as a resource for healthcare professionals as well as the Passport for Care model. CAST models must develop and incorporate an easily understood version of the care summary for patients and families.

#### ***Record of Care***

Upon discharge from active cancer treatment, patients should be given a record of their disease history and treatment regimens. The pilot would use the Children's Oncology Group record – the Summary of Cancer Treatment (Comprehensive). The record will go to both the patient and their primary care provider.

This should include, at a minimum:

- Diagnostic tests performed and results.
- Tumor characteristics (e.g., site(s), stage and grade, hormonal status, genomic characterization, biomarker data).
- Dates of treatment initiation and completion.
- Surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene or other therapies provided, including agents used, treatment protocols identifying number and title of clinical trials (if any), indicators of treatment responses and toxicities.
- Psychosocial, nutritional, and other supportive services provided.
- Full contact information on treating institutions and key individual providers.
- Identification of a key point of contact and coordinator of continuing care.

### ***Survivorship Care Plan Components***

Upon completion of cancer treatment, every childhood cancer patient and their primary health care provider should receive a written follow-up survivorship care plan incorporating available evidence-based standards of care. The discharge plan would include information about cancer type, treatment, and long term/late effects. The survivorship care plan differs from the patient's medical record.

This should include, at a minimum:

- The likely course of recovery from treatment toxicities, as well as need for ongoing health maintenance
- A description of recommended surveillance, cancer screening and other periodic testing and examinations, and the schedule on which they should be performed (and who should provide them).
- Information on possible late and long-term effects and symptoms of treatment exposure
- Information on possible signs of cancer recurrence and second primary tumors.
- Information on the possible effects of cancer on growth and development, including sexual maturation and functioning, marital/partner relationships, school or employment, and fertility and parenting, and the potential need for psychosocial support.
- Specific recommendations for healthy behaviors (e.g., diet, exercise, healthy weight, sunscreen use, virus protection, smoking cessation, osteoporosis prevention).
- Referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider
- Allow follow up care the flexibility to cover surveillance modalities that are needed (but atypical) for childhood cancer survivorship such as diagnostic testing.
- A listing of cancer-related resources and information (Internet-based sources and telephone listings for major cancer support organizations).

### ***Development of Record of Care***

The models must describe who completes the treatment plan – nurses, nurse practitioners, physician assistants, scribes etc.

### ***Benefit Periods***

The childhood cancer survivorship benefit or transition period would run for six months. During this time, the patient would receive a transition visit, plan of care, care dissemination to the patient and/or family and physician or clinic. Providers would participate in a shared care model which would allow for payment for services both to the referring oncologist and primary care provider or clinic. The payments would follow the patient.

### ***Electronic Portability and Operability***

For purposes of electronic health records, models must meet the requirements of a Medicaid program for use of certified electronic health record technology (CEHRT). This requirement will benefit the survivorship model by better supporting the interoperable exchange of health information. Demonstrating EHR capacity is a minimal requirement of the model. Survivorship care summaries must be electronic and portable. Specifically, CMS will favor models that can use EHRs to more easily pull information from the chart and summarize the data. Web portal-based models are of specific interest.

Models must meet confidentiality requirements under HIPPA.

### ***Payment Models***

Under the model, physician practices will enter into payment arrangements that include financial and performance accountability for 6-month episodes of care. The two forms of payment include a per-beneficiary payment for the duration of the episode and the potential for a performance-based payment for episodes of care. The payment assists participating practices in effectively managing and coordinating care for oncology patients during the survivorship episodes of care, while the potential for performance-based payment incentivizes practices to lower the total cost of care and improve care for beneficiaries during treatment episodes. Models will evaluate whether different payments are required for the summary of past treatments versus the development of the survivorship care plan for the future. The goals of the APM are to 1) to improve outcomes, such as decreased costs and improved quality of life; 2) ensure long-term model sustainability; and 3) develop a mechanism to reimburse a survivorship transition visit.

### ***Measure Development***

Public and private entities have addressed cancer treatment rather than survivorship through measure development. Insurers and health care delivery systems do not appear to be measuring cancer survivorship quality. The program will identify and develop clinically relevant measures of cancer survivorship and quality of life and function as well as measures of survivors' care experiences. The program will include quality measures and outcomes, such as health care utilization and quality of life metrics. Functional outcomes will be important.

### ***Data***

Basic data about childhood cancer survivorship is lacking. As appropriate, the model would gather data about the number of childhood cancer survivors in each demonstration program region. CMS would work with other entities such as CDC on broader data assembling.

### **How will funding be awarded?**

CMS would award cooperative agreements to eligible entities (states) to support care redesign efforts within their state. The new funding will cover upfront personnel, infrastructure, and training costs, would help eligible entities provide high-quality, person-and family-centered care to childhood and adolescent cancer survivors.

## **Who will participate in the model?**

The key participants of the CAST model will be the state Medicaid agency. State Medicaid agencies will provide population-level data for the geographic service area, support development of information sharing arrangements and infrastructure, work to align support for the model across entities and help to develop the survivorship APM. CMS will award up to 8 grants to States.

One of the grantees would be the Passport for Care. The Passport for Care is widely used with childhood cancer treatment survivors across the nation and especially in Texas. The survivorship model is run through a late effect algorithm created by Children's Oncology Group. Based on the individual's history, Passport for Care indicates in user friendly terminology potential late-effects patients may experience, and treatments or tests they should undergo. Patients can share their information both digitally and through a hard copy. Patients also have the option to allow their information to be entered in a database for future research. The clinician side of the Passport for Care provides explanations to the comprehensive guidelines for their patient's survivorship care, the potential side effects to those treatments, evaluations that should be performed, and the list of health care providers who have treated their patient. Of note, the Passport for Care provides clinical and non-clinical information including local psychosocial support resources with explanations of each to compensate for primary physicians' lack of knowledge in surveillance protocols.

## **Whom will the model serve?**

The CAST Model will serve all children and adolescents under the Medicaid program starting with the prenatal period through age 21. These individuals will receive care for a six-month period following their active cancer treatment. Through a demonstration, model, the CAST model will explore the creation of a similar category for survivors of childhood cancer which would last for the 6-month period after they finish active cancer care who can participate in the demonstration based on their Medicaid eligibility as a childhood cancer survivor.

## **Risk Stratification Approach and Tiered Service Delivery:**

An important element of the program is a focus on the services provided and associated payment rates. The CAST structure is based on population-wide late effect risk-stratification according to level of need. **Service Integration Levels (SILs)** consist of integrated care coordination levels of increasing intensity appropriate for individual needs. The goal of stratification is to ensure that survivors receive the individualized care they need. Specifically, the model will consider individuals at low, middle and high risk of occurrence and use different services and follow up depending on risk after active therapy. Even within the category of those who have completed curative care differing levels or tiers of care might be merited based on need. The creation of tiers will dictate whether individuals are treated by oncologists for life, go into primary care with five year follow ups or receive other modes of follow up. States should associate payment levels with tiers of coverage.

## Models

The model will require participating states to develop for supporting an initial physician/nurse practitioner handoff or transition visit, subsequent information dissemination of a survivor care plan, follow up by the designated provider, and coverage of diagnostic testing and imaging which may be outside the typical benefit package for an insured via existing state authorities available under Medicaid. The goals of the program are to 1) increase access to survivorship care at the end of active treatment for childhood cancer survivors, 2) ensure the model's sustainability long-term, and (3) develop a mechanism to reimburse a cancer care transition visit.

The model would create a hand off/transition visit per monthly payment that would be available for the six-month period from the patient hand off until they are settled in a clinic or primary care setting.

## How will funding be awarded?

CMS will release a Notice of Funding Opportunity to solicit applications for up to eight cooperative agreements that will implement the CAST Model. Each cooperative agreement will be up to \$16 million for the five-year model period. Applicants will be required to describe how their existing funding sources will be used to deliver services to beneficiaries since model funding may be used only to support model planning and implementation activities. The Notice of Funding Opportunity will specify additional model requirements and eligibility criteria for state applicants.

## What is the model timeline?

The CAST Model will include a **two-year pre-implementation period** in which CMS will work with state Medicaid authorities to develop the infrastructure and procedures necessary for model implementation. A **five-year model implementation period** will follow in which states will implement their models and report required data to CMS.

## Report to Congress

CMMI will report to Congress annually on the demonstration and will provide final recommendations on standards and payments for a survivorship care model at the end of the program.