

115TH CONGRESS
1ST SESSION

H. R. 820

To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2017

Mr. McCAUL (for himself, Ms. SPEIER, Mr. BUTTERFIELD, and Mr. KELLY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Childhood Cancer Survivorship, Treatment, Access, and
6 Research Act of 2017” or the “Childhood Cancer STAR
7 Act”.

8 (b) TABLE OF CONTENTS.—The table of contents for
9 this Act is as follows:

- Sec. 1. Short title; table of contents.
 Sec. 2. Findings.

TITLE I—MAXIMIZING RESEARCH THROUGH DISCOVERY

Subtitle A—Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

- Sec. 101. Children’s cancer biorepositories and biospecimen research.
 Sec. 102. Improving Childhood Cancer Surveillance.

Subtitle B—Pediatric Expertise at NIH

- Sec. 111. Inclusion of at least one pediatric oncologist on the National Cancer
Advisory Board.
 Sec. 112. Sense of Congress regarding pediatric expertise at the National Can-
cer Institute.

Subtitle C—NIH Report on Childhood Cancer Activities

- Sec. 121. Reporting on childhood cancer research projects.

TITLE II—MAXIMIZING DELIVERY: CARE, QUALITY OF LIFE, SURVIVORSHIP, AND CAREGIVER SUPPORT

Subtitle A—Childhood Cancer Survivors’ Quality of Life Act

- Sec. 201. Cancer survivorship programs.
 Sec. 202. Grants to improve care for pediatric cancer survivors.
 Sec. 203. Comprehensive long-term follow-up services for pediatric cancer sur-
vivors.
 Sec. 204. Survivorship demonstration project.

Subtitle B—Coverage and Payment of High Quality Care

- Sec. 211. Report by the Comptroller General.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Each year in the United States there are an
 4 estimated 15,780 children between birth and the age
 5 of 19 diagnosed with cancer. Approximately 1 in 285
 6 children in the United States will be diagnosed with
 7 cancer before their 20th birthday.

8 (2) In 1960, only 4 percent of children with
 9 cancer survived more than 5 years, but today, cure

1 rates have increased to over 80 percent for children
2 and adolescents under age 20.

3 (3) While the cure rates for some childhood
4 cancers are now over 80 percent, the survival rates
5 for many types of cancers in children remain ex-
6 tremely low.

7 (4) According to the Centers for Disease Con-
8 trol and Prevention, cancer continues to be the lead-
9 ing cause of death by disease in children and adoles-
10 cents under the age of 14.

11 (5) By 2020, the population of childhood can-
12 cers survivors is expected to be 500,000 individuals.

13 (6) As many as two-thirds of childhood cancer
14 survivors are likely to experience at least one late ef-
15 fect of treatment, with as many as one-fourth expe-
16 riencing a late effect that is serious or life-threat-
17 ening. Common late effects of childhood cancer are
18 neurocognitive, psychological, cardiopulmonary, en-
19 docrine, and musculoskeletal effects, secondary ma-
20 lignancies, and early death.

21 (7) As a result of disparities in the delivery of
22 cancer care, minority, low-income, and other medi-
23 cally underserved children are more likely to be diag-
24 nosed with late stage disease, experience poorer
25 treatment outcomes, have shorter survival time with

1 less quality of life, and experience a substantially
2 greater likelihood of cancer death.

3 (8) Collection of biospecimens, along with clin-
4 ical and outcome data, on children and adolescents
5 with cancer in the United States is necessary to im-
6 prove childhood and adolescent cancer treatments
7 and cures. Currently biospecimens, and clinical and
8 outcome data, are collected for less than half of chil-
9 dren in the United States with cancer.

10 (9) The late effects of cancer treatment may
11 change as therapies evolve, which means that the
12 monitoring and care of cancer survivors may need to
13 be modified on a routine basis.

14 (10) Despite the intense stress caused by child-
15 hood cancer, there is a lack of standardized and co-
16 ordinated psychosocial care for the children and
17 their families, from the date of diagnosis through
18 treatment and survivorship.

19 (11) The National Academy of Medicine, in its
20 report on cancer survivorship entitled “Childhood
21 Cancer Survivorship: Improving Care and Quality of
22 Life”, states that an organized system of care and
23 a method of care for pediatric cancer survivors is
24 needed.

1 (12) Focused and well-designed research and
2 pilot health delivery programs can answer questions
3 about the optimal ways to provide health care, fol-
4 low-up monitoring services, and survivorship care to
5 those diagnosed with childhood cancer and con-
6 tribute to improvements in the quality of care and
7 quality of life of those individuals through adult-
8 hood.

9 (13) The National Institutes of Health, includ-
10 ing the National Cancer Institute, invest approxi-
11 mately half of their annual appropriations to support
12 basic research that serves as the foundation for
13 translational and clinical research for all diseases
14 and conditions, with the potential to lead to break-
15 throughs for children with cancer. Virtually all
16 progress against cancer—in both children and
17 adults—has been founded in basic research, often in
18 areas not directly related to the disease.

19 (14) The National Cancer Institute supports a
20 number of key research programs specifically to ad-
21 vance childhood cancer care, including precision
22 medicine clinical trials for children with cancer, the
23 Children’s Oncology Group (part of the National
24 Clinical Trials Network of the National Cancer In-
25 stitute), the Pediatric Preclinical Testing Consor-

1 tium, the Pediatric Brain Tumor Consortium, the
 2 Childhood Cancer Survivor Study, the Therapeuti-
 3 cally Applicable Research to Generate Effective
 4 Treatments program and related pediatric cancer
 5 genomics research (including the Pediatric MATCH
 6 Precision Medicine trial), and the Pediatric Oncology
 7 Branch (part of the intramural program of the Na-
 8 tional Cancer Institute, whose mission is to develop
 9 new treatments for pediatric cancer).

10 **TITLE I—MAXIMIZING RE-**
 11 **SEARCH THROUGH DIS-**
 12 **COVERY**

13 **Subtitle A—Caroline Pryce Walker**
 14 **Conquer Childhood Cancer Re-**
 15 **authorization Act**

16 **SEC. 101. CHILDREN’S CANCER BIOREPOSITORIES AND BIO-**
 17 **SPECIMEN RESEARCH.**

18 Section 417E of the Public Health Service Act (42
 19 U.S.C. 285a–11) is amended—

20 (1) by striking subsection (a) and inserting the
 21 following:

22 “(a) CHILDREN’S CANCER BIOREPOSITORIES.—

23 “(1) AWARD.—The Secretary, acting through
 24 the Director of NIH, may make awards to an entity
 25 or entities described in paragraph (4) to build upon

1 existing initiatives to collect biospecimens and clin-
2 ical and demographic information with a goal of col-
3 lection for the vast majority of all children, adoles-
4 cents, and young adults with selected cancer
5 subtypes (and their recurrences) for which current
6 treatments are least effective, through one or more
7 biospecimen research efforts designed to achieve a
8 better understanding of the cause of such cancers
9 (and their recurrences) and the effects of treatments
10 for such cancers.

11 “(2) USE OF FUNDS.—Amounts received under
12 an award under paragraph (1) may be used to carry
13 out the following:

14 “(A) Acquire, preserve, and store high-
15 quality, donated biospecimens and associated
16 clinical and demographic information on chil-
17 dren, adolescents, and young adults diagnosed
18 with cancer in the United States, focusing on
19 children and adolescents enrolled in clinical
20 trials for whom current treatments are least ef-
21 fective. Activities under this subparagraph may
22 include storage of biospecimens and associated
23 clinical and demographic data at biorepositories
24 supported by the National Cancer Institute,
25 such as the Children’s Oncology Group Bio-

1 repository and the Pediatric Cooperative
2 Human Tissue Network as well as through bio-
3 repositories established as appropriate to sup-
4 port the scientific needs of future research ef-
5 forts.

6 “(B) Make such information publicly avail-
7 able, including the repositories described in sub-
8 paragraph (A).

9 “(C) Maintain a secure searchable data-
10 base on stored biospecimens and associated
11 clinical and demographic data from children,
12 adolescents, and young adults with cancer for
13 the conduct of research by scientists and quali-
14 fied health care professionals.

15 “(D) Establish procedures for evaluating
16 applications for access to such biospecimens
17 and clinical and demographic data from re-
18 searchers and other qualified health care pro-
19 fessionals.

20 “(E) Make available and distribute bio-
21 specimens and clinical and demographic data
22 from children, adolescents, and young adults
23 with cancer to researchers and qualified health
24 care professionals for peer-reviewed research at
25 a minimal cost.

1 “(3) NO REQUIREMENT.—No child, adolescent,
2 or young adult with cancer shall be required under
3 this subsection to contribute a specimen to a bio-
4 repository or share clinical or demographic data.

5 “(4) APPLICATION; CONSIDERATIONS.—

6 “(A) APPLICATION.—To be eligible to re-
7 ceive an award under paragraph (1) an entity
8 shall submit an application to the Secretary at
9 such a time, in such manner, and containing
10 such information as the Secretary may reason-
11 ably require.

12 “(B) CONSIDERATIONS.—In evaluating the
13 applications in subparagraph (A), the Secretary
14 shall consider the existing infrastructure of the
15 entity that would allow for the timely capture of
16 biospecimens and related clinical and demo-
17 graphic information for children, adolescents,
18 and young adults with cancer.

19 “(5) PRIVACY PROTECTIONS; CONSENT.—

20 “(A) IN GENERAL.—The Secretary may
21 not make an award under paragraph (1) to an
22 entity unless the Secretary ensures that such
23 entity—

24 “(i) collects biospecimens and associ-
25 ated clinical and demographic information

1 from children and adolescents with appro-
2 priate permission from parents or legal
3 guardians in accordance with Federal and
4 State law; and

5 “(ii) adheres to strict confidentiality
6 to protect the identity and privacy of pa-
7 tients in accordance with Federal and
8 State law.

9 “(B) CONSENT.—The Secretary shall es-
10 tablish an appropriate process for achieving
11 consent from the patient, parent, or legal
12 guardian.

13 “(6) SINGLE POINT OF ACCESS; STANDARD
14 DATA; GUIDELINES AND OVERSIGHT.—

15 “(A) SINGLE POINT OF ACCESS.—The Sec-
16 retary shall ensure that each biorepository sup-
17 ported under paragraph (1) has electronically
18 searchable data for use by researchers and
19 other qualified health care professionals in the
20 manner and to the extent defined by the Sec-
21 retary.

22 “(B) STANDARD DATA.—The Secretary
23 shall require all recipients of an award under
24 paragraph (1) to make available a standard
25 dataset for the purposes of subparagraph (A) in

1 a standard electronic format that enables re-
2 searchers and qualified health care professionals
3 to search.

4 “(C) GUIDELINES AND OVERSIGHT.—The
5 Secretary shall develop and disseminate appro-
6 priate guidelines for the development and main-
7 tenance of the biorepositories supported under
8 this subsection, including appropriate oversight.

9 “(7) COORDINATION.—The Secretary shall en-
10 sure that clinical and demographic information col-
11 lected in accordance with this subsection is collected
12 in coordination with the information collected under
13 section 399E–1.

14 “(8) PROHIBITION ON USE OF FUNDS.—Funds
15 made available to carry out this subsection shall not
16 be used to acquire, preserve, or maintain a biospeci-
17 men collected from a patient if such activity is al-
18 ready covered by funds available from the National
19 Cancer Institute for such purpose.

20 “(9) REPORT.—Not later than 4 years after the
21 date of enactment of the Childhood Cancer Survivor-
22 ship, Treatment, Access, and Research Act of 2017,
23 the Secretary shall submit to Congress a report on—

24 “(A) the number of biospecimens and cor-
25 responding clinical demographic data collected

1 through the biospecimen research efforts sup-
2 ported under paragraph (1);

3 “(B) the number of biospecimens and cor-
4 responding clinical demographic data requested
5 for use by researchers;

6 “(C) any barriers to the collection of bio-
7 specimens and corresponding clinical demo-
8 graphic data;

9 “(D) any barriers experienced by research-
10 ers or health care professionals in accessing the
11 biospecimens and corresponding clinical demo-
12 graphic data necessary for use in research; and

13 “(E) any recommendations with respect to
14 improving the biospecimen and biorepository re-
15 search efforts under this subsection.

16 “(10) DEFINITIONS.—For purposes of this sub-
17 section:

18 “(A) AWARD.—The term ‘award’ includes
19 a grant, contract, cooperative agreement, or
20 other transaction determined by the Secretary.

21 “(B) BIOSPECIMEN.—The term ‘biospeci-
22 men’ includes—

23 “(i) solid tumor tissue or bone mar-
24 row;

25 “(ii) normal or control tissue;

1 “(iii) blood and plasma;
2 “(iv) DNA and RNA extractions;
3 “(v) familial DNA; and
4 “(vi) any other sample required by the
5 Secretary.

6 “(C) CLINICAL AND DEMOGRAPHIC INFOR-
7 MATION.—The term ‘clinical and demographic
8 information’ includes—

9 “(i) date of diagnosis;
10 “(ii) age at diagnosis;
11 “(iii) the patient’s gender, race, eth-
12 nicity, and environmental exposures;
13 “(iv) extent of disease at enrollment;
14 “(v) site of metastases;
15 “(vi) location of primary tumor coded;
16 “(vii) histologic diagnosis;
17 “(viii) tumor marker data when avail-
18 able;
19 “(ix) treatment and outcome data;
20 “(x) information related to specimen
21 quality; and
22 “(xi) any other information required
23 by the Secretary.”; and
24 (2) in subsection (d)—

1 (A) by striking “and section 399E–1” and
2 inserting “and sections 317U, 399E–1, 417H,
3 and 417H–1”;

4 (B) by striking “2009 through 2013” and
5 inserting “2018 through 2022”; and

6 (C) by striking “such purpose” and insert-
7 ing “such purposes”.

8 **SEC. 102. IMPROVING CHILDHOOD CANCER SURVEIL-**
9 **LANCE.**

10 Section 399E–1 of the Public Health Service Act (42
11 U.S.C. 280e–3a) is amended—

12 (1) by redesignating subsection (b) as sub-
13 section (d); and

14 (2) by striking subsection (a) and inserting the
15 following:

16 “(a) IN GENERAL.—The Secretary, acting through
17 the Director of the Centers for Disease Control and Pre-
18 vention, may make awards to State cancer registries to
19 enhance and expand infrastructure to track the epidemi-
20 ology of cancer in children, adolescents, and young adults.
21 Such registries may be updated to include each occurrence
22 of such cancers within a period of time designated by the
23 Secretary.

24 “(b) ACTIVITIES.—The grants described in sub-
25 section (a) may be used for—

1 “(1) identifying, recruiting, and training all po-
2 tential sources for reporting childhood, adolescent,
3 and young adult cancer cases;

4 “(2) developing procedures to implement early
5 inclusion of childhood, adolescent, and young adult
6 cancer cases on State cancer registries through the
7 use of electronic reporting;

8 “(3) purchasing infrastructure to support the
9 early inclusion of childhood, adolescent, and young
10 adult cancer cases on such registries;

11 “(4) submitting deidentified data to the Centers
12 for Disease Control and Prevention for inclusion in
13 a national database of childhood, adolescent, and
14 young adult cancers; and

15 “(5) tracking the late effects of childhood, ado-
16 lescent, and young adult cancers.

17 “(c) COORDINATION.—The Secretary shall ensure
18 that information collected through State cancer registries
19 under this section is collected in coordination with clinical
20 and demographic information collected under section
21 417E(a), as appropriate.”.

1 **Subtitle B—Pediatric Expertise at**
2 **NIH**

3 **SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC**
4 **ONCOLOGIST ON THE NATIONAL CANCER AD-**
5 **VISORY BOARD.**

6 Clause (iii) of section 406(h)(2)(A) of the Public
7 Health Service Act (42 U.S.C. 284a(h)(2)(A)) is amended
8 to read as follows:

9 “(iii) of the members appointed to the Board—

10 “(I) not less than 5 members shall be indi-
11 viduals knowledgeable in environmental carcino-
12 genesis (including carcinogenesis involving occu-
13 pational and dietary factors); and

14 “(II) not less than one member shall be an
15 individual knowledgeable in pediatric oncol-
16 ogy;”.

17 **SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EX-**
18 **PERTISE AT THE NATIONAL CANCER INSTI-**
19 **TUTE.**

20 It is the sense of Congress that the Director of the
21 National Cancer Institute should ensure that all applicable
22 study sections, committees, advisory groups, and panels
23 at the National Cancer Institute include one or more
24 qualified pediatric oncologists, as appropriate.

**Subtitle C—NIH Report on
Childhood Cancer Activities**

**SEC. 121. REPORTING ON CHILDHOOD CANCER RESEARCH
PROJECTS.**

Section 409D(c)(3) of the Public Health Service Act
(42 U.S.C. 284h(c)(3)) is amended by—

(1) striking “public on” and inserting “public
on—

“(A)”;

(2) striking the period at the end and inserting
“; and”; and

(3) inserting at the end the following:

“(B) childhood cancer research projects
conducted or supported by the National Insti-
tutes of Health.”.

**TITLE II—MAXIMIZING DELIV-
ERY: CARE, QUALITY OF LIFE,
SURVIVORSHIP, AND CARE-
GIVER SUPPORT**

**Subtitle A—Childhood Cancer
Survivors’ Quality of Life Act**

SEC. 201. CANCER SURVIVORSHIP PROGRAMS.

(a) CANCER SURVIVORSHIP PROGRAMS.—The Public
Health Service Act is amended by inserting after section
399N of such Act (42 U.S.C. 280g–2) the following:

1 **“SEC. 399N-1. PILOT PROGRAMS TO EXPLORE MODEL SYS-**
2 **TEMS OF CARE FOR PEDIATRIC CANCER SUR-**
3 **VIVORS.**

4 “(a) IN GENERAL.—Not later than 1 year after the
5 date of enactment of the Childhood Cancer Survivorship,
6 Treatment, Access, and Research Act of 2017, the Sec-
7 retary may make awards to eligible entities to establish
8 pilot programs to develop, study, or evaluate model sys-
9 tems for monitoring and caring for childhood cancer sur-
10 vivors throughout their lifespan, including evaluation of
11 shared care and medical home and clinic based models for
12 transition to adult care.

13 “(b) ELIGIBLE ENTITIES.—In this section, the term
14 ‘eligible entity’ means—

15 “(1) a medical school;

16 “(2) a children’s hospital;

17 “(3) a cancer center;

18 “(4) a community-based medical facility; or

19 “(5) any other entity with significant experience
20 and expertise in treating survivors of childhood can-
21 cers.

22 “(c) USE OF FUNDS.—The Secretary may make an
23 award under this section to an eligible entity only if the
24 entity agrees—

25 “(1) to use the award to establish a pilot pro-
26 gram to develop, study, or evaluate one or more

1 model systems for monitoring and caring for cancer
2 survivors; and

3 “(2) in developing, studying, and evaluating
4 such systems, to give special emphasis to—

5 “(A) design of protocols for different mod-
6 els of follow-up care, monitoring, and other sur-
7 vivorship programs (including peer support and
8 mentoring programs);

9 “(B) development of various models for
10 providing multidisciplinary care;

11 “(C) dissemination of information and the
12 provision of training to health care providers
13 about how to provide linguistically and cul-
14 turally competent follow-up care and monitoring
15 to cancer survivors and their families;

16 “(D) development of psychosocial interven-
17 tions and support programs to improve the
18 quality of life of cancer survivors and their fam-
19 ilies;

20 “(E) design of systems for the effective
21 transfer of treatment information and care
22 summaries from cancer care providers to other
23 health care providers (including risk factors and
24 a plan for recommended follow-up care);

1 “(F) dissemination of the information and
2 programs described in subparagraphs (A)
3 through (E) to other health care providers (in-
4 cluding primary care physicians and internists)
5 and to cancer survivors and their families,
6 where appropriate; and

7 “(G) development of initiatives that pro-
8 mote the coordination and effective transition of
9 care between cancer care providers, primary
10 care physicians, and mental health profes-
11 sionals.

12 **“SEC. 399N-2. WORKFORCE DEVELOPMENT COLLABO-**
13 **RATIVE ON MEDICAL AND PSYCHOSOCIAL**
14 **CARE FOR CHILDHOOD CANCER SURVIVORS.**

15 “(a) IN GENERAL.—The Secretary shall, not later
16 than 1 year after the date of enactment of the Childhood
17 Cancer Survivorship, Treatment, Access, and Research
18 Act of 2017, convene a Workforce Development Collabo-
19 rative on Medical and Psychosocial Care for Pediatric
20 Cancer Survivors (referred to in this section as the ‘Col-
21 laborative’). The Collaborative shall be a cross-specialty,
22 multidisciplinary group composed of educators, consumer
23 and family advocates, and providers of psychosocial and
24 biomedical health services.

1 “(b) GOALS AND REPORTS.—The Collaborative shall
2 submit to the Secretary a report establishing a plan to
3 meet the following objectives for medical and psychosocial
4 care workforce development:

5 “(1) Identifying, refining, and broadly dissemi-
6 nating to health care educators information about
7 workforce competencies, models, and curricula rel-
8 evant to providing medical and psychosocial services
9 to persons surviving pediatric cancers.

10 “(2) Adapting curricula for continuing edu-
11 cation of the existing workforce using efficient work-
12 place-based learning approaches.

13 “(3) Developing the skills of faculty and other
14 trainers in teaching psychosocial health care using
15 evidence-based teaching strategies.

16 “(4) Strengthening the emphasis on psycho-
17 social health care in educational accreditation stand-
18 ards and professional licensing and certification
19 exams by recommending revisions to the relevant
20 oversight organizations.

21 “(5) Evaluating the effectiveness of patient
22 navigators in pediatric cancer survivorship care.

23 “(6) Evaluating the effectiveness of peer sup-
24 port programs in the psychosocial care of pediatric
25 cancer patients and survivors.”.

1 (b) TECHNICAL AMENDMENT.—

2 (1) IN GENERAL.—Section 3 of the
3 Hematological Cancer Research Investment and
4 Education Act of 2002 (Public Law 107–172; 116
5 Stat. 541) is amended by striking “section 419C”
6 and inserting “section 417C”.

7 (2) EFFECTIVE DATE.—The amendment made
8 by paragraph (1) shall take effect as if included in
9 section 3 of the Hematological Cancer Research In-
10 vestment and Education Act of 2002 (Public Law
11 107–172; 116 Stat. 541).

12 **SEC. 202. GRANTS TO IMPROVE CARE FOR PEDIATRIC CAN-**
13 **CER SURVIVORS.**

14 (a) IN GENERAL.—Section 417E of the Public
15 Health Service Act (42 U.S.C. 285a–11), as amended by
16 section 101, is further amended—

17 (1) in the section heading, by striking “**RE-**
18 **SEARCH AND AWARENESS**” and inserting “**RE-**
19 **SEARCH, AWARENESS, AND SURVIVORSHIP**”;
20 and

21 (2) by striking subsection (b) and inserting the
22 following:

23 “(b) IMPROVING CARE FOR PEDIATRIC CANCER SUR-
24 VIVORS.—

1 “(1) RESEARCH ON CAUSES OF HEALTH DIS-
2 PARITIES IN PEDIATRIC CANCER SURVIVORSHIP.—

3 “(A) RESEARCH AWARDS.—The Director
4 of NIH, in coordination with ongoing research
5 activities, may conduct or support pediatric
6 cancer survivorship research including in any of
7 the following areas:

8 “(i) Needs and outcomes of pediatric
9 cancer survivors within minority or other
10 medically underserved populations.

11 “(ii) Health disparities in pediatric
12 cancer survivorship outcomes within minor-
13 ity or other medically underserved popu-
14 lations.

15 “(iii) Barriers that pediatric cancer
16 survivors within minority or other medi-
17 cally underserved populations face in re-
18 ceiving follow-up care.

19 “(iv) Familial, socioeconomic, and
20 other environmental factors and the impact
21 of such factors on treatment outcomes and
22 survivorship.

23 “(B) BALANCED APPROACH.—In con-
24 ducting or supporting research under subpara-
25 graph (A)(i) on pediatric cancer survivors with-

1 in minority or other medically underserved pop-
2 ulations, the Director of NIH shall ensure that
3 such research addresses both the physical and
4 the psychological needs of such survivors, as ap-
5 propriate.

6 “(2) RESEARCH ON LATE EFFECTS AND FOL-
7 LOW-UP CARE FOR PEDIATRIC CANCER SUR-
8 VIVORS.—The Director of NIH, in coordination with
9 ongoing research activities, may conduct or support
10 research on follow-up care for pediatric cancer sur-
11 vivors, including in any of the following areas:

12 “(A) The development of indicators used
13 for long-term patient tracking and analysis of
14 the late effects of cancer treatment for pediatric
15 cancer survivors.

16 “(B) The identification of risk factors as-
17 sociated with the late effects of cancer treat-
18 ment.

19 “(C) The identification of predictors of ad-
20 verse neurocognitive and psychosocial outcomes.

21 “(D) The identification of the molecular
22 underpinnings of long-term complications.

23 “(E) The development of risk prediction
24 models to identify those at highest risk of long-
25 term complications.

1 “(F) Initiatives to protect cancer survivors
 2 from the late effects of cancer treatment, by de-
 3 veloping targeted interventions to reduce the
 4 burden of morbidity borne by cancer survivors.

5 “(G) Transitions in care for pediatric can-
 6 cer survivors.

7 “(H) Training of professionals to provide
 8 linguistically and culturally competent follow-up
 9 care to pediatric cancer survivors.

10 “(I) Different models of follow-up care.

11 “(J) Examining the cost-effectiveness of
 12 the different models of follow-up care.”.

13 **SEC. 203. COMPREHENSIVE LONG-TERM FOLLOW-UP SERV-**
 14 **ICES FOR PEDIATRIC CANCER SURVIVORS.**

15 Part B of title III of the Public Health Service Act
 16 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
 17 tion 317T the following:

18 **“SEC. 317U. STANDARDS FOR COMPREHENSIVE LONG-TERM**
 19 **CARE FOR PEDIATRIC CANCER SURVIVORS**
 20 **THROUGH THE LIFESPAN.**

21 “The Secretary may establish a task force to develop
 22 and test standards, outcomes, and metrics for high-quality
 23 childhood cancer survivorship care in consultation with a
 24 full spectrum of representation of experts in late effects
 25 of disease and treatment of childhood cancers, including—

- 1 “(1) oncologists who treat children and adoles-
- 2 cents;
- 3 “(2) oncologists who treat adults;
- 4 “(3) primary care providers engaged in survi-
- 5 vorship care;
- 6 “(4) survivors of childhood cancer;
- 7 “(5) parents of children who have been diag-
- 8 nosed with and treated for cancer and parents of
- 9 long-term survivors;
- 10 “(6) professionals who are engaged in the devel-
- 11 opment of clinical practice guidelines;
- 12 “(7) nurses and social workers;
- 13 “(8) mental health professionals;
- 14 “(9) allied health professionals, including phys-
- 15 ical therapists and occupational therapists;
- 16 “(10) experts in health care quality measure-
- 17 ment and improvement; and
- 18 “(11) others, as the Secretary determines ap-
- 19 propriate.”.

20 **SEC. 204. SURVIVORSHIP DEMONSTRATION PROJECT.**

21 (a) IN GENERAL.—Not later than 1 year after the
22 date of the enactment of this Act, the Secretary of Health
23 and Human Services (referred to in this section as the
24 “Secretary”) may carry out a demonstration project over
25 a 3-year period, designed to improve the quality and effi-

1 ciency of care provided to childhood cancer survivors
2 throughout their lifespan, through improved care coordi-
3 nation as survivors transitions to adult care.

4 (b) SELECTION OF DEMONSTRATION SITES.—

5 (1) MAXIMUM NUMBER OF SITES.—The max-
6 imum number of sites at which the demonstration
7 project under subsection (a) is carried out may not
8 exceed 10.

9 (2) DIVERSITY OF SITES.—In selecting entities
10 to participate in the demonstration project, the Sec-
11 retary may, to the extent practicable, include in such
12 selection—

13 (A) small-, medium-, and large-sized sites;
14 and

15 (B) sites located in different geographic
16 areas.

17 (c) ACTIVITIES UNDER DEMONSTRATION
18 PROJECT.—The activities conducted under the demonstra-
19 tion project under subsection (a) may, in addition to any
20 other activity specified by the Secretary, include activities
21 that seek to develop different models of care coordination,
22 including transitions of care, follow-up care, monitoring,
23 and other survivorship related programs that utilize a
24 multidisciplinary, team based approach to care, including
25 any of the following activities:

1 (1) Coordination of care and transitions of care
2 between cancer care providers, primary care physi-
3 cians, mental health professionals and any other rel-
4 evant providers.

5 (2) Dissemination of information to, and train-
6 ing of, health care providers about linguistically and
7 culturally competent follow-up care specific to cancer
8 survivors.

9 (3) Development of monitoring programs for
10 cancer survivors and their families.

11 (4) Incorporation of peer support and men-
12 toring programs to improve the quality of life of can-
13 cer survivors.

14 (5) Designing systems and models for the effec-
15 tive transfer of treatment information and care sum-
16 maries from cancer care providers to other health
17 care providers (including risk factors and a care
18 plan).

19 (6) Evaluation of functional status and incorpo-
20 ration of specific functional needs into the care plan-
21 ning process.

22 (7) Dissemination of the information on activi-
23 ties and programs conducted under this section to
24 other health care providers (including primary care

1 physicians) and to cancer survivors and their fami-
2 lies, where appropriate.

3 (8) Other items determined by the Secretary.

4 (d) MEASURES.—The Secretary may use the fol-
5 lowing measures to assess the performance of each site:

6 (1) Patient care and patient/family satisfaction
7 measures.

8 (2) Resource utilization measures.

9 (3) Adult survivorship measures, as appro-
10 priate.

11 (e) GAO REPORT.—The Comptroller General of the
12 United States shall submit a report to Congress evaluating
13 the success of the demonstration project. Such report shall
14 include an assessment of the impact of the project upon
15 the quality and cost-efficiency of services furnished to indi-
16 viduals under this title, including an assessment of the sat-
17 isfaction of such individuals with respect to such services
18 that were furnished under such project. Such report shall
19 include recommendations regarding the possible expansion
20 of the demonstration project.

21 **Subtitle B—Coverage and Payment** 22 **of High Quality Care**

23 **SEC. 211. REPORT BY THE COMPTROLLER GENERAL.**

24 (a) IN GENERAL.—The Comptroller General of the
25 United States shall conduct a review and submit rec-

1 ommendations to Congress on existing barriers to obtain-
2 ing and paying for adequate medical care for survivors of
3 childhood cancer.

4 (b) CONSIDERATIONS.—In carrying out the review
5 and formulating recommendations under subsection (a),
6 the Comptroller General shall—

7 (1) identify existing barriers to the availability
8 of complete and coordinated survivorship care for
9 survivors of childhood cancer and to the availability
10 of expert pediatric palliative care, including consider-
11 ation of—

12 (A) understanding and education among
13 patients, health care providers, regulators, and
14 third-party payors;

15 (B) adequacy of payment codes to cover
16 necessary survivorship services;

17 (C) access to necessary medical and other
18 services for such survivors, including the serv-
19 ices described in subsection (c); and

20 (D) lack of pediatric palliative care across
21 all stages of illness and hospice services for pa-
22 tients approaching the end of life; and

23 (2) make recommendations to provide improved
24 access and payment plans for childhood cancer sur-

1 survivorship programs and palliative care, including
2 psychosocial services and coverage of such services.

3 (c) SERVICES DESCRIBED.—The services described in
4 this subsection are the following:

5 (1) Coordinated multidisciplinary long-term fol-
6 low-up care with access to appropriate pediatric sub-
7 specialists and adult subspecialists with specific ex-
8 pertise in survivorship, including subspecialists with
9 expertise in oncology, radiation oncology, surgery,
10 cardiology, psychiatry or psychology, endocrinology,
11 pulmonology, nephrology, dermatology, gynecology,
12 and urology.

13 (2) Appropriate organ function testing (particu-
14 larly screening for potential problems at much
15 younger ages than usually indicated in the general
16 population) and treatment, including—

17 (A) neuropsychological testing and mental
18 health services;

19 (B) fertility testing and treatment;

20 (C) evaluation and treatment for endocrine
21 disorders including growth hormone and testos-
22 terone replacement;

23 (D) diagnostic imaging to screen for late
24 effects of treatment (including subsequent can-
25 cers), such as mammograms and magnetic reso-

1 nance imaging testing to screen for possible
2 breast cancer;

3 (E) screening for cardiac problems, such
4 as echocardiograms;

5 (F) screening for osteoporosis with bone
6 densitometry, including dual x-ray absorptiome-
7 try and monitoring 25-hydroxyvitamin D levels;

8 (G) dental coverage and necessary dental
9 implants;

10 (H) hearing aids and other prosthetic de-
11 vices; and

12 (I) screening for lung problems, such as
13 pulmonary function testing.

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