

114TH CONGRESS
2^D SESSION

H. R. 3381

AN ACT

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,*

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

2 (a) SHORT TITLE.—This Act may be cited as the
 3 “Childhood Cancer Survivorship, Treatment, Access, and
 4 Research Act of 2016” or the “Childhood Cancer STAR
 5 Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
 7 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.

8 **SEC. 2. FINDINGS.**

9 Congress makes the following findings:

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

6 (2) In 1960, only 4 percent of children with
7 cancer survived more than 5 years, but today, cure
8 rates have increased to over 80 percent for children
9 and adolescents under age 20.

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

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

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

20 (6) As many as two-thirds of childhood cancer
21 survivors are likely to experience at least one late ef-
22 fect of treatment, with as many as one-fourth expe-
23 riencing a late effect that is serious or life-threat-
24 ening. Common late effects of childhood cancer are
25 neurocognitive, psychological, cardiopulmonary, en-

1 docrine, and musculoskeletal effects, secondary ma-
2 lignancies, and early death.

3 (7) As a result of disparities in the delivery of
4 cancer care, minority, low-income, and other medi-
5 cally underserved children are more likely to be diag-
6 nosed with late stage disease, experience poorer
7 treatment outcomes, have shorter survival time with
8 less quality of life, and experience a substantially
9 greater likelihood of cancer death.

10 (8) Collection of biospecimens, along with clin-
11 ical and outcome data, on children and adolescents
12 with cancer in the United States is necessary to im-
13 prove childhood and adolescent cancer treatments
14 and cures. Currently biospecimens, and clinical and
15 outcome data, are collected for less than half of chil-
16 dren in the United States with cancer.

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

21 (10) Despite the intense stress caused by child-
22 hood cancer, there is a lack of standardized and co-
23 ordinated psychosocial care for the children and
24 their families, from the date of diagnosis through
25 treatment and survivorship.

1 (11) The Institute of Medicine, in its report on
2 cancer survivorship entitled “Childhood Cancer Sur-
3 vivorship: Improving Care and Quality of Life”,
4 states that an organized system of care and a meth-
5 od of care for pediatric cancer survivors is needed.

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

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

24 (14) The National Cancer Institute supports a
25 number of key research programs specifically to ad-

1 vance childhood cancer care, including precision
2 medicine clinical trials for children with cancer, the
3 Children’s Oncology Group (part of the National
4 Clinical Trials Network of the National Cancer In-
5 stitute), the Pediatric Preclinical Testing Consor-
6 tium, the Pediatric Brain Tumor Consortium, the
7 Childhood Cancer Survivor Study, the Therapeuti-
8 cally Applicable Research to Generate Effective
9 Treatments program and related pediatric cancer
10 genomics research (including the Pediatric MATCH
11 Precision Medicine trial), and the Pediatric Oncology
12 Branch (part of the intramural program of the Na-
13 tional Cancer Institute, whose mission is to develop
14 new treatments for pediatric cancer).

15 **TITLE I—MAXIMIZING RE-**
16 **SEARCH THROUGH DIS-**
17 **COVERY**

18 **Subtitle A—Caroline Pryce Walker**
19 **Conquer Childhood Cancer Re-**
20 **authorization Act**

21 **SEC. 101. CHILDREN’S CANCER BIOREPOSITORIES AND BIO-**
22 **SPECIMEN RESEARCH.**

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

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

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

4 “(1) AWARD.—The Secretary, acting through
5 the Director of NIH, may make awards to an entity
6 or entities described in paragraph (4) to build upon
7 existing initiatives to collect biospecimens and clinical
8 and demographic information with a goal of collection
9 for the vast majority of all children, adolescents,
10 cents, and young adults with selected cancer
11 subtypes (and their recurrences) for which current
12 treatments are least effective, through one or more
13 biospecimen research efforts designed to achieve a
14 better understanding of the cause of such cancers
15 (and their recurrences) and the effects of treatments
16 for such cancers.

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

20 “(A) Acquire, preserve, and store high-
21 quality, donated biospecimens and associated
22 clinical and demographic information on children,
23 adolescents, and young adults diagnosed
24 with cancer in the United States, focusing on
25 children and adolescents enrolled in clinical

1 trials for whom current treatments are least ef-
2 fective. Activities under this subparagraph may
3 include storage of biospecimens and associated
4 clinical and demographic data at biorepositories
5 supported by the National Cancer Institute,
6 such as the Children’s Oncology Group Bio-
7 repository and the Pediatric Cooperative
8 Human Tissue Network as well as through bio-
9 repositories established as appropriate to sup-
10 port the scientific needs of future research ef-
11 forts.

12 “(B) Make such information publicly avail-
13 able, including the repositories described in sub-
14 paragraph (A).

15 “(C) Maintain a secure searchable data-
16 base on stored biospecimens and associated
17 clinical and demographic data from children,
18 adolescents, and young adults with cancer for
19 the conduct of research by scientists and quali-
20 fied health care professionals.

21 “(D) Establish procedures for evaluating
22 applications for access to such biospecimens
23 and clinical and demographic data from re-
24 searchers and other qualified health care pro-
25 fessionals.

1 “(E) Make available and distribute bio-
2 specimens and clinical and demographic data
3 from children, adolescents, and young adults
4 with cancer to researchers and qualified health
5 care professionals for peer-reviewed research at
6 a minimal cost.

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

11 “(4) APPLICATION; CONSIDERATIONS.—

12 “(A) APPLICATION.—To be eligible to re-
13 ceive an award under paragraph (1) an entity
14 shall submit an application to the Secretary at
15 such a time, in such manner, and containing
16 such information as the Secretary may reason-
17 ably require.

18 “(B) CONSIDERATIONS.—In evaluating the
19 applications in subparagraph (A), the Secretary
20 shall consider the existing infrastructure of the
21 entity that would allow for the timely capture of
22 biospecimens and related clinical and demo-
23 graphic information for children, adolescents,
24 and young adults with cancer.

25 “(5) PRIVACY PROTECTIONS; CONSENT.—

1 “(A) IN GENERAL.—The Secretary may
2 not make an award under paragraph (1) to an
3 entity unless the Secretary ensures that such
4 entity—

5 “(i) collects biospecimens and associ-
6 ated clinical and demographic information
7 from children and adolescents with appro-
8 priate permission from parents or legal
9 guardians in accordance with Federal and
10 State law; and

11 “(ii) adheres to strict confidentiality
12 to protect the identity and privacy of pa-
13 tients in accordance with Federal and
14 State law.

15 “(B) CONSENT.—The Secretary shall es-
16 tablish an appropriate process for achieving
17 consent from the patient, parent, or legal
18 guardian.

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

21 “(A) SINGLE POINT OF ACCESS.—The Sec-
22 retary shall ensure that each biorepository sup-
23 ported under paragraph (1) has electronically
24 searchable data for use by researchers and
25 other qualified health care professionals in the

1 manner and to the extent defined by the Sec-
2 retary.

3 “(B) STANDARD DATA.—The Secretary
4 shall require all recipients of an award under
5 this section to make available a standard
6 dataset for the purposes of subparagraph (A) in
7 a standard electronic format that enables re-
8 searchers and qualified health care professionals
9 to search.

10 “(C) GUIDELINES AND OVERSIGHT.—The
11 Secretary shall develop and disseminate appro-
12 priate guidelines for the development and main-
13 tenance of the biorepositories supported under
14 this section, including appropriate oversight.

15 “(7) COORDINATION.—The Secretary shall en-
16 sure that clinical and demographic information col-
17 lected in accordance with this section is collected in
18 coordination with the information collected under
19 section 399E–1.

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

1 “(9) REPORT.—Not later than 4 years after the
2 date of enactment of the Childhood Cancer Survivor-
3 ship, Treatment, Access, and Research Act of 2016,
4 the Secretary shall submit to Congress a report on—

5 “(A) the number of biospecimens and cor-
6 responding clinical demographic data collected
7 through the biospecimen research efforts sup-
8 ported under paragraph (1);

9 “(B) the number of biospecimens and cor-
10 responding clinical demographic data requested
11 for use by researchers;

12 “(C) any barriers to the collection of bio-
13 specimens and corresponding clinical demo-
14 graphic data;

15 “(D) any barriers experienced by research-
16 ers or health care professionals in accessing the
17 biospecimens and corresponding clinical demo-
18 graphic data necessary for use in research; and

19 “(E) any recommendations with respect to
20 improving the biospecimen and biorepository re-
21 search efforts under this subsection.

22 “(10) DEFINITIONS.—For purposes of this sub-
23 section:

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

4 “(B) BIOSPECIMEN.—The term ‘biospeci-
5 men’ includes—

6 “(i) solid tumor tissue or bone mar-
7 row;

8 “(ii) normal or control tissue;

9 “(iii) blood and plasma;

10 “(iv) DNA and RNA extractions;

11 “(v) familial DNA; and

12 “(vi) any other sample required by the
13 Secretary.

14 “(C) CLINICAL AND DEMOGRAPHIC INFOR-
15 MATION.—The term ‘clinical and demographic
16 information’ includes—

17 “(i) date of diagnosis;

18 “(ii) age at diagnosis;

19 “(iii) the patient’s gender, race, eth-
20 nicity, and environmental exposures;

21 “(iv) extent of disease at enrollment;

22 “(v) site of metastases;

23 “(vi) location of primary tumor coded;

24 “(vii) histologic diagnosis;

1 “(viii) tumor marker data when avail-
2 able;

3 “(ix) treatment and outcome data;

4 “(x) information related to specimen
5 quality; and

6 “(xi) any other information required
7 by the Secretary.”; and

8 (2) in subsection (d)—

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

12 (B) by striking “2009 through 2013” and
13 inserting “2017 through 2021”; and

14 (C) by striking “such purpose” and insert-
15 ing “such purposes”.

16 **SEC. 102. IMPROVING CHILDHOOD CANCER SURVEIL-**
17 **LANCE.**

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

20 (1) by redesignating subsection (b) as sub-
21 section (d); and

22 (2) by striking subsection (a) and inserting the
23 following:

24 “(a) **IN GENERAL.**—The Secretary, acting through
25 the Director of the Centers for Disease Control and Pre-

1 vention, may make awards to State cancer registries to
2 enhance and expand infrastructure to track the epidemi-
3 ology of cancer in children, adolescents, and young adults.
4 Such registries may be updated to include each occurrence
5 of such cancers within a period of time designated by the
6 Secretary.

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

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

12 “(2) developing procedures to implement early
13 inclusion of childhood, adolescent, and young adult
14 cancer cases on State cancer registries through the
15 use of electronic reporting;

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

19 “(4) submitting deidentified data to the Centers
20 for Disease Control and Prevention for inclusion in
21 a national database of childhood, adolescent, and
22 young adult cancers; and

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

1 “(c) COORDINATION.—The Secretary shall ensure
2 that information collected through State cancer registries
3 under this section is collected in coordination with clinical
4 and demographic information collected under section
5 417E(a) as appropriate.”.

6 **Subtitle B—Pediatric Expertise at**
7 **NIH**

8 **SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC**
9 **ONCOLOGIST ON THE NATIONAL CANCER AD-**
10 **VISORY BOARD.**

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

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

15 “(I) not less than five members shall be in-
16 dividuals knowledgeable in environmental car-
17 cinogenesis (including carcinogenesis involving
18 occupational and dietary factors); and

19 “(II) not less than one member shall be an
20 individual knowledgeable in pediatric oncol-
21 ogy;”.

1 **SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EX-**
2 **PERTISE AT THE NATIONAL CANCER INSTI-**
3 **TUTE.**

4 It is the sense of Congress that the Director of the
5 National Cancer Institute should ensure that all applicable
6 study sections, committees, advisory groups, and panels
7 at the National Cancer Institute include one or more
8 qualified pediatric oncologists, as appropriate.

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

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

13 Section 409D(c)(3) of the Public Health Service Act
14 (42 U.S.C. 284h(c)(3)) is amended by—

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

17 “(A)”;

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

20 (3) inserting at the end the following:

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

1 **TITLE II—MAXIMIZING DELIV-**
2 **ERY: CARE, QUALITY OF LIFE,**
3 **SURVIVORSHIP, AND CARE-**
4 **GIVER SUPPORT**
5 **Subtitle A—Childhood Cancer**
6 **Survivors’ Quality of Life Act**

7 **SEC. 201. CANCER SURVIVORSHIP PROGRAMS.**

8 (a) CANCER SURVIVORSHIP PROGRAMS.—The Public
9 Health Service Act is amended by inserting after section
10 399N of such Act (42 U.S.C. 280g–2) the following:

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

14 “(a) IN GENERAL.—Not later than 1 year after the
15 date of enactment of this section, the Secretary may make
16 awards to eligible entities to establish pilot programs to
17 develop, study, or evaluate model systems for monitoring
18 and caring for childhood cancer survivors throughout their
19 lifespan, including evaluation of shared care and medical
20 home and clinic based models for transition to adult care.

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

23 “(1) a medical school;

24 “(2) a children’s hospital;

25 “(3) a cancer center;

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

2 “(5) any other entity with significant experience
3 and expertise in treating survivors of childhood can-
4 cers.

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

8 “(1) to use the award to establish a pilot pro-
9 gram to develop, study, or evaluate one or more
10 model systems for monitoring and caring for cancer
11 survivors; and

12 “(2) in developing, studying, and evaluating
13 such systems, to give special emphasis to the fol-
14 lowing:

15 “(A) Design of protocols for different mod-
16 els of follow-up care, monitoring, and other sur-
17 vivorship programs (including peer support and
18 mentoring programs).

19 “(B) Development of various models for
20 providing multidisciplinary care.

21 “(C) Dissemination of information and the
22 provision of training to health care providers
23 about how to provide linguistically and cul-
24 turally competent follow-up care and monitoring
25 to cancer survivors and their families.

1 “(D) Development of psychosocial inter-
2 ventions and support programs to improve the
3 quality of life of cancer survivors and their fam-
4 ilies.

5 “(E) Design of systems for the effective
6 transfer of treatment information and care
7 summaries from cancer care providers to other
8 health care providers (including risk factors and
9 a plan for recommended follow-up care).

10 “(F) Dissemination of the information and
11 programs described in subparagraphs (A)
12 through (E) to other health care providers (in-
13 cluding primary care physicians and internists)
14 and to cancer survivors and their families,
15 where appropriate.

16 “(G) Development of initiatives that pro-
17 mote the coordination and effective transition of
18 care between cancer care providers, primary
19 care physicians, and mental health profes-
20 sionals.

21 **“SEC. 399N-2. WORKFORCE DEVELOPMENT COLLABO-**
22 **RATIVE ON MEDICAL AND PSYCHOSOCIAL**
23 **CARE FOR CHILDHOOD CANCER SURVIVORS.**

24 “(a) IN GENERAL.—The Secretary shall, not later
25 than 1 year after the date of enactment of this Act, con-

1 vene a Workforce Development Collaborative on Medical
2 and Psychosocial Care for Pediatric Cancer Survivors (re-
3 ferred to in this paragraph as the ‘Collaborative’). The
4 Collaborative shall be a cross-specialty, multidisciplinary
5 group composed of educators, consumer and family advo-
6 cates, and providers of psychosocial and biomedical health
7 services.

8 “(b) GOALS AND REPORTS.—The Collaborative shall
9 submit to the Secretary a report establishing a plan to
10 meet the following objectives for medical and psychosocial
11 care workforce development:

12 “(1) Identifying, refining, and broadly dissemi-
13 nating to health care educators information about
14 workforce competencies, models, and curricula rel-
15 evant to providing medical and psychosocial services
16 to persons surviving pediatric cancers.

17 “(2) Adapting curricula for continuing edu-
18 cation of the existing workforce using efficient work-
19 place-based learning approaches.

20 “(3) Developing the skills of faculty and other
21 trainers in teaching psychosocial health care using
22 evidence-based teaching strategies.

23 “(4) Strengthening the emphasis on psycho-
24 social health care in educational accreditation stand-
25 ards and professional licensing and certification

1 exams by recommending revisions to the relevant
2 oversight organizations.

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

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

8 (b) TECHNICAL AMENDMENT.—

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

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall take effect as if included in
16 section 3 of the Hematological Cancer Research In-
17 vestment and Education Act of 2002 (Public Law
18 107–172; 116 Stat. 541).

19 **SEC. 202. GRANTS TO IMPROVE CARE FOR PEDIATRIC CAN-**
20 **CER SURVIVORS.**

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

24 (1) in the section heading, by striking “**RE-**
25 **SEARCH AND AWARENESS**” and inserting “**RE-**

1 **SEARCH, AWARENESS, AND SURVIVORSHIP”;**

2 and

3 (2) by striking subsection (b) and inserting the
4 following:

5 “(b) IMPROVING CARE FOR PEDIATRIC CANCER SUR-
6 VIVORS.—

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

9 “(A) RESEARCH AWARDS.—The Director
10 of NIH, in coordination with ongoing research
11 activities, may conduct or support pediatric
12 cancer survivorship research including any of
13 the following areas:

14 “(i) Needs and outcomes of pediatric
15 cancer survivors within minority or other
16 medically underserved populations.

17 “(ii) Health disparities in pediatric
18 cancer survivorship outcomes within minor-
19 ity or other medically underserved popu-
20 lations.

21 “(iii) Barriers that pediatric cancer
22 survivors within minority or other medi-
23 cally underserved populations face in re-
24 ceiving follow-up care.

1 “(iv) Familial, socioeconomic, and
2 other environmental factors and the impact
3 of such factors on treatment outcomes and
4 survivorship.

5 “(B) BALANCED APPROACH.—In sup-
6 porting research under subparagraph (A)(i) on
7 pediatric cancer survivors within minority or
8 other medically underserved populations, the
9 Director of NIH shall ensure that such research
10 addresses both the physical and the psycho-
11 logical needs of such survivors, as appropriate.

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

18 “(A) The development of indicators used
19 for long-term patient tracking and analysis of
20 the late effects of cancer treatment for pediatric
21 cancer survivors.

22 “(B) The identification of risk factors as-
23 sociated with the late effects of cancer treat-
24 ment.

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

3 “(D) The identification of the molecular
4 underpinnings of long-term complications.

5 “(E) The development of risk prediction
6 models to identify those at highest risk of long-
7 term complications.

8 “(F) Initiatives to protect cancer survivors
9 from the late effects of cancer treatment, by de-
10 veloping targeted interventions to reduce the
11 burden of morbidity borne by cancer survivors.

12 “(G) Transitions in care for pediatric can-
13 cer survivors.

14 “(H) Training of professionals to provide
15 linguistically and culturally competent follow-up
16 care to pediatric cancer survivors.

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

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

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

22 Part B of title III of the Public Health Service Act
23 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
24 tion 317T the following:

1 **“SEC. 317U. STANDARDS FOR COMPREHENSIVE LONG-TERM**
2 **CARE FOR PEDIATRIC CANCER SURVIVORS**
3 **THROUGH THE LIFESPAN.**

4 “The Secretary may establish a task force to develop
5 and test standards, outcomes, and metrics for high-quality
6 childhood cancer survivorship care in consultation with a
7 full spectrum of representation of experts in late effects
8 of disease and treatment of childhood cancers, including—

9 “(1) oncologists who treat children and adoles-
10 cents;

11 “(2) oncologists who treat adults;

12 “(3) primary care providers engaged in survi-
13 vorship care;

14 “(4) survivors of childhood cancer;

15 “(5) parents of children who have been diag-
16 nosed with and treated for cancer and parents of
17 long-term survivors;

18 “(6) professionals who are engaged in the devel-
19 opment of clinical practice guidelines;

20 “(7) nurses and social workers;

21 “(8) mental health professionals;

22 “(9) allied health professionals, including phys-
23 ical therapists and occupational therapists;

24 “(10) experts in health care quality measure-
25 ment and improvement; and

1 “(11) others, as the Secretary determines ap-
2 propriate.”.

3 **SEC. 204. SURVIVORSHIP DEMONSTRATION PROJECT.**

4 (a) IN GENERAL.—Not later than 1 year after the
5 date of the enactment of this Act, the Secretary of Health
6 and Human Services (referred to in this section as the
7 “Secretary”) may carry out a demonstration project over
8 a 3-year period, designed to improve the quality and effi-
9 ciency of care provided to childhood cancer survivors
10 throughout their lifespan, through improved care coordi-
11 nation as survivors transitions to adult care.

12 (b) SELECTION OF DEMONSTRATION SITES.—

13 (1) MAXIMUM NUMBER OF SITES.—The max-
14 imum number of sites at which the demonstration
15 project under subsection (a) is carried out may not
16 exceed 10.

17 (2) DIVERSITY OF SITES.—In selecting entities
18 to participate in the demonstration project, the Sec-
19 retary may, to the extent practicable, include in such
20 selection—

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

22 and

23 (B) sites located in different geographic
24 areas.

1 (c) ACTIVITIES UNDER DEMONSTRATION

2 PROJECT.—The activities conducted under the demonstra-
3 tion project under subsection (a) may, in addition to any
4 other activity specified by the Secretary, include activities
5 that seek to develop different models of care coordination,
6 including transitions of care, follow-up care, monitoring,
7 and other survivorship related programs that utilize a
8 multidisciplinary, team based approach to care, including
9 any of the following activities:

10 (1) Coordination of care and transitions of care
11 between cancer care providers, primary care physi-
12 cians, mental health professionals and any other rel-
13 evant providers.

14 (2) Dissemination of information to, and train-
15 ing of, health care providers about linguistically and
16 culturally competent follow-up care specific to cancer
17 survivors.

18 (3) Development of monitoring programs for
19 cancer survivors and their families.

20 (4) Incorporation of peer support and men-
21 toring programs to improve the quality of life of can-
22 cer survivors.

23 (5) Designing systems and models for the effec-
24 tive transfer of treatment information and care sum-
25 maries from cancer care providers to other health

1 care providers (including risk factors and a care
2 plan).

3 (6) Evaluation of functional status and incorpo-
4 ration of specific functional needs into the care plan-
5 ning process.

6 (7) Dissemination of the information on activi-
7 ties and programs conducted under this section to
8 other health care providers (including primary care
9 physicians) and to cancer survivors and their fami-
10 lies, where appropriate.

11 (8) Other items determined by the Secretary.

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

14 (1) Patient care and patient/family satisfaction
15 measures.

16 (2) Resource utilization measures.

17 (3) Adult survivorship measures, as appro-
18 priate.

19 (e) GAO REPORT.—The Comptroller General of the
20 United States shall submit a report to Congress evaluating
21 the success of the demonstration project. Such report shall
22 include an assessment of the impact of the project upon
23 the quality and cost-efficiency of services furnished to indi-
24 viduals under this title, including an assessment of the sat-
25 isfaction of such individuals with respect to such services

1 that were furnished under such project. Such report shall
2 include recommendations regarding the possible expansion
3 of the demonstration project.

4 **Subtitle B—Coverage and Payment** 5 **of High Quality Care**

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

7 (a) IN GENERAL.—The Comptroller General of the
8 United States shall conduct a review and submit rec-
9 ommendations to Congress on existing barriers to obtain-
10 ing and paying for adequate medical care for survivors of
11 childhood cancer.

12 (b) CONSIDERATIONS.—In carrying out the review
13 and formulating recommendations under subsection (a),
14 the Comptroller General shall—

15 (1) identify existing barriers to the availability
16 of complete and coordinated survivorship care for
17 survivors of childhood cancer and to the availability
18 of expert pediatric palliative care, including consider-
19 ation of—

20 (A) understanding and education among
21 patients, health care providers, regulators, and
22 third-party payors;

23 (B) adequacy of payment codes to cover
24 necessary survivorship services;

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

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

7 (2) make recommendations to provide improved
8 access and payment plans for childhood cancer sur-
9 vivorship programs and palliative care, including
10 psychosocial services and coverage of such services.

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

13 (1) Coordinated multidisciplinary long-term fol-
14 low-up care with access to appropriate pediatric sub-
15 specialists and adult subspecialists with specific ex-
16 pertise in survivorship, including subspecialists with
17 expertise in oncology, radiation oncology, surgery,
18 cardiology, psychiatry or psychology, endocrinology,
19 pulmonology, nephrology, dermatology, gynecology,
20 and urology.

21 (2) Appropriate organ function testing (particu-
22 larly screening for potential problems at much
23 younger ages than usually indicated in the general
24 population) and treatment, including—

1 (A) neuropsychological testing and mental
2 health services;

3 (B) fertility testing and treatment;

4 (C) evaluation and treatment for endocrine
5 disorders including growth hormone and testos-
6 terone replacement;

7 (D) diagnostic imaging to screen for late
8 effects of treatment (including subsequent can-
9 cers), such as mammograms and magnetic reso-
10 nance imaging testing to screen for possible
11 breast cancer;

12 (E) screening for cardiac problems, such
13 as echocardiograms;

14 (F) screening for osteoporosis with bone
15 densitometry, including dual x-ray
16 absorptiometry and monitoring 25
17 hydroxyvitamin D levels;

18 (G) dental coverage and necessary dental
19 implants;

20 (H) hearing aids and other prosthetic de-
21 vices; and

- 1 (I) screening for lung problems, such as
- 2 pulmonary function testing.

Passed the House of Representatives December 6,
2016.

Attest:

Clerk.

114TH CONGRESS
2^D SESSION

H. R. 3381

AN ACT

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