

114TH CONGRESS
1ST SESSION

H. R. 3381

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

IN THE HOUSE OF REPRESENTATIVES

JULY 29, 2015

Mr. McCAUL (for himself, Mr. VAN HOLLEN, Ms. SPEIER, Mr. FLORES, Mr. FITZPATRICK, Mr. HINOJOSA, Mr. STIVERS, Mr. CAPUANO, Mr. KING of New York, Ms. EDWARDS, Mrs. COMSTOCK, Mr. HANNA, Mr. BEN RAY LUJÁN of New Mexico, Mr. HUNTER, Mr. PASCRELL, Mr. GARAMENDI, Ms. JACKSON LEE, Ms. WILSON of Florida, Mr. VEASEY, Mr. HIMES, Ms. CLARK of Massachusetts, Ms. CASTOR of Florida, Mr. SIRES, Ms. TITUS, Mr. NOLAN, Mr. DOGGETT, Mr. MCGOVERN, Mr. RANGEL, and Ms. FRANKEL of Florida) 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

1 Research Act of 2015” or the “Childhood Cancer STAR
2 Act”.

3 (b) TABLE OF CONTENTS.—The table of contents for
4 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. Comprehensive children’s cancer biorepositories.
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 Cancer
Institute.

Subtitle C—NIH Report on Childhood Cancer Activities

Sec. 121. Reporting on childhood malignancy projects.

TITLE II—AVAILABILITY OF PROMISING TREATMENTS

Sec. 201. Expanded access policy.
Sec. 202. Finalizing draft guidance on expanded access.

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

Subtitle A—Childhood Cancer Survivors’ Quality of Life Act

Sec. 301. Cancer survivorship programs.
Sec. 302. Grants to improve care for pediatric cancer survivors.
Sec. 303. Comprehensive long-term follow-up services for pediatric cancer sur-
vivors.
Sec. 304. Survivorship demonstration project.

Subtitle B—Coverage and Payment of High Quality Care

Sec. 311. Report by the Comptroller General.

5 **SEC. 2. FINDINGS.**

6 Congress makes the following findings:

7 (1) Each year in the United States there are an
8 estimated 15,780 children between birth and the age

1 of 19 diagnosed with cancer. Approximately 1 in 285
2 children in the United States will be diagnosed with
3 cancer before their 20th birthday.

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

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

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

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

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

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

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

15 (9) Despite the significant unmet medical need,
16 pharmaceutical companies have been reluctant to de-
17 velop drugs appropriate for children with cancer be-
18 cause it requires making an investment in products
19 that are unlikely to cover the high costs associated
20 with their research, development, marketing, and
21 distribution. Only 3 drugs have been approved by
22 the Food and Drug Administration to treat any type
23 of pediatric cancer since the 1980s, including
24 Unituxin, the first-ever drug approved for high-risk
25 neuroblastoma, for which the sponsor of the drug

1 was rewarded under the Food and Drug Administra-
2 tion’s priority review program to encourage treat-
3 ments for rare pediatric diseases.

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

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

13 (12) The Institute of Medicine, in its report on
14 cancer survivorship entitled “Childhood Cancer Sur-
15 vivorship: Improving Care and Quality of Life”,
16 states that an organized system of care and a meth-
17 od of care for pediatric cancer survivors is needed.

18 (13) Focused and well-designed research and
19 pilot health delivery programs can answer questions
20 about the optimal ways to provide health care, fol-
21 low-up monitoring services, and survivorship care to
22 those diagnosed with childhood cancer and con-
23 tribute to improvements in the quality of care and
24 quality of life of those individuals through adult-
25 hood.

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

11 (15) The National Cancer Institute supports a
12 number of key research programs specifically to ad-
13 vance childhood cancer care, including precision
14 medicine clinical trials for children with cancer, in-
15 cluding the Children’s Oncology Group (part of the
16 National Clinical Trials Network of the National
17 Cancer Institute), the Pediatric Preclinical Testing
18 Program, the Pediatric Brain Tumor Consortium,
19 the Childhood Cancer Survivor Study, the Thera-
20 peutically Applicable Research to Generate Effective
21 Treatments program and related pediatric cancer
22 genomics research, and the Pediatric Oncology
23 Branch (part of the intramural program of the Na-
24 tional Cancer Institute, whose mission is to develop
25 new treatments for pediatric cancer).

1 **TITLE I—MAXIMIZING RE-**
2 **SEARCH THROUGH DIS-**
3 **COVERY**

4 **Subtitle A—Caroline Pryce Walker**
5 **Conquer Childhood Cancer Re-**
6 **authorization Act**

7 **SEC. 101. COMPREHENSIVE CHILDREN’S CANCER BIO-**
8 **REPOSITORIES.**

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

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

13 “(a) COMPREHENSIVE CHILDREN’S CANCER BIO-
14 REPOSITORIES.—

15 “(1) AWARD.—The Secretary, acting through
16 the Director of NIH, may make an award for a du-
17 ration of at least 5 years to an entity or entities de-
18 scribed in paragraph (4) to build upon existing ini-
19 tiatives to collect biospecimens and clinical and de-
20 mographic information for at least 90 percent of all
21 children, adolescents, and young adults with cancer
22 in 1 or more Comprehensive Children’s Cancer Bio-
23 repositories to achieve a better understanding of the
24 cause of such cancers and the effects of treatments
25 for such cancers.

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

4 “(A) Prospectively acquire, preserve, and
5 store high-quality, donated biospecimens and
6 associated clinical and demographic information
7 on children, adolescents, and young adults diag-
8 nosed with cancer in the United States.

9 “(B) 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 “(C) 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 “(D) 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 with appropriate permission
2 from parents or legal guardians in accord-
3 ance with Federal and State law; and

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

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

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

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

21 “(B) STANDARD DATA.—The Secretary
22 shall require all recipients of an award under
23 this section to make available a standard
24 dataset for the purposes of subparagraph (A) in
25 a standard electronic format that enables re-

1 searchers and qualified health care professionals
2 to search.

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

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

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

19 “(9) REPORT.—Not later than 4 years after the
20 date of enactment of the Childhood Cancer Survivor-
21 ship, Treatment, Access, and Research Act of 2015,
22 the Secretary shall submit to Congress a report on—

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

1 through the Comprehensive Children’s Cancer
2 Biorepositories supported 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 Comprehensive Children’s Cancer
15 Biorepository program 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 mechanism 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) patient’s gender, race, and eth-
12 nicity;
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 “2016 through 2020”; 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, shall award grants 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 shall 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).”.

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 and Service Act (42 U.S.C. 284a(h)(2)(A)) is
8 amended 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.

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

3 **SEC. 121. REPORTING ON CHILDHOOD MALIGNANCY**
4 **PROJECTS.**

5 Section 409D(c)(3) of the Public Health Service Act
6 (42 U.S.C. 284h(c)(3)) is amended by—

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

9 “(A)”;

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

12 (3) inserting at the end the following:

13 “(B) the childhood malignancy projects
14 conducted under section 399N.”.

15 **TITLE II—AVAILABILITY OF**
16 **PROMISING TREATMENTS**

17 **SEC. 201. EXPANDED ACCESS POLICY.**

18 Chapter V of the Federal Food, Drug, and Cosmetic
19 Act is amended by inserting after section 561 (21 U.S.C.
20 360bbb) the following:

21 **“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR IN-**
22 **VESTIGATIONAL DRUGS.**

23 “(a) IN GENERAL.—The manufacturer or distributor
24 of one or more investigational drugs for the diagnosis,
25 monitoring, or treatment of one or more serious diseases

1 or conditions shall make publicly available the policy of
2 the manufacturer or distributor on evaluating and re-
3 sponding to requests submitted under section 561(b) for
4 provision of such a drug. A manufacturer or distributor
5 may satisfy the requirement of the preceding sentence by
6 posting such policy as generally applicable to all of such
7 manufacturer's or distributor's investigational drugs.

8 “(b) CONTENT OF POLICY.—A policy described in
9 subsection (a) shall include making publicly available—

10 “(1) contact information for the manufacturer
11 or distributor to facilitate communication about re-
12 quests described in subsection (a);

13 “(2) procedures for making such requests;

14 “(3) the general criteria the manufacturer or
15 distributor will consider or use to approve such re-
16 quests; and

17 “(4) the length of time the manufacturer or dis-
18 tributor anticipates will be necessary to acknowledge
19 receipt of such requests.

20 “(c) NO GUARANTEE OF ACCESS.—The posting of
21 policies by manufacturers and distributors under sub-
22 section (a) shall not serve as a guarantee of access to any
23 specific investigational drug by any individual patient.

1 “(d) REVISED POLICY.—A manufacturer or dis-
2 tributor that has made a policy publicly available as re-
3 quired by this section may revise the policy at any time.

4 “(e) APPLICATION.—This section shall apply to a
5 manufacturer or distributor with respect to an investiga-
6 tional drug beginning on the later of—

7 “(1) the date that is 60 days after the date of
8 enactment of the Childhood Cancer Survivorship,
9 Treatment, Access, and Research Act of 2015; or

10 “(2) the first initiation of a phase 2 or phase
11 3 study (as such terms are defined in section
12 312.21(b) and (c) of title 21, Code of Federal Regu-
13 lations (or any successor regulations)) with respect
14 to such investigational new drug.”.

15 **SEC. 202. FINALIZING DRAFT GUIDANCE ON EXPANDED AC-**
16 **CESS.**

17 (a) IN GENERAL.—Not later than 1 year after the
18 date of enactment of this Act, the Secretary of Health and
19 Human Services shall finalize the draft guidance entitled
20 “Expanded Access to Investigational Drugs for Treatment
21 Use—Qs & As”, dated May 2013.

22 (b) CONTENTS.—The final guidance referred to in
23 subsection (a) shall clearly define how the Secretary of
24 Health and Human Services interprets and uses adverse
25 drug event data reported by investigators in the case of

1 data reported from use under a request submitted under
2 section 561(b) of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 360bbb(b)).

4 **TITLE III—MAXIMIZING DELIV-**
5 **ERY: CARE, QUALITY OF LIFE,**
6 **SURVIVORSHIP, AND CARE-**
7 **GIVER SUPPORT**
8 **Subtitle A—Childhood Cancer**
9 **Survivors’ Quality of Life Act**

10 **SEC. 301. CANCER SURVIVORSHIP PROGRAMS.**

11 (a) CANCER SURVIVORSHIP PROGRAMS.—Subpart 1
12 of part C of title IV of the Public Health Service Act (42
13 U.S.C. 285 et seq.) is amended by adding at the end the
14 following:

15 **“SEC. 417H. PILOT PROGRAMS TO EXPLORE MODEL SYS-**
16 **TEMS OF CARE FOR PEDIATRIC CANCER SUR-**
17 **VIVORS.**

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

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

3 “(1) a medical school;

4 “(2) a children’s hospital;

5 “(3) a cancer center;

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

7 “(5) any other entity with significant experience
8 and expertise in treating survivors of childhood can-
9 cers.

10 “(c) USE OF FUNDS.—The Secretary may make a
11 grant under this section to an eligible entity only if the
12 entity agrees—

13 “(1) to use the grant to establish a pilot pro-
14 gram to develop, study, or evaluate one or more
15 model systems for monitoring and caring for cancer
16 survivors; and

17 “(2) in developing, studying, and evaluating
18 such systems, to give special emphasis to the fol-
19 lowing:

20 “(A) Design of protocols for different mod-
21 els of follow-up care, monitoring, and other sur-
22 vivorship programs (including peer support and
23 mentoring programs).

24 “(B) Development of various models for
25 providing multidisciplinary care.

1 “(C) Dissemination of information and the
2 provision of training to health care providers
3 about how to provide linguistically and cul-
4 turally competent follow-up care and monitoring
5 to cancer survivors and their families.

6 “(D) Development of support programs to
7 improve the quality of life of cancer survivors.

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

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

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

1 **“SEC. 417H-1. WORKFORCE DEVELOPMENT COLLABO-**
2 **RATIVE ON MEDICAL AND PSYCHOSOCIAL**
3 **CARE FOR CHILDHOOD CANCER SURVIVORS.**

4 “(a) IN GENERAL.—The Secretary shall, not later
5 than 1 year after the date of enactment of this Act, con-
6 vene a Workforce Development Collaborative on Medical
7 and Psychosocial Care for Pediatric Cancer Survivors (re-
8 ferred to in this paragraph as the ‘Collaborative’). The
9 Collaborative shall be a cross-specialty, multidisciplinary
10 group composed of educators, consumer and family advo-
11 cates, and providers of psychosocial and biomedical health
12 services.

13 “(b) GOALS AND REPORTS.—The Collaborative shall
14 submit to the Secretary a report establishing a plan to
15 meet the following objectives for medical and psychosocial
16 care workforce development:

17 “(1) Identifying, refining, and broadly dissemi-
18 nating to health care educators information about
19 workforce competencies, models, and curricula rel-
20 evant to providing medical and psychosocial services
21 to persons surviving pediatric cancers.

22 “(2) Adapting curricula for continuing edu-
23 cation of the existing workforce using efficient work-
24 place-based learning approaches.

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

4 “(4) Strengthening the emphasis on psycho-
5 social health care in educational accreditation stand-
6 ards and professional licensing and certification
7 exams by recommending revisions to the relevant
8 oversight organizations.

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

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

14 (b) TECHNICAL AMENDMENT.—

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

20 (2) EFFECTIVE DATE.—The amendment made
21 by paragraph (1) shall take effect as if included in
22 section 3 of the Hematological Cancer Research In-
23 vestment and Education Act of 2002 (Public Law
24 107–172; 116 Stat. 541).

1 **SEC. 302. GRANTS TO IMPROVE CARE FOR PEDIATRIC CAN-**
2 **CER SURVIVORS.**

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

6 (1) in the section heading, by striking “**RE-**
7 **SEARCH AND AWARENESS**” and inserting “**RE-**
8 **SEARCH, AWARENESS, AND SURVIVORSHIP**”;
9 and

10 (2) by striking subsection (b) and inserting the
11 following:

12 “(b) IMPROVING CARE FOR PEDIATRIC CANCER SUR-
13 VIVORS.—

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

16 “(A) GRANTS.—The Director of NIH, with
17 guidance from the Director of the Institute, in
18 coordination with ongoing research activities,
19 shall make grants to entities to conduct re-
20 search relating to—

21 “(i) needs and outcomes of pediatric
22 cancer survivors within minority or other
23 medically underserved populations;

24 “(ii) health disparities in pediatric
25 cancer survivorship outcomes within minor-

1 ity or other medically underserved popu-
2 lations;

3 “(iii) barriers that pediatric cancer
4 survivors within minority or other medi-
5 cally underserved populations face in re-
6 ceiving follow-up care; and

7 “(iv) familial, socioeconomic, and
8 other environmental factors and the impact
9 of such factors on treatment outcomes and
10 survivorship.

11 “(B) BALANCED APPROACH.—In making
12 grants for research under subparagraph (A)(i)
13 on pediatric cancer survivors within minority or
14 other medically underserved populations, the
15 Director of NIH shall ensure that such research
16 addresses both the physical and the psycho-
17 logical needs of such survivors.

18 “(2) RESEARCH ON LATE EFFECTS AND FOL-
19 LOW-UP CARE FOR PEDIATRIC CANCER SUR-
20 VIVORS.—The Director of NIH, in coordination with
21 ongoing research activities, shall conduct or support
22 research on follow-up care for pediatric cancer sur-
23 vivors, with special emphasis given to—

24 “(A) the development of indicators used
25 for long-term patient tracking and analysis of

1 the late effects of cancer treatment for pediatric
2 cancer survivors;

3 “(B) the identification of risk factors asso-
4 ciated with the late effects of cancer treatment;

5 “(C) the identification of predictors of
6 neurocognitive and psychosocial outcomes;

7 “(D) the identification of the molecular
8 underpinnings of long-term complications;

9 “(E) the development of risk prediction
10 models to identify those at highest risk of long-
11 term complications;

12 “(F) initiatives to protect cancer survivors
13 from the late effects of cancer treatment, by de-
14 veloping targeted interventions to reduce the
15 burden of morbidity borne by cancer survivors;

16 “(G) transitions in care for pediatric can-
17 cer survivors;

18 “(H) training of professionals to provide
19 linguistically and culturally competent follow-up
20 care to pediatric cancer survivors;

21 “(I) different models of follow-up care; and

22 “(J) examining the cost-effectiveness of the
23 different models of follow-up care.”.

1 **SEC. 303. COMPREHENSIVE LONG-TERM FOLLOW-UP SERV-**
2 **ICES FOR PEDIATRIC CANCER SURVIVORS.**

3 Part B of title III of the Public Health Service Act
4 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
5 tion 317T the following:

6 **“SEC. 317U. STANDARDS FOR COMPREHENSIVE LONG-TERM**
7 **CARE FOR PEDIATRIC CANCER SURVIVORS**
8 **THROUGH THE LIFESPAN.**

9 “The Secretary shall establish a task force to develop
10 and test standards, outcomes, and metrics for high-quality
11 childhood cancer survivorship care in consultation with a
12 full spectrum of representation of experts in late effects
13 of disease and treatment of childhood cancers, including—

14 “(1) oncologists who treat children and adoles-
15 cents;

16 “(2) oncologists who treat adults;

17 “(3) primary care providers engaged in survi-
18 vorship care;

19 “(4) survivors of childhood cancer;

20 “(5) parents of children who have been diag-
21 nosed with and treated for cancer and parents of
22 long-term survivors;

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

25 “(7) nurses and social workers;

26 “(8) mental health professionals;

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

3 “(10) experts in health care quality measure-
4 ment and improvement; and

5 “(11) others, as the Secretary determines ap-
6 propriate.”.

7 **SEC. 304. SURVIVORSHIP DEMONSTRATION PROJECT.**

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

16 (b) **SELECTION OF DEMONSTRATION SITES.**—

17 (1) **MAXIMUM NUMBER OF SITES.**—The Sec-
18 retary shall ensure that the maximum number of
19 sites does not exceed 10.

20 (2) **DIVERSITY OF SITES.**—In selecting entities
21 to participate in the demonstration project, the Sec-
22 retary shall, to the extent practicable, include in
23 such selection—

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

1 (B) sites located in different geographic
2 areas.

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

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

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

20 (3) Development of monitoring programs for
21 cancer survivors and their families.

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

1 (5) Designing systems and models for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers (including risk factors and a care plan).

2 (6) Evaluation of functional status and incorporation of specific functional needs into the care planning process.

3 (7) Dissemination of the information on activities and programs conducted under this section to other health care providers (including primary care physicians) and to cancer survivors and their families, where appropriate.

4 (8) Other items determined by the Secretary.

5 (d) MEASURES.—The Secretary shall use the following measures to assess the performance of each site:

6 (1) Patient care and satisfaction measures.

7 (2) Resource utilization measures.

8 (3) Adult survivorship measures.

9 (e) GAO REPORT.—The Comptroller General of the United States shall submit a report to Congress evaluating the success of the demonstration project. Such report shall include an assessment of the impact of the project upon the quality and cost-efficiency of services furnished to individuals under this title, including an assessment of the sat-

1 isfaction of such individuals with respect to such services
2 that were furnished under such project. Such report shall
3 include recommendations regarding the possible expansion
4 of the demonstration project.

5 **Subtitle B—Coverage and Payment** 6 **of High Quality Care**

7 **SEC. 311. REPORT BY THE COMPTROLLER GENERAL.**

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

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

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

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

24 (B) adequacy of payment codes to cover
25 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 and
5 hospice services for patients approaching the
6 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 second cancers),
9 such as mammograms and magnetic resonance
10 imaging testing to screen for possible breast
11 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;

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

19 (H) hearing aids; and

20 (I) screening for lung problems, such as
21 pulmonary function testing.

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