

115TH CONGRESS
2D SESSION

S. 292

IN THE HOUSE OF REPRESENTATIVES

MARCH 26, 2018

Referred to the Committee on Energy and Commerce

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 2018” 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.

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 Reporting on Childhood Cancer Activities

Sec. 121. Reporting on childhood cancer research projects.

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

Sec. 201. Cancer survivorship programs.

Sec. 202. Grants to improve care for pediatric cancer survivors.

Sec. 203. Best practices for long-term follow-up services for pediatric cancer
 survivors.

Sec. 204. Technical amendment.

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. CHILDREN’S CANCER BIOREPOSITORIES AND BIO-**
8 **SPECIMEN RESEARCH.**

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

11 (1) in the section heading, by striking “**RE-**
12 **SEARCH AND AWARENESS**” and inserting “**RE-**
13 **SEARCH, AWARENESS, AND SURVIVORSHIP**”;

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

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

17 “(1) AWARD.—The Secretary, acting through
18 the Director of NIH, may make awards to an entity
19 or entities described in paragraph (4) to build upon
20 existing research efforts to collect biospecimens and
21 clinical and demographic information of children,
22 adolescents, and young adults with selected cancer
23 subtypes (and their recurrences) for which current
24 treatments are least effective, in order to achieve a
25 better understanding of the causes of such cancer

1 subtypes (and their recurrences), and the effects and
2 outcomes of treatments for such cancers.

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

6 “(A) Collect and store high-quality, do-
7 nated biospecimens and associated clinical and
8 demographic information on children, adoles-
9 cents, and young adults diagnosed with cancer
10 in the United States, focusing on children, ado-
11 lescents, and young adults with cancer enrolled
12 in clinical trials for whom current treatments
13 are least effective. Activities under this sub-
14 paragraph may include storage of biospecimens
15 and associated clinical and demographic data at
16 existing biorepositories supported by the Na-
17 tional Cancer Institute.

18 “(B) Maintain an interoperable, secure,
19 and searchable database on stored biospecimens
20 and associated clinical and demographic data
21 from children, adolescents, and young adults
22 with cancer for the purposes of research by sci-
23 entists and qualified health care professionals.

24 “(C) Establish and implement procedures
25 for evaluating applications for access to such

1 biospecimens and clinical and demographic data
2 from researchers and other qualified health care
3 professionals.

4 “(D) Provide access to biospecimens and
5 clinical and demographic data from children,
6 adolescents, and young adults with cancer to re-
7 searchers and qualified health care professionals
8 for peer-reviewed research—

9 “(i) consistent with the procedures es-
10 tablished pursuant to subparagraph (C);

11 “(ii) only to the extent permitted by
12 applicable Federal and State law; and

13 “(iii) in a manner that protects per-
14 sonal privacy to the extent required by ap-
15 plicable Federal and State privacy law, at
16 minimum.

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

21 “(4) APPLICATION; CONSIDERATIONS.—

22 “(A) APPLICATION.—To be eligible to re-
23 ceive an award under paragraph (1) an entity
24 shall submit an application to the Secretary at
25 such a time, in such manner, and containing

1 such information as the Secretary may reason-
2 ably require.

3 “(B) CONSIDERATIONS.—In evaluating ap-
4 plications submitted under subparagraph (A),
5 the Secretary shall consider the existing infra-
6 structure of the entity that would allow for the
7 timely capture of biospecimens and related clin-
8 ical and demographic information for children,
9 adolescents, and young adults with cancer for
10 whom current treatments are least effective.

11 “(5) PRIVACY PROTECTIONS AND INFORMED
12 CONSENT.—

13 “(A) IN GENERAL.—The Secretary may
14 not make an award under paragraph (1) to an
15 entity unless the Secretary ensures that such
16 entity—

17 “(i) collects biospecimens and associ-
18 ated clinical and demographic information
19 only from participants who have given
20 their informed consent in accordance with
21 Federal and State law; and

22 “(ii) protects personal privacy to the
23 extent required by applicable Federal and
24 State law, at minimum.

1 “(B) INFORMED CONSENT.—The Secretary
2 shall ensure biospecimens and associated clin-
3 ical and demographic information are collected
4 with informed consent, as described in subpara-
5 graph (A)(i).

6 “(6) GUIDELINES AND OVERSIGHT.—The Sec-
7 retary shall develop and disseminate appropriate
8 guidelines for the development and maintenance of
9 the biorepositories supported under this subsection,
10 including appropriate oversight, to facilitate further
11 research on select cancer subtypes (and their
12 recurrences) in children, adolescents, and young
13 adults with such cancers (and their recurrences).

14 “(7) COORDINATION.—To encourage the great-
15 est possible efficiency and effectiveness of federally
16 supported efforts with respect to the activities de-
17 scribed in this subsection, the Secretary shall ensure
18 the appropriate coordination of programs supported
19 under this section with existing federally supported
20 cancer registry programs and the activities under
21 section 399E–1, as appropriate.

22 “(8) SUPPLEMENT NOT SUPPLANT.—Funds
23 provided under this subsection shall be used to sup-
24 plement, and not supplant, Federal and non-Federal

1 funds available for carrying out the activities de-
2 scribed in this subsection.

3 “(9) REPORT.—Not later than 4 years after the
4 date of enactment of the Childhood Cancer Survivor-
5 ship, Treatment, Access, and Research Act of 2018,
6 the Secretary shall submit to Congress a report on—

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

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

14 “(C) barriers to the collection of biospeci-
15 mens and corresponding clinical demographic
16 data;

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

21 “(E) recommendations with respect to im-
22 proving the biospecimen and biorepository re-
23 search efforts under this subsection.

24 “(10) DEFINITIONS.—For purposes of this sub-
25 section:

1 “(A) AWARD.—The term ‘award’ includes
2 a grant, contract, or cooperative agreement de-
3 termined 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 relevant to
13 cancer research, as required by the Sec-
14 retary.

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

18 “(i) date of diagnosis;

19 “(ii) age at diagnosis;

20 “(iii) the patient’s sex, race, ethnicity,
21 and environmental exposures;

22 “(iv) extent of disease at enrollment;

23 “(v) site of metastases;

24 “(vi) location of primary tumor coded;

25 “(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 applicable information
7 required by the Secretary.”; and
8 (3) in subsection (e), by striking “(42 U.S.C.
9 202 note)”.

10 **SEC. 102. IMPROVING CHILDHOOD CANCER SURVEIL-**
11 **LANCE.**

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

14 (1) in subsection (a)—

15 (A) by striking “shall award a grant” and
16 inserting “may make awards to State cancer
17 registries”; and

18 (B) by striking “track the epidemiology of
19 pediatric cancer into a comprehensive nation-
20 wide registry of actual occurrences of pediatric
21 cancer” and inserting “collect information to
22 better understand the epidemiology of cancer in
23 children, adolescents, and young adults”; and

24 (C) by striking the second sentence and in-
25 serting “Such registries may be updated to in-

1 clude each occurrence of such cancers within a
2 period of time designated by the Secretary.”;

3 (2) by redesignating subsection (b) as sub-
4 section (d);

5 (3) by inserting after subsection (a) the fol-
6 lowing:

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

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

12 “(2) developing practices to ensure early inclu-
13 sion of childhood, adolescent, and young adult can-
14 cer cases in State cancer registries through the use
15 of electronic reporting;

16 “(3) collecting and submitting deidentified data
17 to the Centers for Disease Control and Prevention
18 for inclusion in a national database that includes in-
19 formation on childhood, adolescent, and young adult
20 cancers; and

21 “(4) improving State cancer registries and the
22 database described in paragraph (3), as appropriate,
23 including to support the early inclusion of childhood,
24 adolescent, and young adult cancer cases.

1 “(c) COORDINATION.—To encourage the greatest
 2 possible efficiency and effectiveness of federally supported
 3 efforts with respect to the activities described in this sec-
 4 tion, the Secretary shall ensure the appropriate coordina-
 5 tion of programs supported under this section with other
 6 federally supported cancer registry programs and the ac-
 7 tivities under section 417E(a), as appropriate.”; and

8 (4) in subsection (d), as so redesignated, by
 9 striking “registry established pursuant to subsection
 10 (a)” and inserting “activities described in this sec-
 11 tion”.

12 (b) AUTHORIZATION OF APPROPRIATIONS.—Section
 13 417E(d) of the Public Health Service Act (42 U.S.C.
 14 285a–11(d)) is amended—

15 (1) by striking “2009 through 2013” and in-
 16 serting “2019 through 2023”; and

17 (2) by striking the second sentence.

18 **Subtitle B—Pediatric Expertise at** 19 **NIH**

20 **SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC**
 21 **ONCOLOGIST ON THE NATIONAL CANCER AD-**
 22 **VISORY BOARD.**

23 Clause (iii) of section 406(h)(2)(A) of the Public
 24 Health Service Act (42 U.S.C. 284a(h)(2)(A)) is amend-
 25 ed—

1 (1) by striking “Board not less than five” and
 2 inserting “Board—

3 “(I) not less than 5”;

4 (2) by inserting “and” after the semicolon; and

5 (3) by adding at the end the following:

6 “(II) not less than one member shall be an
 7 individual knowledgeable in pediatric oncol-
 8 ogy;”.

9 **SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EX-**
 10 **PERTISE AT THE NATIONAL CANCER INSTI-**
 11 **TUTE.**

12 It is the sense of Congress that the Director of the
 13 National Cancer Institute should ensure that all applicable
 14 study sections, committees, advisory groups, and panels
 15 at the National Cancer Institute include one or more
 16 qualified pediatric oncologists, as appropriate.

17 **Subtitle C—NIH Reporting on**
 18 **Childhood Cancer Activities**

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

21 The Director of the National Institutes of Health
 22 shall ensure that childhood cancer research projects con-
 23 ducted or supported by the National Institutes of Health
 24 are included in appropriate reports to Congress, which
 25 may include the Pediatric Research Initiative report.

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

5 **SEC. 201. CANCER SURVIVORSHIP PROGRAMS.**

6 (a) PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS
7 OF CARE FOR PEDIATRIC CANCER SURVIVORS.—

8 (1) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the
10 “Secretary”) may make awards to eligible entities to
11 establish pilot programs to develop, study, or evalu-
12 ate model systems for monitoring and caring for
13 childhood cancer survivors throughout their lifespan,
14 including evaluation of models for transition to adult
15 care and care coordination.

16 (2) AWARDS.—

17 (A) TYPES OF ENTITIES.—In making
18 awards under this subsection, the Secretary
19 shall, to the extent practicable, include—

20 (i) small, medium, and large-sized eli-
21 gible entities; and

22 (ii) sites located in different geo-
23 graphic areas, including rural and urban
24 areas.

1 (B) ELIGIBLE ENTITIES.—In this sub-
2 section, the term “eligible entity” means—

3 (i) a medical school;

4 (ii) a children’s hospital;

5 (iii) a cancer center;

6 (iv) a community-based medical facil-
7 ity; or

8 (v) any other entity with significant
9 experience and expertise in treating sur-
10 vivors of childhood cancers.

11 (3) USE OF FUNDS.—Funds awarded under
12 this subsection may be used—

13 (A) to develop, study, or evaluate one or
14 more models for monitoring and caring for can-
15 cer survivors; and

16 (B) in developing, studying, and evaluating
17 such models, to give special emphasis to—

18 (i) design of models of follow-up care,
19 monitoring, and other survivorship pro-
20 grams (including peer support and men-
21 toring programs);

22 (ii) development of models for pro-
23 viding multidisciplinary care;

24 (iii) dissemination of information to
25 health care providers about culturally and

1 linguistically appropriate follow-up care for
2 cancer survivors and their families, as ap-
3 propriate and practicable;

4 (iv) development of psychosocial and
5 support programs to improve the quality of
6 life of cancer survivors and their families,
7 which may include peer support and men-
8 toring programs;

9 (v) design of systems for the effective
10 transfer of treatment information and care
11 summaries from cancer care providers to
12 other health care providers (including risk
13 factors and a plan for recommended follow-
14 up care);

15 (vi) dissemination of the information
16 and programs described in clauses (i)
17 through (v) to other health care providers
18 (including primary care physicians and in-
19 ternists) and to cancer survivors and their
20 families, where appropriate and in accord-
21 ance with Federal and State law; and

22 (vii) development of initiatives that
23 promote the coordination and effective
24 transition of care between cancer care pro-
25 viders, primary care physicians, mental

1 health professionals, and other health care
2 professionals, as appropriate, including
3 models that use a team-based or multi-dis-
4 ciplinary approach to care.

5 (b) WORKFORCE DEVELOPMENT FOR HEALTH CARE
6 PROVIDERS ON MEDICAL AND PSYCHOSOCIAL CARE FOR
7 CHILDHOOD CANCER SURVIVORS.—

8 (1) IN GENERAL.—The Secretary shall, not
9 later than 1 year after the date of enactment of this
10 Act, conduct a review of the activities of the Depart-
11 ment of Health and Human Services related to
12 workforce development for health care providers who
13 treat pediatric cancer patients and survivors. Such
14 review shall include—

15 (A) an assessment of the effectiveness of
16 supportive psychosocial care services for pedi-
17 atric cancer patients and survivors, including
18 pediatric cancer survivorship care patient navi-
19 gators and peer support programs;

20 (B) identification of existing models rel-
21 evant to providing medical and psychosocial
22 services to individuals surviving pediatric can-
23 cers, and programs related to training for
24 health professionals who provide such services
25 to individuals surviving pediatric cancers; and

1 (C) recommendations for improving the
2 provision of psychosocial care for pediatric can-
3 cer survivors and patients.

4 (2) REPORT.—Not later than 2 years after the
5 date of enactment of this Act, the Secretary shall
6 submit to the Committee on Health, Education,
7 Labor, and Pensions of the Senate and Committee
8 on Energy and Commerce of the House of Rep-
9 resentatives, a report concerning the findings and
10 recommendations from the review conducted under
11 paragraph (1).

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 by striking subsection (b)
17 and inserting the following:

18 “(b) IMPROVING CARE FOR PEDIATRIC CANCER SUR-
19 VIVORS.—

20 “(1) RESEARCH ON PEDIATRIC CANCER SURVI-
21 VORSHIP.—The Director of NIH, in coordination
22 with ongoing research activities, may continue to
23 conduct or support pediatric cancer survivorship re-
24 search including in any of the following areas:

1 “(A) Outcomes of pediatric cancer sur-
2 vivors, including within minority or other medi-
3 cally underserved populations and with respect
4 to health disparities of such outcomes.

5 “(B) Barriers to follow-up care for pedi-
6 atric cancer survivors, including within minority
7 or other medically underserved populations.

8 “(C) The impact of relevant factors, which
9 may include familial, socioeconomic, and other
10 environmental factors, on treatment outcomes
11 and survivorship.

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

16 “(E) The identification of, as applicable—

17 “(i) risk factors associated with the
18 late effects of cancer treatment;

19 “(ii) predictors of adverse
20 neurocognitive and psychosocial outcomes;
21 and

22 “(iii) the molecular basis of long-term
23 complications.

24 “(F) The development of targeted inter-
25 ventions to reduce the burden of morbidity

1 borne by cancer survivors in order to protect
2 such cancer survivors from the late effects of
3 cancer.

4 “(2) **BALANCED APPROACH.**—In conducting or
5 supporting research under paragraph (1)(A)(i) on
6 pediatric cancer survivors within minority or other
7 medically underserved populations, the Director of
8 NIH shall ensure that such research addresses both
9 the physical and the psychological needs of such sur-
10 vivors, as appropriate.”.

11 **SEC. 203. BEST PRACTICES FOR LONG-TERM FOLLOW-UP**
12 **SERVICES FOR PEDIATRIC CANCER SUR-**
13 **VIVORS.**

14 The Secretary of Health and Human Services may
15 facilitate the identification of best practices for childhood
16 and adolescent cancer survivorship care, and, as appro-
17 priate, may consult with individuals who have expertise in
18 late effects of disease and treatment of childhood and ado-
19 lescent cancers, which may include—

20 (1) oncologists, which may include pediatric
21 oncologists;

22 (2) primary care providers engaged in survivor-
23 ship care;

24 (3) survivors of childhood and adolescent can-
25 cer;

1 (4) parents of children and adolescents who
2 have been diagnosed with and treated for cancer and
3 parents of long-term survivors;

4 (5) nurses and social workers;

5 (6) mental health professionals;

6 (7) allied health professionals, including phys-
7 ical therapists and occupational therapists; and

8 (8) others, as the Secretary determines appro-
9 priate.

10 **SEC. 204. TECHNICAL AMENDMENT.**

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

15 (b) **EFFECTIVE DATE.**—The amendment made by
16 subsection (a) shall take effect as if included in section
17 3 of the Hematological Cancer Research Investment and
18 Education Act of 2002 (Public Law 107–172; 116 Stat.
19 541).

Passed the Senate March 22, 2018.

Attest:

JULIE E. ADAMS,

Secretary.