I

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Childhood Cancer Survivorship, Treatment, Access, and

Research Act of 2015'' or the ''Childhood Cancer STAR Act''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

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

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

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

(3) While the cure rates for some childhood cancers are now over 80 percent, the survival rates for many types of cancers in children remain extremely low.

(4) According to the Centers for Disease Control and Prevention, cancer continues to be the leading cause of death by disease in children and adolescents under the age of 14.

(5) By 2020, the population of childhood cancers survivors is expected to be 500,000 individuals.

(6) As many as two-thirds of childhood cancer survivors are likely to experience at least one late effect of treatment, with as many as one-fourth experiencing a late effect that is serious or life-threatening. Common late effects of childhood cancer are neurocognitive, psychological, cardiopulmonary, endocrine, and musculoskeletal effects, secondary malignancies, and early death.

(7) As a result of disparities in the delivery of cancer care, minority, low-income, and other medically underserved children are more likely to be diagnosed with late stage disease, experience poorer treatment outcomes, have shorter survival time with less quality of life, and experience a substantially greater likelihood of cancer death.

(8) Collection of biospecimens, along with clinical and outcome data, on the maximum possible number of children with cancer in the United States is necessary to improve childhood cancer treatments and cures. Currently biospecimens, and clinical and outcome data, are collected for less than half of children in the United States with cancer.

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

was rewarded under the Food and Drug Administration's priority review program to encourage treatments for rare pediatric diseases.

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

(11) Despite the intense stress caused by childhood cancer, there is a lack of standardized and coordinated psychosocial care for the children and their families, from the date of diagnosis through treatment and survivorship.

(12) The Institute of Medicine, in its report on cancer survivorship entitled ''Childhood Cancer Survivorship: Improving Care and Quality of Life'', states that an organized system of care and a method of care for pediatric cancer survivors is needed.

(13) Focused and well-designed research and pilot health delivery programs can answer questions about the optimal ways to provide health care, follow-up monitoring services, and survivorship care to those diagnosed with childhood cancer and contribute to improvements in the quality of care and quality of life of those individuals through adulthood.

(14) The National Institutes of Health, including the National Cancer Institute, invest approximately half of their annual appropriations to support basic research that serves as the foundation for translational and clinical research for all diseases and conditions, with the potential to lead to breakthroughs for children with cancer. Virtually all progress against cancer—in both children and adults—has been founded in basic research, often in areas not directly related to the disease.

(15) The National Cancer Institute supports a number of key research programs specifically to advance childhood cancer care, including precision medicine clinical trials for children with cancer, including the Children's Oncology Group (part of the National Clinical Trials Network of the National Cancer Institute), the Pediatric Preclinical Testing Program, the Pediatric Brain Tumor Consortium, the Childhood Cancer Survivor Study, the Therapeutically Applicable Research to Generate Effective Treatments program and related pediatric cancer genomics research, and the Pediatric Oncology Branch (part of the intramural program of the National Cancer Institute, whose mission is to develop new treatments for pediatric cancer).

TITLE I—MAXIMIZING RESEARCH THROUGH DISCOVERY

Subtitle A—Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

SEC. 101. COMPREHENSIVE CHILDREN'S CANCER BIOREPOSITORIES.

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

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

"(a) COMPREHENSIVE CHILDREN'S CANCER BIOREPOSITORIES.—

"(1) AWARD.—The Secretary, acting through the Director of NIH, may make an award for a duration of at least 5 years to an entity or entities described in paragraph (4) to build upon existing initiatives to collect biospecimens and clinical and demographic information for at least 90 percent of all children, adolescents, and young adults with cancer in 1 or more Comprehensive Children's Cancer Biorepositories to achieve a better understanding of the cause of such cancers and the effects of treatments for such cancers.

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

''(A) Prospectively acquire, preserve, and store high-quality, donated biospecimens and associated clinical and demographic information on children, adolescents, and young adults diagnosed with cancer in the United States.

''(B) Maintain a secure searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the conduct of research by scientists and qualified health care professionals.

''(C) Establish procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.

''(D) Make available and distribute biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research at a minimal cost.

''(3) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required under this subsection to contribute a specimen to a Biorepository or share clinical or demographic data.

''(4) APPLICATION; CONSIDERATIONS.—

''(A) APPLICATION.—To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at such a time, in such manner, and containing such information as the Secretary may reasonably require.

''(B) CONSIDERATIONS.—In evaluating the applications in subparagraph (A), the Secretary shall consider the existing infrastructure of the entity that would allow for the timely capture of biospecimens and related clinical and demographic information for children, adolescents, and young adults with cancer.

''(5) PRIVACY PROTECTIONS; CONSENT.—

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

''(i) collects biospecimens and associated clinical and demographic information

from children with appropriate permission from parents or legal guardians in accordance with Federal and State law; and

''(ii) adheres to strict confidentiality to protect the identity and privacy of patients in accordance with Federal and State law.

''(B) CONSENT.—The Secretary shall establish an appropriate process for achieving consent from the patient, parent, or legal guardian.

''(6) SINGLE POINT OF ACCESS; STANDARD DATA; GUIDELINES AND OVERSIGHT.—

''(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that each Biorepository supported under paragraph (1) has electronically searchable data for use by researchers and other qualified health care professionals in the manner and to the extent defined by the Secretary.

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

searchers and qualified health care professionals to search.

''(C) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this section, including appropriate oversight.

''(7) COORDINATION.—The Secretary shall ensure that clinical and demographic information collected in accordance with this section is collected in coordination with the information collected under section 399E–1.

''(8) PROHIBITION ON USE OF FUNDS.—Funds made available to carry out this subsection shall not be used to acquire, preserve, or maintain a biospecimen collected from a patient if such activity is already covered by funds available from the National Cancer Institute for such purpose.

''(9) REPORT.—Not later than 4 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2015, the Secretary shall submit to Congress a report on—

''(A) the number of biospecimens and corresponding clinical demographic data collected

through the Comprehensive Children's Cancer Biorepositories supported under paragraph (1);

"(B) the number of biospecimens and corresponding clinical demographic data requested for use by researchers;

"(C) any barriers to the collection of biospecimens and corresponding clinical demographic data;

"(D) any barriers experienced by researchers or health care professionals in accessing the biospecimens and corresponding clinical demographic data necessary for use in research; and

"(E) any recommendations with respect to improving the Comprehensive Children's Cancer Biorepository program under this subsection.

"(10) DEFINITIONS.—For purposes of this subsection:

"(A) AWARD.—The term 'award' includes a grant, contract, cooperative agreement, or other mechanism determined by the Secretary.

"(B) BIOSPECIMEN.—The term 'biospecimen' includes—

"(i) solid tumor tissue or bone marrow;

"(ii) normal or control tissue;

"(iii) blood and plasma;

"(iv) DNA and RNA extractions;

"(v) familial DNA; and

"(vi) any other sample required by the Secretary.

"(C) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term 'clinical and demographic information' includes—

"(i) date of diagnosis;

"(ii) age at diagnosis;

"(iii) patient's gender, race, and ethnicity;

"(iv) extent of disease at enrollment;

"(v) site of metastases;

"(vi) location of primary tumor coded;

"(vii) histologic diagnosis;

"(viii) tumor marker data when available;

"(ix) treatment and outcome data;

"(x) information related to specimen quality; and

"(xi) any other information required by the Secretary."; and

(2) in subsection (d)—

(A) by striking ''and section 399E–1'' and inserting ''and sections 317U, 399E–1, 417H, and 417H–1'';

(B) by striking ''2009 through 2013'' and inserting ''2016 through 2020''; and

(C) by striking ''such purpose'' and inserting ''such purposes''.

SEC. 102. IMPROVING CHILDHOOD CANCER SURVEILLANCE.

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

(1) by redesignating subsection (b) as subsection (d); and

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

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to State cancer registries to enhance and expand infrastructure to track the epidemiology of cancer in children, adolescents, and young adults. Such registries shall be updated to include each occurrence of such cancers within a period of time designated by the Secretary.

''(b) ACTIVITIES.—The grants described in subsection (a) may be used for—

''(1) identifying, recruiting, and training all potential sources for reporting childhood, adolescent, and young adult cancer cases;

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

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

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

''(5) tracking the late effects of childhood, adolescent, and young adult cancers.

''(c) COORDINATION.—The Secretary shall ensure that information collected through State cancer registries under this section is collected in coordination with clinical and demographic information collected under section 417E(a).''.

Subtitle B—Pediatric Expertise at NIH

SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC ONCOLOGIST ON THE NATIONAL CANCER ADVISORY BOARD.

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

''(iii) of the members appointed to the Board—

''(I) not less than 5 members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors); and

''(II) not less than one member shall be an individual knowledgeable in pediatric oncology;''.

SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EXPERTISE AT THE NATIONAL CANCER INSTITUTE.

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

Subtitle C—NIH Report on Childhood Cancer Activities

SEC. 121. REPORTING ON CHILDHOOD MALIGNANCY PROJECTS.

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

(1) striking ''public on'' and inserting ''public on—

''(A)'';

(2) striking the period at the end and inserting ''; and''; and

(3) inserting at the end the following:

''(B) the childhood malignancy projects conducted under section 399N.''.

TITLE II—AVAILABILITY OF PROMISING TREATMENTS

SEC. 201. EXPANDED ACCESS POLICY.

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

''SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

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

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

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

''(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

''(2) procedures for making such requests;

''(3) the general criteria the manufacturer or distributor will consider or use to approve such requests; and

''(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests.

''(c) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

''(d) REVISED POLICY.—A manufacturer or distributor that has made a policy publicly available as required by this section may revise the policy at any time.

''(e) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

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

''(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational new drug.''.

SEC. 202. FINALIZING DRAFT GUIDANCE ON EXPANDED ACCESS.

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

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

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

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.

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

"SEC. 417H. PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE FOR PEDIATRIC CANCER SURVIVORS.

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

''(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means—

''(1) a medical school;

''(2) a children's hospital;

''(3) a cancer center;

''(4) a community-based medical facility; or

''(5) any other entity with significant experience and expertise in treating survivors of childhood cancers.

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

''(1) to use the grant to establish a pilot program to develop, study, or evaluate one or more model systems for monitoring and caring for cancer survivors; and

''(2) in developing, studying, and evaluating such systems, to give special emphasis to the following:

''(A) Design of protocols for different models of follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs).

''(B) Development of various models for providing multidisciplinary care.

"(C) Dissemination of information and the provision of training to health care providers about how to provide linguistically and culturally competent follow-up care and monitoring to cancer survivors and their families.

"(D) Development of support programs to improve the quality of life of cancer survivors.

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

"(F) Dissemination of the information and programs described in subparagraphs (A) through (E) to other health care providers (including primary care physicians and internists) and to cancer survivors and their families, where appropriate.

"(G) Development of initiatives that promote the coordination and effective transition of care between cancer care providers, primary care physicians, and mental health professionals.

"SEC. 417H–1. WORKFORCE DEVELOPMENT COLLABORATIVE ON MEDICAL AND PSYCHOSOCIAL CARE FOR CHILDHOOD CANCER SURVIVORS.

''(a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of this Act, convene a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer Survivors (referred to in this paragraph as the 'Collaborative'). The Collaborative shall be a cross-specialty, multidisciplinary group composed of educators, consumer and family advocates, and providers of psychosocial and biomedical health services.

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

''(1) Identifying, refining, and broadly disseminating to health care educators information about workforce competencies, models, and curricula relevant to providing medical and psychosocial services to persons surviving pediatric cancers.

''(2) Adapting curricula for continuing education of the existing workforce using efficient workplace-based learning approaches.

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

''(4) Strengthening the emphasis on psychosocial health care in educational accreditation standards and professional licensing and certification exams by recommending revisions to the relevant oversight organizations.

''(5) Evaluating the effectiveness of patient navigators in pediatric cancer survivorship care.

''(6) Evaluating the effectiveness of peer support programs in the psychosocial care of pediatric cancer patients and survivors.''.

(b) TECHNICAL AMENDMENT.—

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

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

SEC. 302. GRANTS TO IMPROVE CARE FOR PEDIATRIC CANCER SURVIVORS.

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

(1) in the section heading, by striking ''**RESEARCH AND AWARENESS**'' and inserting ''**RESEARCH, AWARENESS, AND SURVIVORSHIP**''; and

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

''(b) IMPROVING CARE FOR PEDIATRIC CANCER SURVIVORS.—

''(1) RESEARCH ON CAUSES OF HEALTH DISPARITIES IN PEDIATRIC CANCER SURVIVORSHIP.—

''(A) GRANTS.—The Director of NIH, with guidance from the Director of the Institute, in coordination with ongoing research activities, shall make grants to entities to conduct research relating to—

''(i) needs and outcomes of pediatric cancer survivors within minority or other medically underserved populations;

''(ii) health disparities in pediatric cancer survivorship outcomes within minor-

ity or other medically underserved populations;

"(iii) barriers that pediatric cancer survivors within minority or other medically underserved populations face in receiving follow-up care; and

"(iv) familial, socioeconomic, and other environmental factors and the impact of such factors on treatment outcomes and survivorship.

"(B) BALANCED APPROACH.—In making grants for research under subparagraph (A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors.

"(2) RESEARCH ON LATE EFFECTS AND FOLLOW-UP CARE FOR PEDIATRIC CANCER SURVIVORS.—The Director of NIH, in coordination with ongoing research activities, shall conduct or support research on follow-up care for pediatric cancer survivors, with special emphasis given to—

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

the late effects of cancer treatment for pediatric cancer survivors;

''(B) the identification of risk factors associated with the late effects of cancer treatment;

''(C) the identification of predictors of neurocognitive and psychosocial outcomes;

''(D) the identification of the molecular underpinnings of long-term complications;

''(E) the development of risk prediction models to identify those at highest risk of long-term complications;

''(F) initiatives to protect cancer survivors from the late effects of cancer treatment, by developing targeted interventions to reduce the burden of morbidity borne by cancer survivors;

''(G) transitions in care for pediatric cancer survivors;

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

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

''(J) examining the cost-effectiveness of the different models of follow-up care.''.

SEC. 303. COMPREHENSIVE LONG-TERM FOLLOW-UP SERVICES FOR PEDIATRIC CANCER SURVIVORS.

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

"SEC. 317U. STANDARDS FOR COMPREHENSIVE LONG-TERM CARE FOR PEDIATRIC CANCER SURVIVORS THROUGH THE LIFESPAN.

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

''(1) oncologists who treat children and adolescents;

''(2) oncologists who treat adults;

''(3) primary care providers engaged in survivorship care;

''(4) survivors of childhood cancer;

''(5) parents of children who have been diagnosed with and treated for cancer and parents of long-term survivors;

''(6) professionals who are engaged in the development of clinical practice guidelines;

''(7) nurses and social workers;

''(8) mental health professionals;

''(9) allied health professionals, including physical therapists and occupational therapists;

''(10) experts in health care quality measurement and improvement; and

''(11) others, as the Secretary determines appropriate.''.

SEC. 304. SURVIVORSHIP DEMONSTRATION PROJECT.

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall carry out a demonstration project over a 3-year period, designed to improve the quality and efficiency of care provided to childhood cancer survivors throughout their lifespan, through improved care coordination as survivors transitions to adult care.

(b) SELECTION OF DEMONSTRATION SITES.—

(1) MAXIMUM NUMBER OF SITES.—The Secretary shall ensure that the maximum number of sites does not exceed 10.

(2) DIVERSITY OF SITES.—In selecting entities to participate in the demonstration project, the Secretary shall, to the extent practicable, include in such selection—

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

(B) sites located in different geographic areas.

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

(1) Coordination of care and transitions of care between cancer care providers, primary care physicians, mental health professionals and any other relevant providers.

(2) Dissemination of information to, and training of, health care providers about linguistically and culturally competent follow-up care specific to cancer survivors.

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

(4) Incorporation of peer support and mentoring programs to improve the quality of life of cancer survivors.

(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).

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

(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.

(8) Other items determined by the Secretary.

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

(1) Patient care and satisfaction measures.

(2) Resource utilization measures.

(3) Adult survivorship measures.

(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-

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

Subtitle B—Coverage and Payment of High Quality Care

SEC. 311. REPORT BY THE COMPTROLLER GENERAL.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a review and submit recommendations to Congress on existing barriers to obtaining and paying for adequate medical care for survivors of childhood cancer.

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

(1) identify existing barriers to the availability of complete and coordinated survivorship care for survivors of childhood cancer and to the availability of expert pediatric palliative care, including consideration of—

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

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

(C) access to necessary medical and other services for such survivors, including the services described in subsection (c); and

(D) lack of pediatric palliative care and hospice services for patients approaching the end of life; and

(2) make recommendations to provide improved access and payment plans for childhood cancer survivorship programs and palliative care, including psychosocial services and coverage of such services.

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

(1) Coordinated multidisciplinary long-term follow-up care with access to appropriate pediatric subspecialists and adult subspecialists with specific expertise in survivorship, including subspecialists with expertise in oncology, radiation oncology, surgery, cardiology, psychiatry or psychology, endocrinology, pulmonology, nephrology, dermatology, gynecology, and urology.

(2) Appropriate organ function testing (particularly screening for potential problems at much younger ages than usually indicated in the general population) and treatment, including—

(A) neuropsychological testing and mental health services;

(B) fertility testing and treatment;

(C) evaluation and treatment for endocrine disorders including growth hormone and testosterone replacement;

(D) diagnostic imaging to screen for late effects of treatment (including second cancers), such as mammograms and magnetic resonance imaging testing to screen for possible breast cancer;

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

(F) screening for osteoporosis with bone densitometry, including duel x-ray absorptiometry;

(G) dental coverage and necessary dental implants;

(H) hearing aids; and

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

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