

21st Century Cancer ALERT Act

Senators Kennedy and Hutchison

Section by Section Summary

The 21st Century Cancer ALERT Act is a comprehensive approach to cancer prevention and detection, research and treatment. It invests in cancer research infrastructure and improves collaboration among existing efforts. Prevention and early detection for those most at risk are emphasized through support for innovative initiatives and new technologies such as biomarkers. The legislation addresses the need to increase enrollment in clinical research by increasing access and removing barriers to patients' participation in clinical trials. The bill also includes a plan designed to improve care for cancer survivors. Additional provisions regarding prevention and screening initiatives will increase access to care for underserved populations and reduce the burden of disease and cost of healthcare to the nation.

Section 1 and 2 - Findings and Declaration of Purpose

Section 3- Advancement of the National Cancer Program (NCP)

Modernize the role of the National Cancer Institute (NCI) in coordinating the NCP

- Identifies relevant federal agencies to coordinate with NCI
- Improves the annual budget estimate for the NCP by including the needs of the entire NCP and submitting the budget annually to House and Senate Budget and Appropriations Committees
- Increases participation of other federal agencies in the National Cancer Advisory Board
- Encourages early detection and translational research opportunities

Biological Resource Coordination and Advancement of Technologies for Cancer Research

- Establishes an entity within NCI to support an interconnected network of biorepositories with consistent, interoperable systems for collection, storage, annotation, and information sharing
- Facilitates research by linking cancer registries to other federal data sources including those at Centers for Medicare and Medicaid Services, Social Security Administration, and Centers for Disease Control and Prevention
- Requires hospitals and ambulatory care centers that receive federal funds to offer patients the opportunity to contribute their biospecimens and clinical data to a clinical registry

Section 4 – Comprehensive and Responsible Access to Research, Data, and Outcomes

- Calls for guidance from the Office of Human Research Protection on the use of a centralized Institutional Review Board
- Improves privacy standards in clinical research by clarifying when de-identified patient information may be disclosed
- Calls for HHS to study the advantages and disadvantages of the synchronization of the standards for research under the Common Rule and the Privacy Rule
- Clarifies the application of the Privacy Rule to external researchers

Section 5- Enhanced Focus and Reporting on Cancer Research

- Calls for NCI to report annually on plans and progress regarding research on cancers with low incidence and low survival rates
- Establishes grants program to conduct research on cancers with low incidence and low survival rates

Section 6 – Continuing Access to Care for Prevention and Early Detection

Screening and Early Detection

- Establishes a grant program to states for colorectal cancer screening and referrals for medical treatment (similar to the national breast and cervical cancer early detection program). States are given the option to cover screened persons found to have cancer under Medicaid.

Cancer Prevention

- Authorizes grants for a medical mobile van program to conduct cancer screening and prevention education activities in communities that are underserved and suffer from barriers to preventative cancer care

Access to Prevention and Early Detection for Certain Cancers

- Calls for the Secretary to include cancers with especially low survival rates in the Cancer Genome Atlas Consortium
- Calls for the Secretary to establish formal working groups for cancers with especially low survival rates in the Early Detection Research Network
- Calls for the National Institute of Biomedical Imaging and Bioengineering to ensure that the Quantum Grant program and the Image Guided Interventions program expedite the development of interventions for cancers with low survival rates

Section 7– Early Recognition and Treatment of Cancer Through the Use of Biomarkers

Promote the Discovery and Development of Biomarkers

- Establishes and coordinates federal agencies to establish a highly directed, contract based program that will support the development of innovative biomarker discovery technologies
- Calls for FDA and CMS to work together to create guidelines for clinical study designs that will enable sponsors to generate clinical data that will be adequate for review by both agencies
- Conducts a demonstration project to provide limited regional coverage for biomarker tests and establish procedures for independent research entities to conduct high quality assessments of the efficacy and cost effectiveness of biomarker tests

Section 8: National Cancer Coverage Guidelines

Ensure Patient Access to Clinical Trials

- Facilitates expanded access to clinical trials by requiring ERISA governed health plans to continue to provide coverage of routine care regardless of whether a patient enrolls in a clinical trial

Section 9: Health Professions Workforce

Ensure a Stable Workforce for the Future

- Supports retired nurse military officers to work as nurse faculty
- Directs Secretary of Health and Human Services to identify oncology workforce gaps

Section 10: Patient Navigator Program

Improve Upon Existing Patient Navigator Programs

- Ensures that patient navigators meet minimum core proficiencies
- Reauthorizes the Patient Navigator program through 2015

Section 11: Cancer Care and Coverage Under Medicaid and Medicare

Improvements in Coverage of Cancer Services

- Codifies current Medicare policy to reimburse for routine care while patients are enrolled in clinical trials
- Conducts a demonstration project to evaluate the cost, effectiveness, and potential savings to Medicare of reimbursing providers for comprehensive cancer care planning services to the Medicare population
- Directs states to offer tobacco cessation medications and counseling to pregnant women enrolled in Medicaid

Section 12: Cancer Survivorship and Complete Recovery Initiatives

Childhood Cancers

- Establishes priority areas for NIH activities related to childhood cancer survivorship
- Authorizes grants for research on the causes of health disparities in childhood cancer survivorship and to evaluate follow up care for childhood cancer survivors

Complete Recovery Care

- Defines “complete recovery care” which includes care to address secondary effects of cancer and its treatment, including late and psychosocial effects
- Coordinates complete recovery care activities across federal agencies
- Establishes a Collaborative that will develop a plan for workforce development for complete recovery care

Section 13: Activities of the Food and Drug Administration

Sense of the Senate

- Encourages the FDA to harmonize policies to facilitate the development of drugs; explore clinical trial endpoints; and, modernize the Office of Oncology Drug Products