

104TH CONGRESS  
2D SESSION

# S. 1963

To establish a demonstration project to study and provide coverage of routine patient care costs for medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

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IN THE SENATE OF THE UNITED STATES

JULY 17, 1996

Mr. ROCKEFELLER (for himself and Mr. MACK) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To establish a demonstration project to study and provide coverage of routine patient care costs for medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

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.**

4       This Act may be cited as the “Medicare Cancer Clin-

5       cal Trial Coverage Act of 1996”.

## 1 SEC. 2. MEDICARE CANCER PATIENT DEMONSTRATION

## 2 PROJECT.

3 (a) ESTABLISHMENT.—Not later than January 1,  
4 1997, the Secretary of Health and Human Services (in  
5 this Act referred to as the “Secretary”) shall establish a  
6 demonstration project which provides for payment under  
7 the medicare program under title XVIII of the Social Se-  
8 curity Act (42 U.S.C. 1395 et seq.) of routine patient care  
9 costs—

10 (1) which are provided to an individual diag-  
11 nosed with cancer and enrolled in the medicare pro-  
12 gram under such title as part of the individual’s par-  
13 ticipation in an approved clinical trial program; and  
14 (2) which are not otherwise eligible for payment  
15 under such title for individuals who are entitled to  
16 benefits under such title.

17 (b) APPLICATION.—The beneficiary cost sharing pro-  
18 visions under the medicare program, such as deductibles,  
19 coinsurance, and copayment amounts, shall apply to any  
20 individual participating in a demonstration project con-  
21 ducted under this Act.

22 (c) APPROVED CLINICAL TRIAL PROGRAM.—For  
23 purposes of this Act, the term “approved clinical trial pro-  
24 gram” means a clinical trial program which is approved  
25 by—

26 (1) the National Institutes of Health;

1                             (2) a National Institutes of Health cooperative  
2                             group or a National Institutes of Health center;

3                             (3) the Food and Drug Administration (in the  
4                             form of an investigational new drug or device exemp-  
5                             tion);

6                             (4) the Department of Veterans Affairs;

7                             (5) the Department of Defense; or

8                             (6) a qualified nongovernmental research entity  
9                             identified in the guidelines issued by the National  
10                            Institutes of Health for center support grants.

11                           (d) ROUTINE PATIENT CARE COSTS.—

12                           (1) IN GENERAL.—For purposes of this Act,  
13                             “routine patient care costs” shall include the costs  
14                             associated with the provision of items and services  
15                             that—

16                             (A) would otherwise be covered under the  
17                             medicare program if such items and services  
18                             were not provided in connection with an ap-  
19                             proved clinical trial program; and

20                             (B) are furnished according to the design  
21                             of an approved clinical trial program.

22                           (2) EXCLUSION.—For purposes of this Act,  
23                             “routine patient care costs” shall not include the  
24                             costs associated with the provision of—

## **8 SEC. 3. STUDY, REPORT, AND TERMINATION.**

9         (a) STUDY.—The Secretary shall study the impact on  
10 the medicare program under title XVIII of the Social Se-  
11 curity Act of covering routine patient care costs for indi-  
12 viduals with a diagnosis of cancer and other diagnoses,  
13 who are entitled to benefits under such title and who are  
14 enrolled in an approved clinical trial program.

15 (b) REPORT TO CONGRESS.—Not later than January  
16 1, 2001, the Secretary shall submit a report to Congress  
17 that contains a statement regarding—

21                         (2) a projection of expenditures under the medi-  
22                         care program if coverage of routine patient care  
23                         costs in an approved clinical trial program were ex-  
24                         tended to individuals entitled to benefits under the

1        medicare program who have a diagnosis other than  
2        cancer.

3        (c) TERMINATION.—The provisions of this Act shall  
4        not apply after June 30, 2001.

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