

106TH CONGRESS
1ST SESSION

H. R. 61

To amend title XVIII of the Social Security Act to provide for Medicare reimbursement of routine patient care costs for individuals participating in Federally approved clinical trials and to require a report on costs of requiring coverage of these costs under group health plans and health insurance coverage.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 6, 1999

Mr. BENTSEN (for himself, Mr. HALL of Texas, and Mr. SANDLIN) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for Medicare reimbursement of routine patient care costs for individuals participating in Federally approved clinical trials and to require a report on costs of requiring coverage of these costs under group health plans and health insurance coverage.

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.**

2 This Act may be cited as the “Medicare Clinical Trial
3 Coverage Act of 1999”.

4 **SEC. 2. MEDICARE REIMBURSEMENT FOR INDIVIDUALS**
5 **PARTICIPATING IN CLINICAL TRIALS.**

6 (a) IN GENERAL.—Section 1862 of the Social Secu-
7 rity Act (42 U.S.C. 1395y) is amended—

8 (1) in subsection (a)(1)—

9 (A) by striking “and” at the end of sub-
10 paragraph (H);

11 (B) by striking the semicolon at the end of
12 subparagraph (I) and inserting “, and”; and

13 (C) by adding at the end the following new
14 subparagraph:

15 “(J) in the case of expenses incurred in connec-
16 tion with any phase of a Federally approved clinical
17 trial (as defined in subsection (h)(1)), unless such
18 expenses are for routine patient care costs (as de-
19 fined in subsection (h)(2));”; and

20 (2) by inserting after subsection (g) the follow-
21 ing new subsection:

22 “(h)(1) For purposes of subsection (a)(1)(J), the
23 term ‘Federally approved clinical trial’ means a clinical
24 trial which is approved by any of the following:

25 “(A) The Secretary.

1 “(B) The Director of the the National Insti-
2 tutes of Health.

3 “(C) The Commissioner of the Food and Drug
4 Administration.

5 “(D) The Secretary of Veterans Affairs.

6 “(E) The Secretary of Defense.

7 “(F) The Secretary of Energy.

8 “(G) A nongovernmental research entity (as de-
9 fined in the guidelines of the National Institutes of
10 Health) or a peer-review and approved research pro-
11 gram (as defined by the Secretary).

12 “(2)(A) Subject to subparagraph (B), for purposes
13 of subsection (a)(1)(J), the term ‘routine patient care
14 costs’ includes the costs associated with the provision of
15 items and services that—

16 “(i) would otherwise be covered under this title
17 if such items and services were not provided in con-
18 nection with a Federally approved clinical trial; and

19 “(ii) are furnished according to the design of a
20 Federally approved clinical trial.

21 “(B) Such term does not include the costs associated
22 with the provision of—

23 “(i) an investigational drug or device, unless
24 the Secretary has authorized the manufacturer of

1 such drug or device to charge for such drug or de-
2 vice; or

3 “(ii) any item or service supplied without
4 charge by the sponsor of the Federally approved
5 clinical trial.”.

6 (b) ASSURING COVERAGE UNDER
7 MEDICARE+CHOICE PLANS.—Section 1852(d)(1) of such
8 Act (42 U.S.C. 1395w–22(d)(1)) is amended—

9 (1) by striking “and” at the end of subpara-
10 graph (D);

11 (2) by striking the period at the end of sub-
12 paragraph (E) and inserting “; and”; and

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(F) coverage is provided under the plan
16 for routine patient care costs of Federally ap-
17 proved clinical trials (as such terms are defined
18 in section 1862(h)).”.

19 (c) EFFECTIVE DATE.—The amendments made by
20 this section apply to items and services furnished on or
21 after January 1, 2000.

1 **SEC. 3. REPORT ON COSTS OF COVERAGE OF BENEFITS**
2 **FOR FEDERALLY APPROVED CLINICAL**
3 **TRIALS UNDER GROUP HEALTH PLANS AND**
4 **HEALTH INSURANCE COVERAGE.**

5 The Secretaries of Health and Human Services and
6 Labor shall jointly prepare and submit to Congress a re-
7 port on the costs associated with requiring that group
8 health plans and health insurance coverage do not deny
9 payment of routine patient care costs for services fur-
10 nished in connection with Federally approved clinical trials
11 (as those terms are defined in section 1862(h) of the So-
12 cial Security Act).

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