

111TH CONGRESS  
1ST SESSION

# S. 2766

To provide for the coverage of medically necessary food under Federal health programs and private health insurance.

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IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 2009

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

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## A BILL

To provide for the coverage of medically necessary food under Federal health programs and private health insurance.

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 “Medical Foods Equity  
5 Act of 2009”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Newborns are screened for inborn errors of  
9 metabolism, but treatment for such conditions is not  
10 uniformly covered by insurance.

1           (2) Each year approximately 2,550 children in  
2 the United States are diagnosed with an inborn  
3 error of metabolism disorder, requiring foods modi-  
4 fied to be void of the nutrient or nutrients the  
5 child's body is incapable of processing, or requiring  
6 supplementation with vitamins or amino acids.

7           (3) More than 30 States have passed laws to at  
8 least partially address the inequity in coverage for  
9 medically necessary foods, critical treatment for such  
10 disorders.

11           (4) The cost associated with providing medically  
12 necessary foods presents a large financial burden for  
13 many families.

14           (5) There is no current cure for inborn errors  
15 of metabolism disorders and treatment is necessary  
16 during the entire lifespan of the individual.

17 **SEC. 3. COVERAGE IN FEDERAL HEALTH PROGRAMS OF**  
18 **MEDICALLY NECESSARY FOOD AND FOOD**  
19 **MODIFIED TO BE LOW PROTEIN.**

20 (a) COVERAGE UNDER THE MEDICARE PROGRAM.—

21           (1) COVERAGE OF MEDICALLY NECESSARY  
22 FOOD UNDER THE ORIGINAL MEDICARE FEE-FOR-  
23 SERVICE PROGRAM.—

1 (A) IN GENERAL.—Section 1861(s)(2) of  
2 the Social Security Act (42 U.S.C. 1395x(s)(2))  
3 is amended—

4 (i) in subparagraph (DD), by striking  
5 “and” at the end;

6 (ii) in subparagraph (EE), by insert-  
7 ing “and” at the end; and

8 (iii) by adding at the end the fol-  
9 lowing new subparagraph:

10 “(FF) medically necessary food (as defined  
11 in subsection (hhh)) and food modified to be  
12 low protein that is formulated to be consumed  
13 or administered under the supervision of a  
14 qualified medical provider, for the treatment of  
15 conditions as recommended by the Advisory  
16 Committee on Heritable Disorders in Newborns  
17 and Children, and the medical equipment and  
18 supplies necessary to administer such food.”.

19 (B) DEFINITION.—Section 1861 of such  
20 Act (42 U.S.C. 1395x) is amended by adding at  
21 the end the following new subsection:

22 “(hhh)(1) The term ‘medically necessary food’—

23 “(A) means a food which is formulated to be  
24 consumed or administered enterally under the super-  
25 vision of a qualified medical provider and which is

1 intended for the specific dietary management of a  
2 disease or condition for which distinctive nutritional  
3 requirements, based on recognized scientific prin-  
4 ciples, are established by medical evaluation; and

5 “(B) includes nutritionally modified counter-  
6 parts of traditional foods and other forms of foods  
7 such as formulas, pills, capsules and bars, so long as  
8 consumed or administered enterally.

9 “(2) For purposes of paragraph (1), the term  
10 ‘enterally’ refers to consumption or administration  
11 through the gastrointestinal tract, whether orally or by  
12 tube.”.

13 (C) PAYMENT.—Section 1833(a)(1) of the  
14 Social Security Act (42 U.S.C. 1395l(a)(1)) is  
15 amended—

16 (i) by striking “and” before “(W)”;

17 and

18 (ii) by inserting before the semicolon  
19 at the end the following: “, and (X) with  
20 respect to medically necessary food and  
21 pharmacological doses of vitamins and  
22 amino acids under section 1861(s)(2)(FF),  
23 the amounts paid shall be 80 percent of  
24 the lesser of the actual charge for the serv-  
25 ices or 85 percent of the amount deter-

1           mined under the fee schedule established  
2           under section 1848(b) for the same serv-  
3           ices if furnished by a physician”.

4           (2) INCLUSION OF PHARMACOLOGICAL DOSES  
5           OF VITAMINS AND AMINO ACIDS AS A COVERED PART  
6           D DRUG.—

7           (A) IN GENERAL.—Section 1860D–2(e)(1)  
8           of the Social Security Act (42 U.S.C. 1395w–  
9           102(e)(1)) is amended—

10           (i) in subparagraph (A), by striking  
11           “or”;

12           (ii) in subparagraph (B), by striking  
13           the comma at the end and inserting “, or”;  
14           and

15           (iii) by adding at the end the fol-  
16           lowing new subparagraph:

17           “(C) pharmacological doses of vitamins  
18           and amino acids used for the treatment of in-  
19           born errors of metabolism, for the treatment of  
20           conditions as recommended by the Advisory  
21           Committee on Heritable Disorders in Newborns  
22           and Children and as prescribed by a qualified  
23           medical provider,”.

24           (B) EFFECTIVE DATE.—The amendments  
25           made by subparagraph (A) shall apply to plan

1           years beginning on or after the date that is 6  
2           months after date of enactment of this Act.

3           (b) COVERAGE UNDER THE MEDICAID PROGRAM.—

4           (1) DEFINITION OF MEDICAL ASSISTANCE.—

5           Section 1905 of the Social Security Act (42 U.S.C.  
6           1396d) is amended—

7                   (A) in subsection (a)—

8                           (i) by redesignating paragraph (28) as  
9                           paragraph (30);

10                           (ii) in paragraph (27), by striking at  
11                           the end “and”; and

12                           (iii) by inserting after paragraph (27)  
13                           the following new paragraphs:

14                           “(28) medically necessary food (as defined in  
15                           subsection (y)) and food modified to be low protein  
16                           that is formulated to be consumed or administered  
17                           under the supervision of a qualified medical pro-  
18                           vider, for the treatment of conditions as rec-  
19                           ommended by the Advisory Committee on Heritable  
20                           Disorders in Newborns and Children, and the med-  
21                           ical equipment and supplies necessary to administer  
22                           such food;

23                           “(29) pharmacological doses of vitamins and  
24                           amino acids used for the treatment of inborn errors  
25                           of metabolism, for the treatment of conditions as

1 recommended by the Advisory Committee on Heri-  
2 table Disorders in Newborns and Children and as  
3 prescribed by a qualified medical provider; and”;

4 (B) by adding at the end the following new

5 subsection:

6 “(y) MEDICALLY NECESSARY FOOD DEFINED.—

7 “(1) IN GENERAL.—For purposes of subsection  
8 (a)(28), the term ‘medically necessary food’—

9 “(A) means a food which is formulated to  
10 be consumed or administered enterally under  
11 the supervision of a qualified medical provider  
12 and which is intended for the specific dietary  
13 management of a disease or condition for which  
14 distinctive nutritional requirements, based on  
15 recognized scientific principles, are established  
16 by medical evaluation; and

17 “(B) includes nutritionally modified coun-  
18 terparts of traditional foods and other forms of  
19 foods such as formulas, pills, capsules and bars,  
20 so long as consumed or administered enterally.

21 “(2) ENTERALLY.—For purposes of paragraph  
22 (1), the term ‘enterally’ refers to consumption or ad-  
23 ministration through the gastrointestinal tract,  
24 whether orally or by tube.”.

1           (2)       MANDATORY        BENEFITS.—Section  
2       1902(a)(10)(A) of the Social Security Act (42  
3       U.S.C. 1396a(a)(10)(A)) is amended, in the matter  
4       preceding clause (i), by striking “and (21)” and in-  
5       serting “, (21), (28), and (29)”.

6           (3) CONFORMING AMENDMENTS.—

7           (A)       MEDICALLY        NEEDY.—Section  
8       1902(a)(10)(C)(iv) of such Act (42 U.S.C.  
9       1396a(a)(10)(C)(iv)) is amended by striking  
10       “and (17) of section 1905(a) or the care and  
11       services listed in any 7 of the paragraphs num-  
12       bered (1) through (24)” and inserting “(17),  
13       (28), and (29) of section 1905(a) or the care  
14       and services listed in any 7 of the paragraphs  
15       numbered (1) through (24) or (28) or (29)”.

16          (B) EXCEPTION TO REBATE EXCLUSION.—  
17       Section 1927(d)(2)(F) of the Social Security  
18       Act (42 U.S.C. 1396r–8(d)(2)(F)) is amended  
19       by inserting “, pharmacological doses of vita-  
20       mins and amino acids used for the treatment of  
21       inborn errors of metabolism, for the treatment  
22       of conditions as recommended by the Advisory  
23       Committee on Heritable Disorders in Newborns  
24       and Children and as prescribed by a qualified  
25       medical provider,” after “prenatal vitamins”.

1           (4) EXCEPTION TO EFFECTIVE DATE IF STATE  
2           LEGISLATION REQUIRED.—In the case of a State  
3           plan for medical assistance under title XIX of the  
4           Social Security Act which the Secretary of Health  
5           and Human Services (referred to in this Act as the  
6           “Secretary”) determines requires State legislation  
7           (other than legislation appropriating funds) in order  
8           for the plan to meet the additional requirement im-  
9           posed by the amendments made by this subsection,  
10          the State plan shall not be regarded as failing to  
11          comply with the requirements of such title solely on  
12          the basis of its failure to meet this additional re-  
13          quirement before the first day of the first calendar  
14          quarter beginning after the close of the first regular  
15          session of the State legislature that begins after the  
16          date of the enactment of this Act. For purposes of  
17          the previous sentence, in the case of a State that has  
18          a 2-year legislative session, each year of such session  
19          shall be deemed to be a separate regular session of  
20          the State legislature.

21          (c) COVERAGE UNDER CHIP.—

22               (1) REQUIRED COVERAGE.—Section 2103(e) of  
23               the Social Security Act (42 U.S.C. 1397cc(e)) is  
24               amended by inserting after paragraph (8) the fol-  
25               lowing:

1           “(9) MEDICALLY NECESSARY FOOD.—

2                   “(A) IN GENERAL.—The child health as-  
3           sistance provided to a targeted low-income child  
4           under the plan shall include coverage of medi-  
5           cally necessary food and food modified to be low  
6           protein that is formulated to be consumed or  
7           administered under the supervision of a quali-  
8           fied medical provider, for the treatment of con-  
9           ditions as recommended by the Advisory Com-  
10          mittee on Heritable Disorders in Newborns and  
11          Children, and the medical equipment and sup-  
12          plies necessary to administer such food.

13                   “(B) DEFINITIONS.—In this paragraph—

14                           “(i) the term ‘medically necessary  
15           food’—

16                                   “(I) means a food which is for-  
17                                   mulated to be consumed or adminis-  
18                                   tered enterally under the supervision  
19                                   of a qualified medical provider and  
20                                   which is intended for the specific die-  
21                                   tary management of a disease or con-  
22                                   dition for which distinctive nutritional  
23                                   requirements, based on recognized sci-  
24                                   entific principles, are established by  
25                                   medical evaluation; and

1                   “(II) includes nutritionally modi-  
2                   fied counterparts of traditional foods  
3                   and other forms of foods such as for-  
4                   mulas, pills, capsules and bars, so  
5                   long as consumed or administered  
6                   enterally; and

7                   “(ii) the term ‘enterally’ refers to con-  
8                   sumption or administration through the  
9                   gastrointestinal tract, whether orally or by  
10                  tube.

11                  “(10) VITAMINS AND AMINO ACIDS.—The child  
12                  health assistance provided to a targeted low-income  
13                  child under the plan shall include coverage of phar-  
14                  macological doses of vitamins and amino acids used  
15                  for the treatment of inborn errors of metabolism, for  
16                  the treatment of conditions as recommended by the  
17                  Advisory Committee on Heritable Disorders in  
18                  Newborns and Children and as prescribed by a  
19                  qualified medical provider.”.

20                  (2) CONFORMING AMENDMENTS.—

21                  (A) MANDATORY BENEFITS.—Section  
22                  2103(a) of the Social Security Act (42 U.S.C.  
23                  1397cc(a)) is amended, in the matter preceding  
24                  paragraph (1), by striking “, and (7)” and in-  
25                  serting “, (7), (9), and (10)”.

1 (B) DEFINITION OF CHILD HEALTH AS-  
2 SISTANCE.—Section 2110(a) of such Act (42  
3 U.S.C. 1397jj) is amended—

4 (i) by redesignating paragraph (28) as  
5 paragraph (30); and

6 (ii) by inserting after paragraph (27)  
7 the following:

8 “(28) Medically necessary food (as defined in  
9 section 2103(c)(9)(B)(i)) and food modified to be  
10 low protein that is formulated to be consumed or ad-  
11 ministered under the supervision of a qualified med-  
12 ical provider, for the treatment of conditions as rec-  
13 ommended by the Advisory Committee on Heritable  
14 Disorders in Newborns and Children, and the med-  
15 ical equipment and supplies necessary to administer  
16 such food.

17 “(29) Pharmacological doses of vitamins and  
18 amino acids used for the treatment of inborn errors  
19 of metabolism, for the treatment of conditions as  
20 recommended by the Advisory Committee on Heri-  
21 table Disorders in Newborns and Children and as  
22 prescribed by a qualified medical provider.”.

23 (d) AVAILABILITY OF MEDICALLY NECESSARY FOOD,  
24 FOOD MODIFIED TO BE LOW PROTEIN, AND RELATED  
25 ITEMS UNDER THE TRICARE PROGRAM.—Section

1 1077(a)(8) of title 10, United States Code, is amended  
2 by striking “including” and all that follows and inserting  
3 “including the following:

4           “(A) Well-baby care that includes one  
5 screening of an infant for the level of lead in  
6 the blood of the infant.

7           “(B) Medically necessary food (as defined  
8 in section 1861(hhh) of the Social Security Act)  
9 and food modified to be low protein that is for-  
10 mulated to be consumed or administered under  
11 the supervision of a qualified medical provider,  
12 for the treatment of conditions as recommended  
13 by the Advisory Committee on Heritable Dis-  
14 orders in Newborns and Children, and the med-  
15 ical equipment and supplies necessary to admin-  
16 ister such food.

17           “(C) Pharmacological doses of vitamins  
18 and amino acids used for the treatment of in-  
19 born errors of metabolism and other conditions  
20 as recommended by the Advisory Committee on  
21 Heritable Disorders in Newborns and Chil-  
22 dren.”.

1 **SEC. 4. COVERAGE IN THE PRIVATE INSURANCE MARKET**  
 2 **OF MEDICALLY NECESSARY FOOD AND FOOD**  
 3 **MODIFIED TO BE LOW PROTEIN.**

4 (a) GROUP HEALTH PLANS.—

5 (1) AMENDMENTS TO ERISA.—

6 (A) IN GENERAL.—Subpart B of part 7 of  
 7 title I of the Employee Retirement Income Se-  
 8 curity Act of 1974 (29 U.S.C. 1185 et seq.) is  
 9 amended by adding at the end the following:

10 **“SEC. 715. COVERAGE OF MEDICALLY NECESSARY FOOD**  
 11 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

12 “(a) DEFINITION.—In this section—

13 “(1) the term ‘medically necessary food’—

14 “(A) means a food which is formulated to  
 15 be consumed or administered enterally under  
 16 the supervision of a qualified medical provider  
 17 and which is intended for the specific dietary  
 18 management of a disease or condition for which  
 19 distinctive nutritional requirements, based on  
 20 recognized scientific principles, are established  
 21 by medical evaluation; and

22 “(B) includes nutritionally modified coun-  
 23 terparts of traditional foods and other forms of  
 24 foods such as formulas, pills, capsules and bars,  
 25 so long as consumed or administered enterally.

1           “(2) the term ‘enterally’ refers to consumption  
2 or administration through the gastrointestinal tract,  
3 whether orally or by tube.

4           “(b) COVERAGE.—

5           “(1) MEDICALLY NECESSARY FOOD AND FOOD  
6 MODIFIED TO BE LOW PROTEIN.—A group health  
7 plan, or a health insurance issuer that provides  
8 health insurance coverage in connection with a group  
9 health plan, shall provide coverage for medically nec-  
10 essary food and food modified to be low protein that  
11 is formulated to be consumed or administered under  
12 the supervision of a qualified medical provider, for  
13 the treatment of conditions as recommended by the  
14 Advisory Committee on Heritable Disorders in  
15 Newborns and Children, and the medical equipment  
16 and supplies necessary to administer such food.

17           “(2) VITAMINS AND AMINO ACIDS.—A group  
18 health plan, or a health insurance issuer that pro-  
19 vides health insurance coverage in connection with a  
20 group health plan, that provides prescription drug  
21 coverage shall provide coverage for pharmacological  
22 doses of vitamins and amino acids used for the  
23 treatment of inborn errors of metabolism, for the  
24 treatment of conditions as recommended by the Ad-  
25 visory Committee on Heritable Disorders in

1 Newborns and Children and as prescribed by a  
 2 qualified medical provider, to the same extent as  
 3 other prescription drug coverage under such plan or  
 4 coverage.”.

5 (B) CONFORMING AMENDMENT.—The  
 6 table of contents in section 1 of such Act is  
 7 amended by inserting after the item relating to  
 8 section 714 the following new item:

“Sec. 715. Coverage of medically necessary food and food modified to be low  
 protein.”.

9 (2) AMENDMENTS TO THE PUBLIC HEALTH  
 10 SERVICE ACT.—Subpart 2 of part A of title XXVII  
 11 of the Public Health Service Act (42 U.S.C. 300gg–  
 12 4 et seq.) is amended by adding at the end the fol-  
 13 lowing new section:

14 **“SEC. 2708. COVERAGE OF MEDICALLY NECESSARY FOOD**  
 15 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

16 “(a) DEFINITIONS.—In this section—

17 “(1) the term ‘medically necessary food’—

18 “(A) means a food which is formulated to  
 19 be consumed or administered enterally under  
 20 the supervision of a qualified medical provider  
 21 and which is intended for the specific dietary  
 22 management of a disease or condition for which  
 23 distinctive nutritional requirements, based on

1 recognized scientific principles, are established  
2 by medical evaluation; and

3 “(B) includes nutritionally modified coun-  
4 terparts of traditional foods and other forms of  
5 foods such as formulas, pills, capsules and bars,  
6 so long as consumed or administered enterally.

7 “(2) the term ‘enterally’ refers to consumption  
8 or administration through the gastrointestinal tract,  
9 whether orally or by tube.

10 “(b) COVERAGE.—

11 “(1) MEDICALLY NECESSARY FOOD AND FOOD  
12 MODIFIED TO BE LOW PROTEIN.—A group health  
13 plan, or a health insurance issuer that provides  
14 health insurance coverage in connection with a group  
15 health plan, shall provide coverage for medically nec-  
16 essary food and food modified to be low protein that  
17 is formulated to be consumed or administered under  
18 the supervision of a qualified medical provider, for  
19 the treatment of conditions as recommended by the  
20 Advisory Committee on Heritable Disorders in  
21 Newborns and Children, and the medical equipment  
22 and supplies necessary to administer such food.

23 “(2) VITAMINS AND AMINO ACIDS.—A group  
24 health plan, or a health insurance issuer that pro-  
25 vides health insurance coverage in connection with a

1 group health plan, that provides prescription drug  
 2 coverage, shall provide coverage for pharmacological  
 3 doses of vitamins and amino acids used for the  
 4 treatment of inborn errors of metabolism, for the  
 5 treatment of conditions as recommended by the Ad-  
 6 visory Committee on Heritable Disorders in  
 7 Newborns and Children and as prescribed by a  
 8 qualified medical provider, to the same extent as  
 9 other prescription drug coverage under such plan or  
 10 coverage.”.

11 (3) AMENDMENTS TO THE INTERNAL REVENUE  
 12 CODE.—

13 (A) IN GENERAL.—Subchapter B of chap-  
 14 ter 100 of the Internal Revenue Code of 1986  
 15 (relating to other group health plan require-  
 16 ments) is amended by inserting after section  
 17 9813 the following new section:

18 **“SEC. 9814. COVERAGE OF MEDICALLY NECESSARY FOOD**  
 19 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

20 “(a) DEFINITIONS.—In this section—

21 “(1) the term ‘medically necessary food’—

22 “(A) means a food which is formulated to  
 23 be consumed or administered enterally under  
 24 the supervision of a qualified medical provider  
 25 and which is intended for the specific dietary

1 management of a disease or condition for which  
2 distinctive nutritional requirements, based on  
3 recognized scientific principles, are established  
4 by medical evaluation; and

5 “(B) includes nutritionally modified coun-  
6 terparts of traditional foods and other forms of  
7 foods such as formulas, pills, capsules and bars,  
8 so long as consumed or administered enterally.

9 “(2) the term ‘enterally’ refers to consumption  
10 or administration through the gastrointestinal tract,  
11 whether orally or by tube.

12 “(b) COVERAGE.—

13 “(1) MEDICALLY NECESSARY FOOD AND FOOD  
14 MODIFIED TO BE LOW PROTEIN.—A group health  
15 plan, or a health insurance issuer that provides  
16 health insurance coverage in connection with a group  
17 health plan, shall provide coverage for necessary  
18 medically necessary food and food modified to be low  
19 protein that is formulated to be consumed or admin-  
20 istered under the supervision of a qualified medical  
21 provider, for the treatment of conditions as rec-  
22 ommended by the Advisory Committee on Heritable  
23 Disorders in Newborns and Children, and the med-  
24 ical equipment and supplies necessary to administer  
25 such food.

1           “(2) VITAMINS AND AMINO ACIDS.—A group  
2 health plan, or a health insurance issuer that pro-  
3 vides health insurance coverage in connection with a  
4 group health plan, that provides prescription drug  
5 coverage, shall provide coverage for pharmacological  
6 doses of vitamins and amino acids used for the  
7 treatment of inborn errors of metabolism, for the  
8 treatment of conditions as recommended by the Ad-  
9 visory Committee on Heritable Disorders in  
10 Newborns and Children and as prescribed by a  
11 qualified medical provider, to the same extent as  
12 other prescription drug coverage under such plan or  
13 coverage.”.

14           (B) CONFORMING AMENDMENT.—The  
15 table of sections for subchapter B of chapter  
16 100 of such Code is amended by inserting after  
17 the item relating to section 9813 the following  
18 new item:

“Sec. 9814. Coverage of medically necessary food and food modified to be low  
protein.”.

19           (b) INDIVIDUAL MARKET.—Subpart 3 of part B of  
20 title XXVII of the Public Health Service Act (42 U.S.C.  
21 300gg–51 et seq.) is amended by adding at the end the  
22 following new section:

1 **“SEC. 2754. COVERAGE OF MEDICALLY NECESSARY FOOD**  
2 **AND FOOD MODIFIED TO BE LOW PROTEIN.**

3 “The provisions of section 2708 shall apply to health  
4 insurance coverage offered by a health insurance issuer  
5 in the individual market in the same manner as they apply  
6 to health insurance coverage offered by a health insurance  
7 issuer in connection with a group health plan in the small  
8 or large group market.”.

9 **SEC. 5. EFFECTIVE DATE; DETERMINATION OF MINIMUM**  
10 **YEARLY COVERAGE.**

11 (a) **EFFECTIVE DATE.**—The amendments made by  
12 sections 3 and 4 shall apply to plan years beginning after  
13 the date that is 180 days after the date of enactment of  
14 this Act.

15 (b) **DETERMINATION BY SECRETARY.**—

16 (1) **IN GENERAL.**—Prior to the date described  
17 under subsection (a), the Secretary of Health and  
18 Human Services (referred to in this Act as the “Sec-  
19 retary”) shall determine the minimum yearly cov-  
20 erage for all health insurance plans pursuant to the  
21 amendments made by this Act. Such minimum year-  
22 ly coverage shall apply to an individual during any  
23 period when the individual is covered under the plan  
24 and for as long as deemed medically necessary. The  
25 Secretary may establish age-specific minimum levels  
26 of coverage and periodically update these levels

1 based on a standard cost of living index, the actual  
2 cost of treatment, and other appropriate measures  
3 as determined by the Secretary.

4 (2) NO PREEMPTION.—The minimum yearly  
5 coverage determined by the Secretary under para-  
6 graph (1) shall not preempt any State standards  
7 that require a higher minimum yearly coverage level  
8 for the same services and benefits.

○