

106TH CONGRESS  
1ST SESSION

# S. 1641

To amend the Employee Retirement Income Security Act of 1974, Public Health Service Act, and the Internal Revenue Code of 1986 to require that group and individual health insurance coverage and group health plans provide coverage of cancer screening.

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 24, 1999

Mrs. FEINSTEIN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Employee Retirement Income Security Act of 1974, Public Health Service Act, and the Internal Revenue Code of 1986 to require that group and individual health insurance coverage and group health plans provide coverage of cancer screening.

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 “Cancer Screening Cov-  
5 erage Act of 1999”.

6 **SEC. 2. CANCER SCREENING COVERAGE.**

7 (a) GROUP HEALTH PLANS.—

1           (1) PUBLIC HEALTH SERVICE ACT AMEND-  
2           MENTS.—

3           (A) IN GENERAL.—Subpart 2 of part A of  
4           title XXVII of the Public Health Service Act  
5           (42 U.S.C. 300gg–4 et seq.) is amended by  
6           adding at the end the following new section:

7           **“SEC. 2707. COVERAGE OF CANCER SCREENING.**

8           “(a) REQUIREMENT.—A group health plan, and a  
9           health insurance issuer offering group health insurance  
10          coverage, shall provide coverage and payment under the  
11          plan or coverage for the following items and services under  
12          terms and conditions that are no less favorable than the  
13          terms and conditions applicable to other screening benefits  
14          otherwise provided under the plan or coverage:

15          “(1) MAMMOGRAMS.—In the case of a female  
16          participant or beneficiary who is 40 years of age or  
17          older, or is under 40 years of age but is at high risk  
18          (as defined in subsection (e)) of developing breast  
19          cancer, an annual mammography (as defined in sec-  
20          tion 1861(jj) of the Social Security Act) conducted  
21          by a facility that has a certificate (or provisional cer-  
22          tificate) issued under section 354 of the Public  
23          Health Service Act.

24          “(2) CLINICAL BREAST EXAMINATIONS.—In the  
25          case of a female participant or beneficiary who—

1           “(A)(i) is 40 years of age or older or (ii)  
 2           is at least 20 (but less than 40) years of age  
 3           and is at high risk of developing breast cancer,  
 4           an annual clinical breast examination; or

5           “(B) is at least 20, but less than 40, years  
 6           of age and who is not at high risk of developing  
 7           breast cancer, a clinical breast examination  
 8           each 3 years.

9           “(3) PAP TESTS AND PELVIC EXAMINATIONS.—  
 10          In the case of a female participant or beneficiary  
 11          who is 18 years of age or older, or who is under 18  
 12          years of age and is or has been sexually active—

13                 “(A) an annual diagnostic laboratory test  
 14                 (popularly known as a ‘pap smear’) consisting  
 15                 of a routine exfoliative cytology test (Papani-  
 16                 colaou test) provided to a woman for the pur-  
 17                 pose of early detection of cervical or vaginal  
 18                 cancer and including an interpretation by a  
 19                 qualified health professional of the results of  
 20                 the test; and

21                 “(B) an annual pelvic examination.

22           “(4) COLORECTAL CANCER SCREENING PROCE-  
 23          DURES.—In the case of a participant or beneficiary  
 24          who is 50 years of age or older, or who is under 50  
 25          years of age and is at high risk of developing

1 colorectal cancer, the procedures described in section  
2 1861(pp)(1) of the Social Security Act (42 U.S.C.  
3 1395x(pp)(1)) or section 4104(a)(2) of the Balanced  
4 Budget Act of 1997 (111 Stat. 362), shall be fur-  
5 nished to the individual for the purpose of early de-  
6 tection of colorectal cancer. The group health plan  
7 or health insurance issuer shall provide coverage for  
8 the method and frequency of colorectal cancer  
9 screening determined to be appropriate by a health  
10 care provider treating such participant or bene-  
11 ficiary, in consultation with the participant or bene-  
12 ficiary.

13 “(5) PROSTATE CANCER SCREENING.—In the  
14 case of a participant or beneficiary who is 50 years  
15 of age or older, or who is a male who is at high risk  
16 for prostate cancer (such as an African American or  
17 a male who has a history of prostate cancer in close  
18 family members), an annual test consisting of any  
19 (or all) of the procedures described in section  
20 1861(oo)(2) of Social Security Act (42 U.S.C.  
21 1395x(oo)(2)) provided for the purpose of early de-  
22 tection of prostate cancer.

23 “(6) OTHER TESTS AND PROCEDURES.—Such  
24 other tests or procedures for the detection of cancer,  
25 and modifications to the tests and procedures, with

1 such frequency, as the Secretary determines to be  
2 appropriate, in consultation with appropriate organi-  
3 zations and agencies, for the diagnosis or detection  
4 of cancer.

5 “(b) PROHIBITIONS.—A group health plan, and a  
6 health insurance issuer offering group health insurance  
7 coverage in connection with a group health plan, shall  
8 not—

9 “(1) deny to an individual eligibility, or contin-  
10 ued eligibility, to enroll or to renew coverage under  
11 the terms of the plan, solely for the purpose of  
12 avoiding the requirements of this section;

13 “(2) provide monetary payments or rebates to  
14 individuals to encourage such individuals to accept  
15 less than the minimum protections available under  
16 this section;

17 “(3) penalize or otherwise reduce or limit the  
18 reimbursement of a provider because such provider  
19 provided care to an individual participant or bene-  
20 ficiary in accordance with this section; or

21 “(4) provide incentives (monetary or otherwise)  
22 to a provider to induce such provider to provide care  
23 to an individual participant or beneficiary in a man-  
24 ner inconsistent with this section.

25 “(c) RULES OF CONSTRUCTION.—

1           “(1) Nothing in this section shall be construed  
2           to require an individual who is a participant or bene-  
3           ficiary to undergo a procedure, examination, or test  
4           described in subsection (a).

5           “(2) Nothing in this section shall be construed  
6           as preventing a group health plan or issuer from im-  
7           posing deductibles, coinsurance, or other cost-shar-  
8           ing in relation to benefits described in subsection (a)  
9           consistent with such subsection, except that such co-  
10          insurance or other cost-sharing shall not discrimi-  
11          nate on any basis related to the coverage required  
12          under this section.

13          “(d) NOTICE.—A group health plan under this part  
14          shall comply with the notice requirement under section  
15          714(d) of the Employee Retirement Income Security Act  
16          of 1974 with respect to the requirements of this section  
17          as if such section applied to such plan.

18          “(e) HIGH RISK DEFINED.—For purposes of this  
19          section, an individual is considered to be at ‘high risk’ of  
20          developing a particular type of cancer if, under guidelines  
21          developed or recognized by the Secretary based upon sci-  
22          entific evidence, the individual—

23                  “(1) has one or more close family members who  
24                  have developed that type of cancer;

25                  “(2) has previously had that type of cancer;

1           “(3) has the presence of an appropriate recog-  
2 nized gene marker that is identified as putting the  
3 individual at a higher risk of developing that type of  
4 cancer; or

5           “(4) has other predisposing factors that signifi-  
6 cantly increases the risk of the individual con-  
7 tracting that type of cancer.

8 For purposes of this subsection, the term ‘type of cancer’  
9 includes other types of cancer that the Secretary recog-  
10 nizes as closely related for purposes of establishing risk.”.

11           (B) TECHNICAL AMENDMENT.—Section  
12 2723(c) of the Public Health Service Act (42  
13 U.S.C. 300gg–23(c)) is amended by striking  
14 “section 2704” and inserting “sections 2704  
15 and 2707”.

16           (2) ERISA AMENDMENTS.—

17           (A) IN GENERAL.—Subpart B of part 7 of  
18 subtitle B of title I of the Employee Retirement  
19 Income Security Act of 1974 (29 U.S.C. 1185  
20 et seq.) is amended by adding at the end the  
21 following new section:

22 **“SEC. 714. COVERAGE OF CANCER SCREENING.**

23           “(a) REQUIREMENT.—A group health plan, and a  
24 health insurance issuer offering group health insurance  
25 coverage, shall provide coverage and payment under the

1 plan or coverage for the following items and services under  
2 terms and conditions that are no less favorable than the  
3 terms and conditions applicable to other screening benefits  
4 otherwise provided under the plan or coverage:

5           “(1) MAMMOGRAMS.—In the case of a female  
6 participant or beneficiary who is 40 years of age or  
7 older, or is under 40 years of age but is at high risk  
8 (as defined in subsection (e)) of developing breast  
9 cancer, an annual mammography (as defined in sec-  
10 tion 1861(jj) of the Social Security Act) conducted  
11 by a facility that has a certificate (or provisional cer-  
12 tificate) issued under section 354 of the Public  
13 Health Service Act.

14           “(2) CLINICAL BREAST EXAMINATIONS.—In the  
15 case of a female participant or beneficiary who—

16                   “(A)(i) is 40 years of age or older or (ii)  
17 is at least 20 (but less than 40) years of age  
18 and is at high risk of developing breast cancer,  
19 an annual clinical breast examination; or

20                   “(B) is at least 20, but less than 40, years  
21 of age and who is not at high risk of developing  
22 breast cancer, a clinical breast examination  
23 each 3 years.

24           “(3) PAP TESTS AND PELVIC EXAMINATIONS.—  
25 In the case of a female participant or beneficiary

1 who is 18 years of age or older, or who is under 18  
2 years of age and is or has been sexually active—

3 “(A) an annual diagnostic laboratory test  
4 (popularly known as a ‘pap smear’) consisting  
5 of a routine exfoliative cytology test (Papani-  
6 colaou test) provided to a woman for the pur-  
7 pose of early detection of cervical or vaginal  
8 cancer and including an interpretation by a  
9 qualified health professional of the results of  
10 the test; and

11 “(B) an annual pelvic examination.

12 “(4) COLORECTAL CANCER SCREENING PROCE-  
13 DURES.—In the case of a participant or beneficiary  
14 who is 50 years of age or older, or who is under 50  
15 years of age and is at high risk of developing  
16 colorectal cancer, the procedures described in section  
17 1861(pp)(1) of the Social Security Act (42 U.S.C.  
18 1395x(pp)(1)) or section 4104(a)(2) of the Balanced  
19 Budget Act of 1997 (111 Stat. 362), shall be fur-  
20 nished to the individual for the purpose of early de-  
21 tection of colorectal cancer. The group health plan  
22 or health insurance issuer shall provided coverage  
23 for the method and frequency of colorectal cancer  
24 screening determined to be appropriate by a health  
25 care provider treating such participant or bene-

1       ficiary, in consultation with the participant or bene-  
2       ficiary.

3           “(5) PROSTATE CANCER SCREENING.—In the  
4       case of a participant or beneficiary who is 50 years  
5       of age or older, or who is a male who is at high risk  
6       for prostate cancer (such as an African American or  
7       a male who has a history of prostate cancer in close  
8       family members), an annual test consisting of any  
9       (or all) of the procedures described in section  
10      1861(oo)(2) of Social Security Act (42 U.S.C.  
11      1395x(oo)(2)) provided for the purpose of early de-  
12      tection of prostate cancer.

13          “(6) OTHER TESTS AND PROCEDURES.—Such  
14      other tests or procedures for the detection of cancer,  
15      and modifications to the tests and procedures, with  
16      such frequency, as the Secretary determines to be  
17      appropriate, in consultation with appropriate organi-  
18      zations and agencies, for the diagnosis or detection  
19      of cancer.

20          “(b) PROHIBITIONS.—A group health plan, and a  
21      health insurance issuer offering group health insurance  
22      coverage in connection with a group health plan, may  
23      not—

24           “(1) deny to an individual eligibility, or contin-  
25      ued eligibility, to enroll or to renew coverage under

1 the terms of the plan, solely for the purpose of  
2 avoiding the requirements of this section;

3 “(2) provide monetary payments or rebates to  
4 individuals to encourage such individuals to accept  
5 less than the minimum protections available under  
6 this section;

7 “(3) penalize or otherwise reduce or limit the  
8 reimbursement of a provider because such provider  
9 provided care to an individual participant or bene-  
10 ficiary in accordance with this section; or

11 “(4) provide incentives (monetary or otherwise)  
12 to a provider to induce such provider to provide care  
13 to an individual participant or beneficiary in a man-  
14 ner inconsistent with this section.

15 “(c) RULES OF CONSTRUCTION.—

16 “(1) Nothing in this section shall be construed  
17 to require an individual who is a participant or bene-  
18 ficiary to undergo a procedure, examination, or test  
19 described in subsection (a).

20 “(2) Nothing in this section shall be construed  
21 as preventing a group health plan or issuer from im-  
22 posing deductibles, coinsurance, or other cost-shar-  
23 ing in relation to benefits described in subsection (a)  
24 consistent with such subsection, except that such co-  
25 insurance or other cost-sharing shall not discrimi-

1       nate on any basis related to the coverage required  
2       under this section.

3       “(d) NOTICE UNDER GROUP HEALTH PLAN.—The  
4       imposition of the requirement of this section shall be treat-  
5       ed as a material modification in the terms of the plan de-  
6       scribed in section 102(a)(1), for purposes of assuring no-  
7       tice of such requirements under the plan; except that the  
8       summary description required to be provided under the  
9       last sentence of section 104(b)(1) with respect to such  
10      modification shall be provided by not later than 60 days  
11      after the first day of the first plan year in which such  
12      requirement apply.

13      “(e) HIGH RISK DEFINED.—For purposes of this  
14      section, an individual is considered to be at ‘high risk’ of  
15      developing a particular type of cancer if, under guidelines  
16      developed or recognized by the Secretary based upon sci-  
17      entific evidence, the individual—

18              “(1) has one or more close family members who  
19              have developed that type of cancer;

20              “(2) has previously had that type of cancer;

21              “(3) has the presence of an appropriate recog-  
22              nized gene marker that is identified as putting the  
23              individual at a higher risk of developing that type of  
24              cancer; or

1           “(4) has other predisposing factors that signifi-  
2           cantly increases the risk of the individual con-  
3           tracting that type of cancer.

4 For purposes of this subsection, the term ‘type of cancer’  
5 includes other types of cancer that the Secretary recog-  
6 nizes as closely related for purposes of establishing risk.”.

7           (B) TECHNICAL AMENDMENTS.—

8           (i) Section 731(c) of the Employee  
9           Retirement Income Security Act of 1974  
10           (29 U.S.C. 1191(c)) is amended by strik-  
11           ing “section 711” and inserting “sections  
12           711 and 714”.

13           (ii) Section 732(a) of the Employee  
14           Retirement Income Security Act of 1974  
15           (29 U.S.C. 1191a(a)) is amended by strik-  
16           ing “section 711” and inserting “sections  
17           711 and 714”.

18           (iii) The table of contents in section 1  
19           of the Employee Retirement Income Secu-  
20           rity Act of 1974 is amended by inserting  
21           after the item relating to section 713 the  
22           following new item:

“Sec. 714. Coverage of cancer screening.”.

23           (3) INTERNAL REVENUE CODE AMEND-  
24           MENTS.—Subchapter B of chapter 100 of the Inter-  
25           nal Revenue Code of 1986 is amended—

1 (A) in the table of sections, by inserting  
2 after the item relating to section 9812 the fol-  
3 lowing new item:

“Sec. 9813. Coverage of cancer screening.”; and

4 (B) by inserting after section 9812 the fol-  
5 lowing:

6 **“SEC. 9813. COVERAGE OF CANCER SCREENING.**

7 “(a) REQUIREMENT.—A group health plan shall pro-  
8 vide coverage and payment under the plan for the fol-  
9 lowing items and services under terms and conditions that  
10 are no less favorable than the terms and conditions appli-  
11 cable to other screening benefits otherwise provided under  
12 the plan:

13 “(1) MAMMOGRAMS.—In the case of a female  
14 participant or beneficiary who is 40 years of age or  
15 older, or is under 40 years of age but is at high risk  
16 (as defined in subsection (d)) of developing breast  
17 cancer, an annual mammography (as defined in sec-  
18 tion 1861(jj) of the Social Security Act) conducted  
19 by a facility that has a certificate (or provisional cer-  
20 tificate) issued under section 354 of the Public  
21 Health Service Act.

22 “(2) CLINICAL BREAST EXAMINATIONS.—In the  
23 case of a female participant or beneficiary who—

24 “(A)(i) is 40 years of age or older or (ii)  
25 is at least 20 (but less than 40) years of age

1 and is at high risk of developing breast cancer,  
2 an annual clinical breast examination; or

3 “(B) is at least 20, but less than 40, years  
4 of age and who is not at high risk of developing  
5 breast cancer, a clinical breast examination  
6 each 3 years.

7 “(3) P<sub>AP</sub> TESTS AND PELVIC EXAMINATIONS.—  
8 In the case of a female participant or beneficiary  
9 who is 18 years of age or older, or who is under  
10 18 years of age and is or has been sexually active—

11 “(A) an annual diagnostic laboratory test  
12 (popularly known as a ‘pap smear’) consisting  
13 of a routine exfoliative cytology test (Papani-  
14 colaou test) provided to a woman for the pur-  
15 pose of early detection of cervical or vaginal  
16 cancer and including an interpretation by a  
17 qualified health professional of the results of  
18 the test; and

19 “(B) an annual pelvic examination.

20 “(4) COLORECTAL CANCER SCREENING PROCE-  
21 DURES.—In the case of a participant or beneficiary  
22 who is 50 years of age or older, or who is under 50  
23 years of age and is at high risk of developing  
24 colorectal cancer, the procedures described in section  
25 1861(pp)(1) of the Social Security Act (42 U.S.C.

1 1395x(pp)(1)) or section 4104(a)(2) of the Balanced  
2 Budget Act of 1997 (111 Stat. 362), shall be fur-  
3 nished to the individual for the purpose of early de-  
4 tection of colorectal cancer. The group health plan  
5 or health insurance issuer shall provide coverage for  
6 the method and frequency of colorectal cancer  
7 screening determined to be appropriate by a health  
8 care provider treating such participant or bene-  
9 ficiary, in consultation with the participant or bene-  
10 ficiary.

11 “(5) PROSTATE CANCER SCREENING.—In the  
12 case of a participant or beneficiary who is 50 years  
13 of age or older, or who is a male who is at high risk  
14 for prostate cancer (such as an African American or  
15 a male who has a history of prostate cancer in close  
16 family members), an annual test consisting of any  
17 (or all) of the procedures described in section  
18 1861(oo)(2) of Social Security Act (42 U.S.C.  
19 1395x(oo)(2)) provided for the purpose of early de-  
20 tection of prostate cancer.

21 “(6) OTHER TESTS AND PROCEDURES.—Such  
22 other tests or procedures for the detection of cancer,  
23 and modifications to the tests and procedures, with  
24 such frequency, as the Secretary determines to be  
25 appropriate, in consultation with appropriate organi-

1 zations and agencies, for the diagnosis or detection  
2 of cancer.

3 “(b) PROHIBITIONS.—A group health plan may not—

4 “(1) deny to an individual eligibility, or contin-  
5 ued eligibility, to enroll or to renew coverage under  
6 the terms of the plan, solely for the purpose of  
7 avoiding the requirements of this section;

8 “(2) provide monetary payments or rebates to  
9 individuals to encourage such individuals to accept  
10 less than the minimum protections available under  
11 this section;

12 “(3) penalize or otherwise reduce or limit the  
13 reimbursement of a provider because such provider  
14 provided care to an individual participant or bene-  
15 ficiary in accordance with this section; or

16 “(4) provide incentives (monetary or otherwise)  
17 to a provider to induce such provider to provide care  
18 to an individual participant or beneficiary in a man-  
19 ner inconsistent with this section.

20 “(c) RULES OF CONSTRUCTION.—

21 “(1) Nothing in this section shall be construed  
22 to require an individual who is a participant or bene-  
23 ficiary to undergo a procedure, examination, or test  
24 described in subsection (a).

1           “(2) Nothing in this section shall be construed  
2           as preventing a group health plan from imposing  
3           deductibles, coinsurance, or other cost-sharing in re-  
4           lation to benefits described in subsection (a) con-  
5           sistent with such subsection, except that such coin-  
6           surance or other cost-sharing shall not discriminate  
7           on any basis related to the coverage required under  
8           this section.

9           “(d) HIGH RISK DEFINED.—For purposes of this  
10          section, an individual is considered to be at ‘high risk’ of  
11          developing a particular type of cancer if, under guidelines  
12          developed or recognized by the Secretary based upon sci-  
13          entific evidence, the individual—

14                 “(1) has one or more close family members who  
15                 have developed that type of cancer;

16                 “(2) has previously had that type of cancer;

17                 “(3) has the presence of an appropriate recog-  
18                 nized gene marker that is identified as putting the  
19                 individual at a higher risk of developing that type of  
20                 cancer; or

21                 “(4) has other predisposing factors that signifi-  
22                 cantly increases the risk of the individual con-  
23                 tracting that type of cancer.

1 For purposes of this subsection, the term ‘type of cancer’  
 2 includes other types of cancer that the Secretary recog-  
 3 nizes as closely related for purposes of establishing risk.”.

4 (b) INDIVIDUAL HEALTH INSURANCE.—

5 (1) IN GENERAL.—Part B of title XXVII of the  
 6 Public Health Service Act is amended by inserting  
 7 after section 2752 (42 U.S.C. 300gg–52) the fol-  
 8 lowing new section:

9 **“SEC. 2753. STANDARD RELATING PATIENT FREEDOM OF**  
 10 **CHOICE.**

11 “(a) IN GENERAL.—The provisions of section 2707  
 12 (other than subsection (d)) shall apply to health insurance  
 13 coverage offered by a health insurance issuer in the indi-  
 14 vidual market with respect to an enrollee under such cov-  
 15 erage in the same manner as they apply to health insur-  
 16 ance coverage offered by a health insurance issuer in con-  
 17 nection with a group health plan in the small or large  
 18 group market to a participant or beneficiary in such plan.

19 “(b) NOTICE.—A health insurance issuer under this  
 20 part shall comply with the notice requirement under sec-  
 21 tion 714(d) of the Employee Retirement Income Security  
 22 Act of 1974 with respect to the requirements referred to  
 23 in subsection (a) as if such section applied to such issuer  
 24 and such issuer were a group health plan.”.

1           (2)     TECHNICAL     AMENDMENT.—Section  
2     2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2))  
3     is amended by striking “section 2751” and inserting  
4     “sections 2751 and 2753”.

5     (c) EFFECTIVE DATES.—

6           (1) GROUP HEALTH PLANS.—Subject to para-  
7     graph (3), the amendments made by subsection (a)  
8     shall apply with respect to group health plans for  
9     plan years beginning on or after January 1, 2000.

10          (2) INDIVIDUAL PLANS.—The amendment made  
11     by subsection (b) shall apply with respect to health  
12     insurance coverage offered, sold, issued, renewed, in  
13     effect, or operated in the individual market on or  
14     after such date.

15          (3) COLLECTIVE BARGAINING AGREEMENT.—In  
16     the case of a group health plan maintained pursuant  
17     to 1 or more collective bargaining agreements be-  
18     tween employee representatives and 1 or more em-  
19     ployers ratified before the date of enactment of this  
20     Act, the amendments made to subsection (a) shall  
21     not apply to plan years beginning before the later  
22     of—

23                 (A) the date on which the last collective  
24                 bargaining agreements relating to the plan ter-  
25                 minates (determined without regard to any ex-

1           tension thereof agreed to after the date of en-  
2           actment of this Act), or

3                       (B) January 1, 2000.

4           For purposes of subparagraph (A), any plan amend-  
5           ment made pursuant to a collective bargaining  
6           agreement relating to the plan which amends the  
7           plan solely to conform to any requirement added by  
8           subsection (a) shall not be treated as a termination  
9           of such collective bargaining agreement.

10          (d) COORDINATED REGULATIONS.—Section 104(1)  
11 of Health Insurance Portability and Accountability Act of  
12 1996 is amended by striking “this subtitle (and the  
13 amendments made by this subtitle and section 401)” and  
14 inserting “the provisions of part 7 of subtitle B of title  
15 I of the Employee Retirement Income Security Act of  
16 1974, the provisions of parts A and C of title XXVII of  
17 the Public Health Service Act, and chapter 100 of the In-  
18 ternal Revenue Code of 1986”.

19          (e) MODIFICATION OF COVERAGE.—

20               (1) IN GENERAL.—The Secretary of Health and  
21           Human Services may, by regulation, modify the cov-  
22           erage requirements applicable pursuant to the  
23           amendments made by this Act to reflect changes in  
24           medical practice or new scientific knowledge, on the

1 Secretary's own initiative or upon petition of an in-  
2 dividual or organization.

3 (2) CONSULTATION.—In modifying coverage re-  
4 quirements under paragraph (1), the Secretary of  
5 Health and Human Services shall consult with ap-  
6 propriate organizations, experts, and agencies.

7 (3) PETITIONS.—The Secretary of Health and  
8 Human Services may issue requirements for the pe-  
9 titioning process under paragraph (1), including re-  
10 quirements that the petition be in writing and in-  
11 clude scientific or medical bases for the modification  
12 sought. Upon receipt of such a petition, the Sec-  
13 retary shall respond to the petitioner and decide  
14 whether to propose a regulation proposing a change  
15 within 90 days of such receipt. If a regulation is re-  
16 quired, the Secretary shall propose such regulation  
17 within 6 months of such determination. The Sec-  
18 retary shall provide the petitioner the reasons for  
19 the decision of the Secretary. The Secretary may  
20 make changes requested by a petitioner in whole or  
21 in part.

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