

# Union Calendar No. 409

105<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4382

[Report No. 105-713]

To amend the Public Health Service Act to revise and extend the program for mammography quality standards.

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## IN THE HOUSE OF REPRESENTATIVES

AUGUST 3, 1998

Mr. BLILEY (for himself, Mr. BILIRAKIS, Mr. DINGELL, Mr. BROWN of Ohio, Mr. HASTERT, Mr. WAXMAN, Mr. BARTON of Texas, Mr. TOWNS, Mr. UPTON, Mr. PALLONE, Mr. GREENWOOD, Mr. DEUTSCH, Mr. DEAL of Georgia, Ms. ESHOO, Mr. BURR of North Carolina, Mr. STUPAK, Mr. BILBRAY, Mr. GREEN, Mr. LAZIO of New York, Mr. STRICKLAND, Mrs. CUBIN, Ms. DEGETTE, Mr. HALL of Texas, and Ms. FURSE) introduced the following bill; which was referred to the Committee on Commerce

SEPTEMBER 14, 1998

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on August 3, 1998]

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## A BILL

To amend the Public Health Service Act to revise and extend the program for mammography quality standards.

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 “Mammography Quality*  
3 *Standards Reauthorization Act of 1998”.*

4 **SEC. 2. AUTHORIZATION OF APPROPRIATIONS.**

5 (a) *IN GENERAL.*—Section 354(r)(2) of the Public  
6 Health Service Act (42 U.S.C. 263b(r)(2)) is amended in  
7 each of subparagraphs (A) and (B) by striking “1997” and  
8 inserting “2002”.

9 (b) *TECHNICAL AMENDMENTS.*—Section 354(r)(2) of  
10 the Public Health Service Act (42 U.S.C. 263b(r)(2)) is  
11 amended in subparagraph (A) by striking “subsection (q)”  
12 and inserting “subsection (p)”, and in subparagraph (B)  
13 by striking “fiscal year” and inserting “fiscal years”.

14 **SEC. 3. APPLICATION OF CURRENT VERSION OF APPEAL**  
15 **REGULATIONS.**

16 Section 354(d)(2)(B) of the Public Health Service Act  
17 (42 U.S.C. 263b(d)(2)(B)) is amended by striking “42  
18 C.F.R. 498 and in effect on the date of the enactment of  
19 this section” and inserting “part 498 of title 42, Code of  
20 Federal Regulations”.

21 **SEC. 4. ACCREDITATION STANDARDS.**

22 (a) *IN GENERAL.*—Section 354(e)(1)(B) of the Public  
23 Health Service Act (42 U.S.C. 263b(e)(1)(B)) is amended—

24 (1) in clause (i), by striking “practicing physi-  
25 cians” each place such term appears and inserting  
26 “review physicians”; and

1           (2) in clause (ii), by striking “financial relation-  
2           ship” and inserting “relationship”.

3           (b) *DEFINITION.*—Section 354(a) of the Public Health  
4 Service Act (42 U.S.C. 263b(a)) is amended by adding at  
5 the end the following:

6           “(8) *REVIEW PHYSICIAN.*—The term ‘review phy-  
7           sician’ means a physician as prescribed by the Sec-  
8           retary under subsection (f)(1)(D) who meets such ad-  
9           ditional requirements as may be established by an ac-  
10          creditation body under subsection (e) and approved  
11          by the Secretary to review clinical images under sub-  
12          section (e)(1)(B)(i) on behalf of the accreditation  
13          body.”.

14 **SEC. 5. CLARIFICATION OF FACILITIES’ RESPONSIBILITY TO**  
15 **RETAIN MAMMOGRAM RECORDS.**

16          Section 354(f)(1)(G) of the Public Health Service Act  
17 (42 U.S.C. 263b(f)(1)(G)) is amended by striking clause (i)  
18 and inserting the following:

19                           “(i) a facility that performs any mam-  
20                           mogram—

21   “(I) except as provided in sub-  
22   clause (II), maintain the mammogram  
23   in the permanent medical records of  
24   the patient for a period of not less than  
25   5 years, or not less than 10 years if no

1            *subsequent mammograms of such pa-*  
 2            *tient are performed at the facility, or*  
 3            *longer if mandated by State law; and*

4                    *“(II) upon the request of or on be-*  
 5            *half of the patient, transfer the mam-*  
 6            *mogram to a medical institution, to a*  
 7            *physician of the patient, or to the pa-*  
 8            *tient directly; and”.*

9    **SEC. 6. DIRECT REPORTS TO PATIENTS.**

10            *Section 354(f)(1)(G)(ii) of the Public Health Service*  
 11    *Act (42 U.S.C. 263b(f)(1)(G)(ii)) is amended by striking*  
 12    *subclause (IV) and inserting the following:*

13                    *“(IV) whether or not such a physician*  
 14            *is available or there is no such physician,*  
 15            *a summary of the written report shall be*  
 16            *sent directly to the patient in terms easily*  
 17            *understood by a lay person; and”.*

18    **SEC. 7. SCOPE OF INSPECTIONS.**

19            *Section 354(g)(1)(A) of the Public Health Service Act*  
 20    *(42 U.S.C. 263b(g)(1)(A)) is amended in the first sen-*  
 21    *tence—*

22                    *(1) by striking “certified”; and*

23                    *(2) by inserting “the certification requirements*  
 24            *under subsection (b) and” after “compliance with”.*

1 **SEC. 8. DEMONSTRATION PROGRAM REGARDING FRE-**  
2 **QUENCY OF INSPECTIONS.**

3 *Section 354(g) of the Public Health Service Act (42*  
4 *U.S.C. 263b(g)) is amended—*

5 *(1) in paragraph (1)(E), by inserting “, subject*  
6 *to paragraph (6)” before the period; and*

7 *(2) by adding at the end the following para-*  
8 *graph:*

9 *“(6) DEMONSTRATION PROGRAM.—*

10 *“(A) IN GENERAL.—The Secretary may es-*  
11 *tablish a demonstration program under which*  
12 *inspections under paragraph (1) of selected fa-*  
13 *ilities are conducted less frequently by the Sec-*  
14 *retary (or as applicable, by State or local agen-*  
15 *cies acting on behalf of the Secretary) than the*  
16 *interval specified in subparagraph (E) of such*  
17 *paragraph.*

18 *“(B) REQUIREMENTS.—Any demonstration*  
19 *program under subparagraph (A) shall be car-*  
20 *ried out in accordance with the following:*

21 *“(i) The program may not be imple-*  
22 *mented before April 1, 2001. Preparations*  
23 *for the program may be carried out prior to*  
24 *such date.*

25 *“(ii) In carrying out the program, the*  
26 *Secretary may not select a facility for in-*

1 *clusion in the program unless the facility is*  
2 *substantially free of incidents of noncompli-*  
3 *ance with the standards under subsection*  
4 *(f). The Secretary may at any time provide*  
5 *that a facility will no longer be included in*  
6 *the program.*

7 *“(iii) The number of facilities selected*  
8 *for inclusion in the program shall be suffi-*  
9 *cient to provide a statistically significant*  
10 *sample, subject to compliance with clause*  
11 *(ii).*

12 *“(iv) Facilities that are selected for in-*  
13 *clusion in the program shall be inspected at*  
14 *such intervals as the Secretary determines*  
15 *will reasonably ensure that the facilities are*  
16 *maintaining compliance with such stand-*  
17 *ards.”.*

18 **SEC. 9. CLARIFICATION OF AUTHORITY TO DELEGATE IN-**  
19 **SPECTION RESPONSIBILITY TO LOCAL GOV-**  
20 **ERNMENT AGENCIES.**

21 *Section 354 of the Public Health Service Act (42*  
22 *U.S.C. 263b) is amended—*

23 *(1) in subsections (a)(4), (g)(1), (g)(3), and*  
24 *(g)(4), by inserting “or local” after “State” each*  
25 *place such term appears;*

1           (2) *in the heading of subsection (g)(3), by insert-*  
2           *ing “OR LOCAL” after “STATE”; and*

3           (3) *in subsection (i)(1)(D)—*

4                   (A) *by inserting “or local” after “State” the*  
5                   *first place such term appears; and*

6                   (B) *by inserting “or local agency” after*  
7                   *“State” the second place such term appears.*

8 **SEC. 10. PATIENT NOTIFICATION CONCERNING HEALTH**  
9                   **RISKS.**

10           (a) *REQUIREMENT.—Section 354(h) of the Public*  
11           *Health Service Act (42 U.S.C. 263b(h)) is amended—*

12                   (1) *by redesignating paragraphs (2) and (3) as*  
13                   *paragraphs (3) and (4), respectively; and*

14                   (2) *by inserting after paragraph (1) the follow-*  
15                   *ing:*

16                   “(2) *PATIENT INFORMATION.—If the Secretary*  
17                   *determines that the quality of mammography per-*  
18                   *formed by a facility (whether or not certified pursu-*  
19                   *ant to subsection (c)) was so inconsistent with the*  
20                   *quality standards established pursuant to subsection*  
21                   *(f) as to present a significant risk to individual or*  
22                   *public health, the Secretary may require such facility*  
23                   *to notify patients who received mammograms at such*  
24                   *facility, and their referring physicians, of the defi-*  
25                   *ciencies presenting such risk, the potential harm re-*

1 *sulting, appropriate remedial measures, and such*  
2 *other relevant information as the Secretary may re-*  
3 *quire.”.*

4 *(b) CIVIL MONEY PENALTY.—Section 354(h)(3) of the*  
5 *Public Health Service Act (42 U.S.C. 263b(h)(3)), as red-*  
6 *esignated by subsection (a)(1), is amended—*

7 *(1) by striking “and” at the end of subpara-*  
8 *graph (B);*

9 *(2) by redesignating subparagraph (C) as sub-*  
10 *paragraph (D); and*

11 *(3) by inserting after subparagraph (B) the fol-*  
12 *lowing:*

13 *“(C) each failure to notify a patient of risk*  
14 *as required by the Secretary pursuant to para-*  
15 *graph (2), and”.*

16 *(c) CONFORMING AMENDMENT.—Section 354(h)(4) of*  
17 *the Public Health Service Act (42 U.S.C. 263b(h)(4)), as*  
18 *redesignated by subsection (a)(1), is amended by striking*  
19 *“paragraphs (1) and (2)” and inserting “paragraphs (1)*  
20 *through (3)”.*

21 **SEC. 11. REQUIREMENT TO COMPLY WITH INFORMATION**  
22 **REQUESTS.**

23 *Section 354(i)(1)(C) of the Public Health Service Act*  
24 *(42 U.S.C. 263b(i)(1)(C)) is amended—*

1           (1) by inserting after “Secretary” the first place  
2           such term appears the following: “(or of an accredita-  
3           tion body approved pursuant to subsection (e))”; and

4           (2) by inserting after “Secretary” the second  
5           place such term appears the following: “(or such ac-  
6           creditation body or State carrying out certification  
7           program requirements pursuant to subsection (q))”.

8   **SEC. 12. ADJUSTMENT TO SEVERITY OF SANCTIONS.**

9           Section 354(i)(2)(A) of the Public Health Service Act  
10          (42 U.S.C. 263b(i)(2)(A)) is amended by striking “makes  
11          the finding” and all that follows and inserting the follow-  
12          ing: “has reason to believe that the circumstance of the case  
13          will support one or more of the findings described in para-  
14          graph (1) and that—

15                           “(i) the failure or violation was inten-  
16                           tional; or

17                           “(ii) the failure or violation presents a  
18                           serious risk to human health.”.

19   **SEC. 13. TECHNICAL AMENDMENT.**

20          Section 354(q)(4)(B) of the Public Health Service Act  
21          (42 U.S.C. 263b(q)(4)(B)) is amended by striking “accred-  
22          ited” and inserting “certified”.

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