

105TH CONGRESS
2D SESSION

H. R. 4382

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

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

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Mammography Quality
5 Standards Reauthorization Act of 1998”.

6 **SEC. 2. AUTHORIZATION OF APPROPRIATIONS.**

7 (a) IN GENERAL.—Subparagraphs (A) and (B) of
8 section 354(r)(2) of the Public Health Service Act (42

1 U.S.C. 263b(r)(2)) are each amended by striking “1997”
 2 and inserting “2002”.

3 (b) TECHNICAL AMENDMENT.—Section 354(r)(2)(A)
 4 of the Public Health Service Act (42 U.S.C.
 5 263b(r)(2)(A)) is amended by striking “subsection (q)”
 6 and inserting “subsection (p)”.

7 **SEC. 3. APPLICATION OF CURRENT VERSION OF APPEAL**
 8 **REGULATIONS.**

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

14 **SEC. 4. ACCREDITATION STANDARDS.**

15 (a) IN GENERAL.—Section 354(e)(1)(B) of the Pub-
 16 lic Health Service Act (42 U.S.C. 263b(e)(1)(B)) is
 17 amended—

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

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

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

1 “(8) REVIEW PHYSICIAN.—The term ‘review
 2 physician’ means a physician as prescribed by the
 3 Secretary under subsection (f)(1)(D) who meets
 4 such additional requirements as may be established
 5 by an accreditation body under subsection (e) and
 6 approved by the Secretary to review clinical images
 7 under subsection (e)(1)(B)(i) on behalf of the ac-
 8 creditation body.”.

9 **SEC. 5. CLARIFICATION OF FACILITIES’ RESPONSIBILITY**
 10 **TO RETAIN MAMMOGRAM RECORDS.**

11 Section 354(f)(1)(G) of the Public Health Service Act
 12 (42 U.S.C. 263b(f)(1)(G)) is amended by striking clause
 13 (i) and inserting the following:

14 “(i) a facility that performs any mam-
 15 mogram—

16 “(I) except as provided in sub-
 17 clause (II), maintain the mammogram
 18 in the permanent medical records of
 19 the patient for a period of not less
 20 than 5 years, or not less than 10
 21 years if no subsequent mammograms
 22 of such patient are performed at the
 23 facility, or longer if mandated by
 24 State law; and

1 “(II) upon the request of or on
2 behalf of the patient, transfer the
3 mammogram to a medical institution,
4 to a physician of the patient, or to the
5 patient directly; and”.

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

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

10 “(IV) a summary of the written re-
11 port shall be sent directly to the patient in
12 terms easily understood by a lay person;
13 and”.

14 **SEC. 7. SCOPE OF INSPECTIONS.**

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

18 (1) by striking “certified”; and

19 (2) by inserting “the certification requirements
20 under subsection (b) and” after “compliance with”.

21 **SEC. 8. DEMONSTRATION PROGRAM REGARDING FRE-**
22 **QUENCY OF INSPECTIONS.**

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

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

3 (2) by adding at the end the following para-
4 graph:

5 “(6) DEMONSTRATION PROGRAM.—

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

14 “(B) REQUIREMENTS.—Any demonstra-
15 tion program under subparagraph (A) shall be
16 carried out in accordance with the following:

17 “(i) The program may not be imple-
18 mented before April 1, 2001. Preparations
19 for the program may be carried out prior
20 to such date.

21 “(ii) In carrying out the program, the
22 Secretary may not select a facility for in-
23 clusion in the program unless the facility is
24 substantially free of incidents of non-
25 compliance with the standards under sub-

1 section (f). The Secretary may at any time
 2 provide that a facility will no longer be in-
 3 cluded in the program.

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

9 “(iv) Facilities that are selected for
 10 inclusion in the program shall be inspected
 11 at such intervals as the Secretary deter-
 12 mines will ensure that the facilities are
 13 maintaining compliance with such stand-
 14 ards.”.

15 **SEC. 9. CLARIFICATION OF AUTHORITY TO DELEGATE IN-**
 16 **SPECTION RESPONSIBILITY TO LOCAL GOV-**
 17 **ERNMENT AGENCIES.**

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

20 (1) in subsections (a)(4), (g)(1), (g)(3), and
 21 (g)(4), by inserting “or local” after “State” each
 22 place such term appears;

23 (2) in the heading of subsection (g)(3), by in-
 24 serting “OR LOCAL” after “STATE”; and

25 (3) in subsection (i)(1)(D)—

1 (A) by inserting “or local” after “State”
 2 the first place such term appears; and

3 (B) by inserting “or local agency” after
 4 “State” the second place such term appears.

5 **SEC. 10. PATIENT NOTIFICATION CONCERNING HEALTH**
 6 **RISKS.**

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

9 (1) by redesignating paragraphs (2) and (3) as
 10 paragraphs (3) and (4), respectively; and

11 (2) by inserting after paragraph (1) the follow-
 12 ing:

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

1 (b) CIVIL MONEY PENALTY.—Section 354(h)(3) of
 2 the Public Health Service Act (42 U.S.C. 263b(h)(3)), as
 3 redesignated by subsection (a)(1), is amended—

4 (1) by striking “and” at the end of subpara-
 5 graph (B);

6 (2) by redesignating subparagraph (C) as sub-
 7 paragraph (D); and

8 (3) by inserting after subparagraph (B) the fol-
 9 lowing:

10 “(C) each failure to notify a patient of risk
 11 as required by the Secretary pursuant to para-
 12 graph (2), and”.

13 (c) CONFORMING AMENDMENT.—Section 354(h)(4)
 14 of the Public Health Service Act (42 U.S.C. 263b(h)(4)),
 15 as redesignated by subsection (a)(1), is amended by strik-
 16 ing “paragraphs (1) and (2)” and inserting “paragraphs
 17 (1) through (3)”.

18 **SEC. 11. REQUIREMENT TO COMPLY WITH INFORMATION**
 19 **REQUESTS.**

20 Section 354(i)(1)(C) of the Public Health Service Act
 21 (42 U.S.C. 263b(i)(1)(C)) is amended—

22 (1) by inserting after “Secretary” the first
 23 place such term appears the following: “(or of an ac-
 24 creditation body approved pursuant to subsection
 25 (e))”; and

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

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

6 Section 354(i)(2)(A) of the Public Health Service Act
7 (42 U.S.C. 263b(i)(2)(A)) is amended by striking “makes
8 the finding” and all that follows and inserting the follow-
9 ing: “has reason to believe that the circumstance of the
10 case will support one or more of the findings described
11 in paragraph (1) and that—

12 “(i) the failure or violation was inten-
13 tional; or

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

16 **SEC. 13. TECHNICAL AMENDMENT.**

17 Section 354(q)(4)(B) of the Public Health Service
18 Act (42 U.S.C. 263b(q)(4)(B)) is amended by striking
19 “accredited” and inserting “certified”.

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