

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

**H. R. 4382**

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**AN ACT**

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

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## AN ACT

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”  
8 and 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  
17 Act (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  
19 of this section” and inserting “part 498 of title 42, Code  
20 of Federal Regulations”.

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

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

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

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

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

9 “(8) REVIEW PHYSICIAN.—The term ‘review  
10 physician’ means a physician as prescribed by the  
11 Secretary under subsection (f)(1)(D) who meets  
12 such additional requirements as may be established  
13 by an accreditation body under subsection (e) and  
14 approved by the Secretary to review clinical images  
15 under subsection (e)(1)(B)(i) on behalf of the ac-  
16 creditation body.”.

17 **SEC. 5. CLARIFICATION OF FACILITIES’ RESPONSIBILITY**  
18 **TO RETAIN MAMMOGRAM RECORDS.**

19 Section 354(f)(1)(G) of the Public Health Service Act  
20 (42 U.S.C. 263b(f)(1)(G)) is amended by striking clause  
21 (i) and inserting the following:

22 “(i) a facility that performs any mam-  
23 mogram—

24 “(I) except as provided in sub-  
25 clause (II), maintain the mammogram

1 in the permanent medical records of  
2 the patient for a period of not less  
3 than 5 years, or not less than 10  
4 years if no subsequent mammograms  
5 of such patient are performed at the  
6 facility, or longer if mandated by  
7 State law; and

8 “(II) upon the request of or on  
9 behalf of the patient, transfer the  
10 mammogram to a medical institution,  
11 to a physician of the patient, or to the  
12 patient directly; and”.

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

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

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

22 **SEC. 7. SCOPE OF INSPECTIONS.**

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

1 (1) by striking “certified”; and

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

4 **SEC. 8. DEMONSTRATION PROGRAM REGARDING FRE-**  
5 **QUENCY OF INSPECTIONS.**

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

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

10 (2) by adding at the end the following para-  
11 graph:

12 “(6) DEMONSTRATION PROGRAM.—

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

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

24 “(i) The program may not be imple-  
25 mented before April 1, 2001. Preparations

1 for the program may be carried out prior  
2 to such date.

3 “(ii) In carrying out the program, the  
4 Secretary may not select a facility for in-  
5 clusion in the program unless the facility is  
6 substantially free of incidents of non-  
7 compliance with the standards under sub-  
8 section (f). The Secretary may at any time  
9 provide that a facility will no longer be in-  
10 cluded in the program.

11 “(iii) The number of facilities selected  
12 for inclusion in the program shall be suffi-  
13 cient to provide a statistically significant  
14 sample, subject to compliance with clause  
15 (ii).

16 “(iv) Facilities that are selected for  
17 inclusion in the program shall be inspected  
18 at such intervals as the Secretary deter-  
19 mines will reasonably ensure that the fa-  
20 cilities are maintaining compliance with  
21 such standards.”.

1 **SEC. 9. CLARIFICATION OF AUTHORITY TO DELEGATE IN-**  
2 **SPECTION RESPONSIBILITY TO LOCAL GOV-**  
3 **ERNMENT AGENCIES.**

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

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

9 (2) in the heading of subsection (g)(3), by in-  
10 sserting “OR LOCAL” after “STATE”; and

11 (3) in subsection (i)(1)(D)—

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

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

16 **SEC. 10. PATIENT NOTIFICATION CONCERNING HEALTH**  
17 **RISKS.**

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

20 (1) by redesignating paragraphs (2) and (3) as  
21 paragraphs (3) and (4), respectively; and

22 (2) by inserting after paragraph (1) the follow-  
23 ing:

24 “(2) PATIENT INFORMATION.—If the Secretary  
25 determines that the quality of mammography per-  
26 formed by a facility (whether or not certified pursu-

1 ant to subsection (c)) was so inconsistent with the  
2 quality standards established pursuant to subsection  
3 (f) as to present a significant risk to individual or  
4 public health, the Secretary may require such facility  
5 to notify patients who received mammograms at  
6 such facility, and their referring physicians, of the  
7 deficiencies presenting such risk, the potential harm  
8 resulting, appropriate remedial measures, and such  
9 other relevant information as the Secretary may re-  
10 quire.”.

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

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

16 (2) by redesignating subparagraph (C) as sub-  
17 paragraph (D); and

18 (3) by inserting after subparagraph (B) the fol-  
19 lowing:

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

23 (c) CONFORMING AMENDMENT.—Section 354(h)(4)  
24 of the Public Health Service Act (42 U.S.C. 263b(h)(4)),  
25 as redesignated by subsection (a)(1), is amended by strik-

1 ing “paragraphs (1) and (2)” and inserting “paragraphs  
2 (1) through (3)”.

3 **SEC. 11. REQUIREMENT TO COMPLY WITH INFORMATION**  
4 **REQUESTS.**

5 Section 354(i)(1)(C) of the Public Health Service Act  
6 (42 U.S.C. 263b(i)(1)(C)) is amended—

7 (1) by inserting after “Secretary” the first  
8 place such term appears the following: “(or of an ac-  
9 creditation body approved pursuant to subsection  
10 (e))”; and

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

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

16 Section 354(i)(2)(A) of the Public Health Service Act  
17 (42 U.S.C. 263b(i)(2)(A)) is amended by striking “makes  
18 the finding” and all that follows and inserting the follow-  
19 ing: “has reason to believe that the circumstance of the  
20 case will support one or more of the findings described  
21 in paragraph (1) and that—

22 “(i) the failure or violation was inten-  
23 tional; or

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

1 **SEC. 13. TECHNICAL AMENDMENT.**

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

Passed the House of Representatives September 15,  
1998.

Attest:

*Clerk.*