

105TH CONGRESS
1ST SESSION

S. 537

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 12, 1997

Referred to the Committee on Commerce

AN ACT

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

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”.

1 **SEC. 2. AUTHORIZATION OF APPROPRIATIONS.**

2 (a) IN GENERAL.—Subparagraphs (A) and (B) of
 3 section 354(r)(2) of the Public Health Service Act (42
 4 U.S.C. 263b(r)(2) (A) and (B)) are each amended by
 5 striking “1997” and inserting “2002”.

6 (b) TECHNICAL AMENDMENT.—Section 354(r)(2)(A)
 7 of the Public Health Service Act (42 U.S.C.
 8 263b(r)(2)(A)) is amended by striking “subsection (q)”
 9 and inserting “subsection (p)”.

10 **SEC. 3. APPLICATION OF CURRENT VERSION OF APPEAL**
 11 **REGULATIONS.**

12 Section 354(d)(2)(B) of the Public Health Service
 13 Act (42 U.S.C. 263b(d)(2)(B)) is amended by striking
 14 “and in effect on the date of enactment of this section”.

15 **SEC. 4. CLARIFICATION OF FACILITIES’ RESPONSIBILITY**
 16 **TO RETAIN MAMMOGRAM RECORDS.**

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

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

22 “(I) except as provided in sub-
 23 clause (II), maintain the mammogram
 24 in the permanent medical records of
 25 the patient for a period of not less
 26 than 5 years, or not less than 10

1 years if no additional mammograms of
 2 such patient are performed at the fa-
 3 cility, or longer if mandated by State
 4 law; and

5 “(II) upon the request of or on
 6 behalf of the patient, forward the
 7 mammogram to a medical institution
 8 or a physician of the patient; and”.

9 **SEC. 5. SCOPE OF INSPECTIONS.**

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

13 (1) by striking “certified”; and

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

16 **SEC. 6. CLARIFICATION OF AUTHORITY TO DELEGATE IN-**
 17 **SPECTION RESPONSIBILITY TO LOCAL GOV-**
 18 **ERNMENT AGENCIES.**

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

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

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

1 (3) in subsection (i)(1)(D)—

2 (A) by inserting “or local” after “State”
 3 the first place it appears; and

4 (B) by inserting “or local agency” after
 5 “State” the second place it appears.

6 **SEC. 7. PATIENT NOTIFICATION CONCERNING HEALTH**
 7 **RISKS.**

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

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

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

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

1 other relevant information as the Secretary may re-
 2 quire.”.

3 (b) CIVIL MONEY PENALTY.—Section 354(h)(3) of
 4 the Public Health Service Act (42 U.S.C. 263b(h)(3)), as
 5 so redesignated, is amended—

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

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

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

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

15 **SEC. 8. REQUIREMENT TO COMPLY WITH INFORMATION**
 16 **REQUESTS.**

17 Section 354(i)(1)(C) of the Public Health Service Act
 18 (42 U.S.C. 263b(i)(1)(C)) is amended—

19 (1) by inserting after “Secretary”, the first
 20 place it appears “(or of an accreditation body ap-
 21 proved pursuant to subsection (e))”; and

22 (2) by inserting after “Secretary”, the second
 23 place it appears “(or such accreditation body or cer-
 24 tifying entity)”.

1 **SEC. 9. ADJUSTMENT TO SEVERITY OF SANCTIONS.**

2 Section 354(i)(2)(A) of the Public Health Service Act
 3 (42 U.S.C. 263b(i)(2)(A)) is amended by striking “makes
 4 the finding” and all that follows and inserting the follow-
 5 ing: “has reason to believe that the circumstance of the
 6 case will support one or more of the findings described
 7 in paragraph (1) and that—

8 “(i) the failure or violation was inten-
 9 tional, or

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

12 **SEC. 10. TECHNICAL AMENDMENT.**

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

Passed the Senate November 9, 1997.

Attest:

GARY SISCO,
Secretary.