

104TH CONGRESS
2D SESSION

H. R. 4217

To promote safer motherhood through improved surveillance and research on pregnancy outcomes through health professional and public education regarding pregnancy-related morbidity and mortality, through increased public education concerning folic acid supplements, through requiring health plan coverage of minimum hospital stays for childbirth, and through establishment of quality standards for facilities performing ultrasound procedures.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 1996

Mrs. SCHROEDER (for herself, Mr. DINGELL, Ms. MCKINNEY, Mrs. LOWEY, Mrs. CLAYTON, Ms. NORTON, and Mrs. MEEK of Florida) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Economic and Educational Opportunities, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To promote safer motherhood through improved surveillance and research on pregnancy outcomes through health professional and public education regarding pregnancy-related morbidity and mortality, through increased public education concerning folic acid supplements, through requiring health plan coverage of minimum hospital stays for childbirth, and through establishment of quality standards for facilities performing ultrasound procedures.

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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Safe Motherhood Act of 1996”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 this Act is as follows:

8 **TITLE I—EPIDEMIOLOGICAL**
9 **AND EDUCATIONAL ACTIVI-**
10 **TIES REGARDING PREG-**
11 **NANCY-RELATED COMPLICA-**
12 **TIONS**

13 **SEC. 101. SHORT TITLE; FINDINGS.**

14 (a) **SHORT TITLE.**—This title may be cited as the
15 “Pregnancy-Related Morbidity and Mortality Surveillance
16 and Research Act”.

17 (b) **FINDINGS.**—The Congress finds as follows:

18 (1) Each year women in the United States die
19 as a result of pregnancy-related complications, in-
20 cluding pregnancy-induced hypertension, embolism,
21 hemmorage, infection, and ectopic pregnancy.

22 (2) Sufficient data on the incidence and preva-
23 lence of pregnancy-related complications, including
24 with respect to deaths, is not available because the

1 systems in the United States for the collection of
2 such data is limited.

3 (3) The lack of sufficient data has had a det-
4 rimental effect on the state of medical knowledge on
5 the prevention and treatment of pregnancy-related
6 complications.

7 (4) The state of medical knowledge can be im-
8 proved by improving the systems for collecting data,
9 and by using the data as a basis for research on the
10 prevention and treatment of pregnancy-related com-
11 plications.

12 **SEC. 102. CENTERS FOR DISEASE CONTROL AND PREVEN-**
13 **TION; EPIDEMIOLOGICAL DATA AND PUBLIC**
14 **EDUCATION.**

15 Part C of title III of the Public Health Service Act
16 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
17 tion 317F the following section:

18 “EPIDEMIOLOGICAL DATA AND PUBLIC EDUCATION
19 REGARDING PREGNANCY-RELATED COMPLICATIONS

20 “SEC. 317G. (a) TECHNICAL ASSISTANCE TO STATES
21 FOR COLLECTION OF DATA.—The Secretary, acting
22 through the Director of the Centers for Disease Control
23 and Prevention, shall provide technical assistance to the
24 States for the purpose of assisting with the following ac-
25 tivities:

1 “(1) Collecting data on the incidence and preva-
2 lence of pregnancy-related complications.

3 “(2) Identifying and reporting the risk factors
4 associated with such complications.

5 “(3) Identifying and reporting cases in which
6 pregnancy-related complications were a contributing
7 factor in the death of the patients involved, and
8 identifying and reporting the risk-factors associated
9 with such cases.

10 “(b) PUBLIC EDUCATION.—The Secretary, acting
11 through the Director of the Centers for Disease Control
12 and Prevention, shall carry out activities to educate health
13 professionals and the public on the prevention of preg-
14 nancy-related complications and the treatments available
15 for such complications.

16 “(c) DEFINITION.—For purposes of this section, the
17 term ‘pregnancy-related complication’ means a disease,
18 disorder, or other medical condition that is related to preg-
19 nancy.

20 “(d) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) TECHNICAL ASSISTANCE FOR COLLECTION
22 OF DATA.—For the purpose of carrying out sub-
23 section (a), there are authorized to be appropriated
24 \$25,000,000.

1 “(2) PUBLIC EDUCATION.—For the purpose of
2 carrying out subsection (b), there are authorized to
3 be appropriated \$25,000,000.”.

4 **SEC. 103. COMPREHENSIVE EPIDEMIOLOGICAL REPORT TO**
5 **CONGRESS.**

6 (a) STUDY.—

7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services, acting through the Director of the
9 Centers for Disease Control and Prevention, shall
10 carry out a study for the purpose of determining the
11 following:

12 (A)(i) The national incidence and preva-
13 lence of each of ectopic pregnancy,
14 preeclampsia, placenta previa, abruptio
15 placentae, all hypertensive disorders of preg-
16 nancy, and such other pregnancy-related com-
17 plications as the Secretary determines to be ap-
18 propriate.

19 (ii) The risk factors associated with the
20 complications specified in clause (i).

21 (B) The overall national incidence and
22 prevalence of pregnancy-related complications
23 (considering all types of complications together,
24 except to the extent that data is not collected
25 under subparagraph (A) on a complication).

1 (C)(i) The national incidence and preva-
2 lence of cases in which pregnancy-related com-
3 plications were a contributing factor in the
4 death of the patients involved, including a spec-
5 ification of the incidence and prevalence of such
6 cases according to the type of complication in-
7 volved.

8 (ii) The risk factors associated with the
9 cases specified in clause (i).

10 (D) The extent of the effectiveness of Fed-
11 eral and State activities for the collection of epi-
12 demiological data on pregnancy-related com-
13 plications, including consideration of the extent
14 to which cases of such complications are not
15 being identified.

16 (E) The extent to which research on the
17 prevention and treatment of pregnancy-related
18 complications is being conducted in the United
19 States, including a specification of any areas
20 that have received insufficient study.

21 (2) RECOMMENDATIONS OF SECRETARY.—In
22 addition to the determinations required in paragraph
23 (1), the study under such paragraph shall include
24 the recommendations of the Secretary for the follow-
25 ing:

1 (A) Improving the effectiveness of Federal
2 and State activities for the collection of the epi-
3 demiological data described in paragraph (1),
4 including developing and implementing a uni-
5 form system for collecting and exchanging the
6 data.

7 (B) An agenda for the conduct and sup-
8 port by the Federal Government of research on
9 preventing and treating pregnancy-related com-
10 plications, including the following:

11 (i) Research to determine whether
12 there is a significant relationship between
13 the development of such complications and
14 multiple births, unintended pregnancy,
15 treatments for infertility, sexually trans-
16 mitted diseases, and the lack of access to
17 health care.

18 (ii) Other research to identify women
19 who may be at risk for such complications.

20 (C) Statutory or administrative modifica-
21 tions to the program of education established in
22 section 317G(b) of the Public Health Service
23 Act (as added by section 102 of this Act).

24 (b) REPORT.—Not later than 3 years after the date
25 of the enactment of this Act, the Secretary shall complete

1 the study required in subsection (a) and submit to the
2 Congress the findings made in the study.

3 (c) DEFINITIONS.—For purposes of this section:

4 (1) The term “pregnancy-related complication”
5 means a disease, disorder, or other medical condition
6 that is related to pregnancy.

7 (2) The term “Secretary” means the Secretary
8 of Health and Human Services.

9 (d) AUTHORIZATION OF APPROPRIATIONS.—For the
10 purpose of carrying out this section, there is authorized
11 to be appropriated \$50,000,000 for each of the fiscal years
12 1997 through 1999.

13 **TITLE II—PUBLIC EDUCATION**
14 **REGARDING FOLIC ACID AS DI-**
15 **ETARY SUPPLEMENT**

16 **SEC. 201. SHORT TITLE; FINDINGS.**

17 (a) SHORT TITLE.—This title may be cited as the
18 “Folic Acid Public Education Act”.

19 (b) FINDINGS.—The Congress finds as follows:

20 (1) Folic acid, a vitamin of the B complex, is
21 effective in preventing the serious, common birth de-
22 fects spina bifida and anencephaly, but only if the
23 woman involved consumes the vitamin daily before
24 she becomes pregnant and during the initial days
25 after she becomes pregnant.

1 (2) Only 25 percent of women of reproductive
2 age in the United States consume a sufficient daily
3 quantity of folic acid, and this percentage can, with-
4 in 5 years, be increased to 50 percent if effective ac-
5 tivities are carried out to educate the public.

6 **SEC. 202. ROLE OF FOLIC ACID IN PREVENTION OF BIRTH**
7 **DEFECTS; EDUCATION THROUGH HEALTH**
8 **PROFESSIONALS.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services, acting through the Director of the Cen-
11 ters for Disease Control and Prevention, may carry out
12 a program to encourage physicians, nurses, nutritionists,
13 and other health professionals to educate patients that
14 consuming a daily supplement of folic acid is effective in
15 preventing birth defects.

16 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
17 purpose of carrying out this section, there is authorized
18 to be appropriated \$20,000,000 for each of the fiscal years
19 1997 through 1999.

20 **TITLE III—NEWBORNS’ AND**
21 **MOTHERS’ HEALTH PROTEC-**
22 **TION ACT OF 1996**

23 **SEC. 301. SHORT TITLE OF TITLE.**

24 This title may be cited as the “Newborns’ and Moth-
25 ers’ Health Protection Act of 1996”.

1 **SEC. 302. FINDINGS.**

2 Congress finds that—

3 (1) the length of post-delivery inpatient care
4 should be based on the unique characteristics of
5 each mother and her newborn child, taking into con-
6 sideration the health of the mother, the health and
7 stability of the newborn, the ability and confidence
8 of the mother and father to care for the newborn,
9 the adequacy of support systems at home, and the
10 access of the mother and newborn to appropriate fol-
11 low-up health care; and

12 (2) the timing of the discharge of a mother and
13 her newborn child from the hospital should be made
14 by the attending provider in consultation with the
15 mother.

16 **SEC. 303. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
17 **STAY FOLLOWING BIRTH.**

18 (a) IN GENERAL.—Except as provided in subsection
19 (b), a health plan or an employee health benefit plan that
20 provides maternity benefits, including benefits for child-
21 birth, shall ensure that coverage is provided with respect
22 to a mother who is a participant, beneficiary, or policy-
23 holder under such plan and her newborn child for a mini-
24 mum of 48 hours of inpatient length of stay following a
25 normal vaginal delivery, and a minimum of 96 hours of
26 inpatient length of stay following a caesarean section,

1 without requiring the attending provider to obtain author-
2 ization from the health plan or employee health benefit
3 plan.

4 (b) EXCEPTION.—Notwithstanding subsection (a), a
5 health plan or an employee health benefit plan shall not
6 be required to provide coverage for post-delivery inpatient
7 length of stay for a mother who is a participant, bene-
8 ficiary, or policyholder under such plan and her newborn
9 child for the period referred to in subsection (a) if—

10 (1) a decision to discharge the mother and her
11 newborn child prior to the expiration of such period
12 is made by the attending provider in consultation
13 with the mother; and

14 (2) the health plan or employee health benefit
15 plan provides coverage for post-delivery follow-up
16 care as described in section 304.

17 **SEC. 304. POST-DELIVERY FOLLOW-UP CARE.**

18 (a) IN GENERAL.—

19 (1) GENERAL RULE.—In the case of a decision
20 to discharge a mother and her newborn child from
21 the inpatient setting prior to the expiration of 48
22 hours following a normal vaginal delivery or 96
23 hours following a caesarean section, the health plan
24 or employee health benefit plan shall provide cov-
25 erage for timely post-delivery care. Such health care

1 shall be provided to a mother and her newborn child
2 by a registered nurse, physician, nurse practitioner,
3 nurse midwife or physician assistant experienced in
4 maternal and child health in—

5 (A) the home, a provider’s office, a hos-
6 pital, a birthing center, an intermediate care fa-
7 cility, a federally qualified health center, a fed-
8 erally qualified rural health clinic, or a State
9 health department maternity clinic; or

10 (B) another setting determined appropriate
11 under regulations promulgated by the Sec-
12 retary, in consultation with the Secretary of
13 Health and Human Services;

14 except that such coverage shall ensure that the
15 mother has the option to be provided with such care
16 in the home.

17 (2) CONSIDERATIONS BY SECRETARY.—In pro-
18 mulgating regulations under paragraph (1)(B), the
19 Secretary shall consider telemedicine and other inno-
20 vative means to provide follow-up care and shall con-
21 sider care in both urban and rural settings.

22 (b) TIMELY CARE.—As used in subsection (a), the
23 term “timely post-delivery care” means health care that
24 is provided—

1 (1) following the discharge of a mother and her
2 newborn child from the inpatient setting; and

3 (2) in a manner that meets the health care
4 needs of the mother and her newborn child, that
5 provides for the appropriate monitoring of the condi-
6 tions of the mother and child, and that occurs not
7 later than the 72-hour period immediately following
8 discharge.

9 (c) CONSISTENCY WITH STATE LAW.—The Secretary
10 shall, with respect to regulations promulgated under sub-
11 section (a) concerning appropriate post-delivery care set-
12 tings, ensure that, to the extent practicable, such regula-
13 tions are consistent with State licensing and practice laws.

14 **SEC. 305. PROHIBITIONS.**

15 In implementing the requirements of this title, a
16 health plan or an employee health benefit plan may not—

17 (1) deny enrollment, renewal, or continued cov-
18 erage to a mother and her newborn child who are
19 participants, beneficiaries or policyholders based on
20 compliance with this title;

21 (2) provide monetary payments or rebates to
22 mothers to encourage such mothers to request less
23 than the minimum coverage required under this
24 title;

1 (3) penalize or otherwise reduce or limit the re-
2 imbursement of an attending provider because such
3 provider provided treatment in accordance with this
4 title; or

5 (4) provide incentives (monetary or otherwise)
6 to an attending provider to induce such provider to
7 provide treatment to an individual policyholder, par-
8 ticipant, or beneficiary in a manner inconsistent with
9 this title.

10 **SEC. 306. NOTICE.**

11 (a) **EMPLOYEE HEALTH BENEFIT PLAN.**—An em-
12 ployee health benefit plan shall provide conspicuous notice
13 to each participant regarding coverage required under this
14 title not later than 120 days after the date of enactment
15 of this Act, and as part of its summary plan description.

16 (b) **HEALTH PLAN.**—A health plan shall provide no-
17 tice to each policyholder regarding coverage required
18 under this title. Such notice shall be in writing, promi-
19 nently positioned, and be transmitted—

20 (1) in a mailing made within 120 days of the
21 date of enactment of this Act by such plan to the
22 policyholder; and

23 (2) as part of the annual informational packet
24 sent to the policyholder.

1 **SEC. 307. APPLICABILITY.**

2 (a) CONSTRUCTION.—

3 (1) IN GENERAL.—A requirement or standard
4 imposed under this title on a health plan shall be
5 deemed to be a requirement or standard imposed on
6 the health plan issuer. Such requirements or stand-
7 ards shall be enforced by the State insurance com-
8 missioner for the State involved or the official or of-
9 ficials designated by the State to enforce the re-
10 quirements of this title. In the case of a health plan
11 offered by a health plan issuer in connection with an
12 employee health benefit plan, the requirements or
13 standards imposed under this title shall be enforced
14 with respect to the health plan issuer by the State
15 insurance commissioner for the State involved or the
16 official or officials designated by the State to enforce
17 the requirements of this title.

18 (2) LIMITATION.—Except as provided in section
19 308(c), the Secretary shall not enforce the require-
20 ments or standards of this title as they relate to
21 health plan issuers or health plans. In no case shall
22 a State enforce the requirements or standards of
23 this title as they relate to employee health benefit
24 plans.

25 (b) RULE OF CONSTRUCTION.—Nothing in this title
26 shall be construed to affect or modify the provisions of

1 section 514 of the Employee Retirement Income Security
2 Act of 1974 (29 U.S.C. 1144).

3 (c) RULE OF CONSTRUCTION.—Nothing in this title
4 shall be construed to require that a mother who is a par-
5 ticipant, beneficiary, or policyholder covered under this
6 title—

7 (1) give birth in a hospital; or

8 (2) stay in the hospital for a fixed period of
9 time following the birth of her child.

10 **SEC. 308. ENFORCEMENT.**

11 (a) HEALTH PLAN ISSUERS.—Each State shall re-
12 quire that each health plan issued, sold, renewed, offered
13 for sale or operated in such State by a health plan issuer
14 meet the standards established under this title. A State
15 shall submit such information as required by the Secretary
16 demonstrating effective implementation of the require-
17 ments of this title.

18 (b) EMPLOYEE HEALTH BENEFIT PLANS.—With re-
19 spect to employee health benefit plans, the standards es-
20 tablished under this title shall be enforced in the same
21 manner as provided for under sections 502, 504, 506, and
22 510 of the Employee Retirement Income Security Act of
23 1974 (29 U.S.C. 1132, 1134, 1136, and 1140). The civil
24 penalties contained in paragraphs (1) and (2) of section
25 502(c) of such Act (29 U.S.C. 1132(c) (1) and (2)) shall

1 apply to any information required by the Secretary to be
2 disclosed and reported under this section.

3 (c) FAILURE TO ENFORCE.—In the case of the fail-
4 ure of a State to substantially enforce the standards and
5 requirements set forth in this title with respect to health
6 plans, the Secretary, in consultation with the Secretary
7 of Health and Human Services, shall enforce the stand-
8 ards of this title in such State. In the case of a State
9 that fails to substantially enforce the standards set forth
10 in this title, each health plan issuer operating in such
11 State shall be subject to civil enforcement as provided for
12 under sections 502, 504, 506, and 510 of the Employee
13 Retirement Income Security Act of 1974 (29 U.S.C. 1132,
14 1134, 1136, and 1140). The civil penalties contained in
15 paragraphs (1) and (2) of section 502(c) of such Act (29
16 U.S.C. 1132(c) (1) and (2)) shall apply to any information
17 required by the Secretary to be disclosed and reported
18 under this section.

19 (d) REGULATIONS.—The Secretary, in consultation
20 with the Secretary of Health and Human Services, may
21 promulgate such regulations as may be necessary or ap-
22 propriate to carry out this title.

23 **SEC. 309. DEFINITIONS.**

24 As used in this title:

1 (1) ATTENDING PROVIDER.—The term “attend-
2 ing provider” shall include—

3 (A) the obstetrician-gynecologists, pediatri-
4 cians, family physicians, and other physicians
5 primarily responsible for the care of a mother
6 and newborn; and

7 (B) the nurse midwives and nurse practi-
8 tioners primarily responsible for the care of a
9 mother and her newborn child in accordance
10 with State licensure and certification laws.

11 (2) BENEFICIARY.—The term “beneficiary” has
12 the meaning given such term under section 3(8) of
13 the Employee Retirement Income Security Act of
14 1974 (29 U.S.C. 1002(8)).

15 (3) EMPLOYEE HEALTH BENEFIT PLAN.—

16 (A) IN GENERAL.—The term “employee
17 health benefit plan” means any employee wel-
18 fare benefit plan, governmental plan, or church
19 plan (as defined under paragraphs (1), (32),
20 and (33) of section 3 of the Employee Retire-
21 ment Income Security Act of 1974 (29 U.S.C.
22 1002 (1), (32), and (33))) that provides or pays
23 for health benefits (such as provider and hos-
24 pital benefits) for participants and beneficiaries
25 whether—

- 1 (i) directly;
- 2 (ii) through a health plan offered by
- 3 a health plan issuer as defined in para-
- 4 graph (4); or
- 5 (iii) otherwise.

6 (B) RULE OF CONSTRUCTION.—An em-

7 ployee health benefit plan shall not be con-

8 strued to be a health plan or a health plan is-

9 suer.

10 (C) ARRANGEMENTS NOT INCLUDED.—

11 Such term does not include the following, or

12 any combination thereof:

13 (i) Coverage only for accident, or dis-

14 ability income insurance, or any combina-

15 tion thereof.

16 (ii) Medicare supplemental health in-

17 surance (as defined under section

18 1882(g)(1) of the Social Security Act).

19 (iii) Coverage issued as a supplement

20 to liability insurance.

21 (iv) Liability insurance, including gen-

22 eral liability insurance and automobile li-

23 ability insurance.

24 (v) Workers compensation or similar

25 insurance.

1 (vi) Automobile medical payment in-
2 surance.

3 (vii) Coverage for a specified disease
4 or illness.

5 (viii) Hospital or fixed indemnity in-
6 surance.

7 (ix) Short-term limited duration in-
8 surance.

9 (x) Credit-only, dental-only, or vision-
10 only insurance.

11 (xi) A health insurance policy provid-
12 ing benefits only for long-term care, nurs-
13 ing home care, home health care, commu-
14 nity-based care, or any combination there-
15 of.

16 (4) GROUP PURCHASER.—The term “group
17 purchaser” means any person (as defined under
18 paragraph (9) of section 3 of the Employee Retirement
19 Income Security Act of 1974 (29 U.S.C.
20 1002(9)) or entity that purchases or pays for health
21 benefits (such as provider or hospital benefits) on
22 behalf of participants or beneficiaries in connection
23 with an employee health benefit plan.

24 (5) HEALTH PLAN.—

1 (A) IN GENERAL.—The term “health plan”
2 means any group health plan or individual
3 health plan.

4 (B) GROUP HEALTH PLAN.—The term
5 “group health plan” means any contract, policy,
6 certificate or other arrangement offered by a
7 health plan issuer to a group purchaser that
8 provides or pays for health benefits (such as
9 provider and hospital benefits) in connection
10 with an employee health benefit plan.

11 (C) INDIVIDUAL HEALTH PLAN.—The term
12 “individual health plan” means any contract,
13 policy, certificate or other arrangement offered
14 to individuals by a health plan issuer that pro-
15 vides or pays for health benefits (such as pro-
16 vider and hospital benefits) and that is not a
17 group health plan.

18 (D) ARRANGEMENTS NOT INCLUDED.—
19 Such term does not include the following, or
20 any combination thereof:

21 (i) Coverage only for accident, or dis-
22 ability income insurance, or any combina-
23 tion thereof.

- 1 (ii) Medicare supplemental health in-
2 surance (as defined under section
3 1882(g)(1) of the Social Security Act).
- 4 (iii) Coverage issued as a supplement
5 to liability insurance.
- 6 (iv) Liability insurance, including gen-
7 eral liability insurance and automobile li-
8 ability insurance.
- 9 (v) Workers compensation or similar
10 insurance.
- 11 (vi) Automobile medical payment in-
12 surance.
- 13 (vii) Coverage for a specified disease
14 or illness.
- 15 (viii) Hospital or fixed indemnity in-
16 surance.
- 17 (ix) Short-term limited duration in-
18 surance.
- 19 (x) Credit-only, dental-only, or vision-
20 only insurance.
- 21 (xi) A health insurance policy provid-
22 ing benefits only for long-term care, nurs-
23 ing home care, home health care, commu-
24 nity-based care, or any combination there-
25 of.

1 (E) CERTAIN PLANS INCLUDED.—Such
2 term includes any plan or arrangement not de-
3 scribed in any clause of subparagraph (D)
4 which provides for benefit payments, on a peri-
5 odic basis, for—

6 (i) a specified disease or illness, or
7 (ii) a period of hospitalization,
8 without regard to the costs incurred or services
9 rendered during the period to which the pay-
10 ments relate.

11 (6) HEALTH PLAN ISSUER.—The term “health
12 plan issuer” means any entity that is licensed (prior
13 to or after the date of enactment of this Act) by a
14 State to offer a health plan.

15 (7) PARTICIPANT.—The term “participant” has
16 the meaning given such term under section 3(7) of
17 the Employee Retirement Income Security Act of
18 1974 (29 U.S.C. 1002(7)).

19 (8) SECRETARY.—The term “Secretary” unless
20 otherwise specified means the Secretary of Labor.

21 **SEC. 310. PREEMPTION.**

22 (a) IN GENERAL.—The provisions of sections 3, 5,
23 and 6 relating to inpatient care shall not preempt a State
24 law or regulation—

1 (1) that provides greater protections to patients
2 or policyholders than those required in this title;

3 (2) that requires health plans to provide cov-
4 erage for at least 48 hours of inpatient length of
5 stay following a normal vaginal delivery, and at least
6 96 hours of inpatient length of stay following a cae-
7 sarean section;

8 (3) that requires health plans to provide cov-
9 erage for maternity and pediatric care in accordance
10 with guidelines established by the American College
11 of Obstetricians and Gynecologists, the American
12 Academy of Pediatrics, or other established profes-
13 sional medical associations; or

14 (4) that leaves decisions regarding appropriate
15 length of stay entirely to the attending provider, in
16 consultation with the mother.

17 (b) FOLLOW-UP CARE.—The provisions of section
18 304 relating to follow-up care shall not preempt those pro-
19 visions of State law or regulation that provide greater pro-
20 tection to patients or policyholders than those required
21 under this title or that provide mothers and newborns with
22 an option of timely post delivery follow-up care (as defined
23 in section 304(b)) in the home.

1 (c) EMPLOYEE HEALTH BENEFIT PLANS.—Nothing
2 in this section affects the application of this title to em-
3 ployee health benefit plans, as defined in section 309(3).

4 **SEC. 311. REPORTS TO CONGRESS CONCERNING CHILD-**
5 **BIRTH.**

6 (a) FINDINGS.—Congress finds that—

7 (1) childbirth is one part of a continuum of ex-
8 perience that includes prepregnancy, pregnancy and
9 prenatal care, labor and delivery, the immediate
10 postpartum period, and a longer period of adjust-
11 ment for the newborn, the mother, and the family;

12 (2) health care practices across this continuum
13 are changing in response to health care financing
14 and delivery system changes, science and clinical re-
15 search, and patient preferences; and

16 (3) there is a need to—

17 (A) examine the issues and consequences
18 associated with the length of hospital stays fol-
19 lowing childbirth;

20 (B) examine the follow-up practices for
21 mothers and newborns used in conjunction with
22 shorter hospital stays;

23 (C) identify appropriate health care prac-
24 tices and procedures with regard to the hospital
25 discharge of newborns and mothers;

1 (D) examine the extent to which such care
2 is affected by family and environmental factors;
3 and

4 (E) examine the content of care during
5 hospital stays following childbirth.

6 (b) ADVISORY PANEL.—

7 (1) IN GENERAL.—Not later than 90 days after
8 the date of enactment of this Act, the Secretary of
9 Health and Human Services shall establish an advisory
10 panel (hereafter referred to in this section as
11 the “advisory panel”) to—

12 (A) guide and review methods, procedures,
13 and data collection necessary to conduct the
14 study described in subsection (c) that is intended
15 to enhance the quality, safety, and effectiveness
16 of health care services provided to
17 mothers and newborns;

18 (B) develop a consensus among the members
19 of the advisory panel regarding the appropriateness
20 of the specific requirements of this
21 title; and

22 (C) prepare and submit to the Secretary of
23 Health and Human Services, as part of the report
24 of the Secretary submitted under subsection
25 (d), a report summarizing the consensus

1 developed under subparagraph (B) if any, in-
2 cluding the reasons for not reaching such a con-
3 sensus.

4 (2) PARTICIPATION.—

5 (A) DEPARTMENT REPRESENTATIVES.—

6 The Secretary of Health and Human Services
7 shall ensure that representatives from within
8 the Department of Health and Human Services
9 that have expertise in the area of maternal and
10 child health or in outcomes research are ap-
11 pointed to the advisory panel established under
12 paragraph (1).

13 (B) REPRESENTATIVES OF PUBLIC AND
14 PRIVATE SECTOR ENTITIES.—

15 (i) IN GENERAL.—The Secretary of
16 Health and Human Services shall ensure
17 that members of the advisory panel include
18 representatives of public and private sector
19 entities having knowledge or experience in
20 one or more of the following areas:

21 (I) Patient care.

22 (II) Patient education.

23 (III) Quality assurance.

24 (IV) Outcomes research.

25 (V) Consumer issues.

1 (ii) REQUIREMENT.—The panel shall
2 include representatives from each of the
3 following categories:

4 (I) Health care practitioners.

5 (II) Health plans.

6 (III) Hospitals.

7 (IV) Employers.

8 (V) States.

9 (VI) Consumers.

10 (c) STUDIES.—

11 (1) IN GENERAL.—The Secretary of Health and
12 Human Services shall conduct a study of—

13 (A) the factors affecting the continuum of
14 care with respect to maternal and child health
15 care, including outcomes following childbirth;

16 (B) the factors determining the length of
17 hospital stay following childbirth;

18 (C) the diversity of negative or positive
19 outcomes affecting mothers, infants, and fami-
20 lies;

21 (D) the manner in which post natal care
22 has changed over time and the manner in which
23 that care has adapted or related to changes in
24 the length of hospital stay, taking into ac-
25 count—

1 (i) the types of post natal care avail-
2 able and the extent to which such care is
3 accessed; and

4 (ii) the challenges associated with pro-
5 viding post natal care to all populations,
6 including vulnerable populations, and solu-
7 tions for overcoming these challenges; and
8 (E) the financial incentives that may—

9 (i) impact the health of newborns and
10 mothers; and

11 (ii) influence the clinical decisionmak-
12 ing of health care providers.

13 (2) RESOURCES.—The Secretary of Health and
14 Human Services shall provide to the advisory panel
15 the resources necessary to carry out the duties of
16 the advisory panel.

17 (d) REPORTS.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services shall prepare and submit to the
20 Committee on Labor and Human Resources of the
21 Senate and the Committee on Commerce of the
22 House of Representatives a report that contains—

23 (A) a summary of the study conducted
24 under subsection (c);

1 (B) a summary of the best practices used
2 in the public and private sectors for the care of
3 newborns and mothers;

4 (C) recommendations for improvements in
5 prenatal care, post natal care, delivery and fol-
6 low-up care, and whether the implementation of
7 such improvements should be accomplished by
8 the private health care sector, Federal or State
9 governments, or any combination thereof; and

10 (D) limitations on the databases in exist-
11 ence on the date of enactment of this Act.

12 (2) SUBMISSION OF REPORTS.—The Secretary
13 of Health and Human Services shall prepare and
14 submit to the Committees referred to in paragraph
15 (1)—

16 (A) an initial report concerning the study
17 conducted under subsection (c) and the report
18 required under subsection (d), not later than 18
19 months after the date of enactment of this Act;

20 (B) an interim report concerning such
21 study and report not later than 3 years after
22 the date of enactment of this Act; and

23 (C) a final report concerning such study
24 and report not later than 5 years after the date
25 of enactment of this Act.

1 (e) TERMINATION OF PANEL.—The advisory panel
2 shall terminate on the date that occurs 60 days after the
3 date on which the last report is submitted under this sec-
4 tion.

5 **SEC. 312. EFFECTIVE DATE.**

6 Except as otherwise provided for in this title, the pro-
7 visions of this title shall apply as follows:

8 (1) With respect to health plans, such provi-
9 sions shall apply to such plans on the first day of
10 the contract year beginning on or after January 1,
11 1997.

12 (2) With respect to employee health benefit
13 plans, such provisions shall apply to such plans on
14 the first day of the first plan year beginning on or
15 after January 1, 1997.

16 **TITLE IV—ULTRASOUND**

17 **SEC. 401. SHORT TITLE.**

18 This title may be cited as the “Ultrasound Quality
19 Standards Act of 1996”.

20 **SEC. 402. CERTIFICATION OF ULTRASOUND FACILITIES.**

21 Part F of title III of the Public Health Service Act
22 (42 U.S.C. 262 et seq.) is amended by adding at the end
23 the following new subpart:

1 “Subpart 4—Ultrasonography Facilities

2 **“SEC. 355. CERTIFICATION OF ULTRASOUND FACILITIES.**

3 “(a) DEFINITIONS.—As used in this section:

4 “(1) ACCREDITATION BODY.—The term ‘ac-
5 creditation body’ means a body that has been ap-
6 proved by the Secretary under subsection (e)(1)(A)
7 to accredit ultrasound facilities.

8 “(2) CERTIFICATE.—The term ‘certificate’
9 means the certificate described in subsection (b)(1).

10 “(3) FACILITY.—

11 “(A) IN GENERAL.—The term ‘facility’
12 means a hospital, outpatient department, clinic,
13 radiology practice, or mobile unit, an office of
14 a physician, or other facility as determined by
15 the Secretary, that conducts fetal ultrasound
16 activities screening.

17 “(B) ACTIVITIES.—For the purposes of
18 this section, the activities of a facility include
19 the operation of ultrasound equipment, the in-
20 terpretation of the ultrasound, and any produc-
21 tion of a permanent record of such
22 ultrasonography, including videotapes.

23 “(4) INSPECTION.—The term ‘inspection’
24 means an onsite evaluation of the facility by the Sec-
25 retary or State agency on behalf of the Secretary.

1 “(5) FETAL ULTRASOUND.—The term ‘fetal
2 ultrasound’ means ultrasonography performed on a
3 pregnant woman for purposes of viewing the fetus.

4 “(b) CERTIFICATE REQUIREMENT.—

5 “(1) CERTIFICATE.—No facility may conduct
6 an examination or procedure described in paragraph
7 (2) involving ultrasonography after October 1, 1997,
8 unless the facility obtains—

9 “(A) a certificate—

10 “(i) that is issued, and, if applicable,
11 renewed, by the Secretary in accordance
12 with subsection (c)(1);

13 “(ii) that is applicable to the examina-
14 tion or procedure to be conducted; and

15 “(iii) that is displayed prominently in
16 such facility; or

17 “(B) a provisional certificate—

18 “(i) that is issued by the Secretary in
19 accordance with subsection (c)(2);

20 “(ii) that is applicable to the examina-
21 tion or procedure to be conducted; and

22 “(iii) that is displayed prominently in
23 such facility.

24 The reference to a certificate in this section includes
25 a provisional certificate.

1 “(2) EXAMINATION OR PROCEDURE.—A facility
2 shall obtain a certificate in order to—

3 “(A) operate ultrasound equipment that is
4 used to image the fetus;

5 “(B) provide for the interpretation of a
6 fetal ultrasound examination produced by such
7 equipment at the facility; and

8 “(C) provide for the processing of film or
9 videotape of the ultrasound images produced.

10 “(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

11 “(1) IN GENERAL.—The Secretary may issue or
12 renew a certificate for a facility if the person or
13 agent described in subsection (d)(1)(A) meets the
14 applicable requirements of subsection (d)(1) with re-
15 spect to the facility. The Secretary may issue or
16 renew a certificate under this paragraph for not
17 more than 3 years.

18 “(2) PROVISIONAL CERTIFICATE.—The Sec-
19 retary may issue a provisional certificate for an en-
20 tity to enable the entity to qualify as a facility. The
21 applicant for a provisional certificate shall meet the
22 requirements of subsection (d)(1), except providing
23 information required by clause (iii) of subsection
24 (d)(1)(A). A provisional certificate may be in effect
25 no longer than 6 months from the date it is issued,

1 except that it may be extended once for a period of
2 not more than 90 days if the owner, lessor, or agent
3 of the facility demonstrates to the Secretary that
4 without such extension access to medically necessary
5 fetal ultrasonography in the geographic area served
6 by the facility would be significantly reduced and if
7 the owner, lessor, or agent of the facility will de-
8 scribe in a report to the Secretary steps that will be
9 taken to qualify the facility for certification under
10 subsection (b)(1).

11 “(d) APPLICATION FOR CERTIFICATE.—

12 “(1) SUBMISSION.—The Secretary may issue or
13 renew a certificate for a facility if—

14 “(A) the person who owns or leases the fa-
15 cility or an authorized agent of the person, sub-
16 mits to the Secretary, in such form and manner
17 as the Secretary shall prescribe, an application
18 that contains at a minimum—

19 “(i) a description of the manufac-
20 turer, model, and type of each instrument
21 used in the performance of fetal
22 ultrasonography by the facility;

23 “(ii) a description of the procedures
24 currently used to provide fetal
25 ultrasonography at the facility, including—

1 “(I) the types of procedures per-
2 formed and the number of such proce-
3 dures performed in the prior 12
4 months; and

5 “(II) the names and qualifica-
6 tions (educational background, train-
7 ing, and experience) of the personnel
8 performing fetal ultrasonography and
9 interpreting the ultrasound images;

10 “(iii) proof of accreditation in such
11 manner as the Secretary shall prescribe;
12 and

13 “(B) the person or agent submits to the
14 Secretary—

15 “(i) a satisfactory assurance that the
16 facility will be operated in accordance with
17 standards established by the Secretary
18 under subsection (f) to assure the safety,
19 accuracy, and medical necessity of the fetal
20 ultrasonography;

21 “(ii) a satisfactory assurance that the
22 facility will—

23 “(I) permit inspections under
24 subsection (g);

1 “(II) make such records and in-
2 formation available, and submit such
3 reports, to the Secretary as the Sec-
4 retary may require; and

5 “(III) update the information
6 submitted under subparagraph (A) or
7 assurances submitted under this sub-
8 paragraph on a timely basis as re-
9 quired by the Secretary; and

10 “(iii) such other information as the
11 Secretary may require.

12 An applicant shall not be required to provide in an
13 application under subparagraph (A) any information
14 which the applicant has supplied to the accreditation
15 body which accredited the applicant, except as re-
16 quired by the Secretary.

17 “(2) APPEAL.—If the Secretary denies an ap-
18 plication for the certification of a facility submitted
19 under paragraph (1)(A), the Secretary shall provide
20 the owner or lessor of the facility or the agent of the
21 owner or lessor who submitted such application—

22 “(A) a statement of the grounds on which
23 the denial is based, and

24 “(B) an opportunity for an appeal in ac-
25 cordance with the procedures set forth in regu-

1 lations of the Secretary published at 42 C.F.R.
2 498 and in effect on the date of the enactment
3 of this section.

4 “(3) EFFECT OF DENIAL.—If the application
5 for the certification of a facility is denied, the facil-
6 ity may not operate unless the denial of the applica-
7 tion is overturned at the conclusion of the adminis-
8 trative appeals process provided in the regulations
9 referred to in paragraph (2)(B).

10 “(e) ACCREDITATION.—

11 “(1) APPROVAL OF ACCREDITATION BODIES.—

12 “(A) IN GENERAL.—The Secretary may
13 approve a private nonprofit organization or
14 State agency to accredit facilities for purposes
15 of subsection (d)(1)(A)(iii) if the accreditation
16 body meets the standards for accreditation es-
17 tablished by the Secretary as described in sub-
18 paragraph (B) and provides the assurances re-
19 quired by subparagraph (C).

20 “(B) STANDARDS.—The Secretary shall
21 establish standards for accreditation bodies, in-
22 cluding—

23 “(i) standards that prohibit individ-
24 uals conducting the reviews from maintain-
25 ing any financial relationship to the facility

1 undergoing review which would constitute
2 a conflict of interest;

3 “(ii) standards that limit the imposi-
4 tion of fees for accreditation to reasonable
5 amounts;

6 “(iii) standards that are equal to
7 standards established under subsection (f)
8 which are relevant to accreditation as de-
9 termined by the Secretary; and

10 “(iv) such additional standards as the
11 Secretary may require.

12 “(C) ASSURANCES.—The accrediting body
13 shall provide the Secretary satisfactory assur-
14 ances that the body will—

15 “(i) comply with the standards as de-
16 scribed in subparagraph (B);

17 “(ii) comply with the requirements de-
18 scribed in paragraph (4);

19 “(iii) submit to the Secretary the
20 name of any facility for which the accredi-
21 tation body denies, suspends, or revokes
22 accreditation;

23 “(iv) notify the Secretary in a timely
24 manner before the accreditation body
25 changes the standards of the body;

1 “(v) notify each facility accredited by
2 the accreditation body if the Secretary
3 withdraws approval of the accreditation
4 body under paragraph (2) in a timely man-
5 ner; and

6 “(vi) provide such other additional in-
7 formation as the Secretary may require.

8 “(D) REGULATIONS.—Not later than 9
9 months after the date of the enactment of this
10 section, the Secretary shall promulgate regula-
11 tions under which the Secretary may approve
12 one or more accreditation bodies.

13 “(2) WITHDRAWAL OF APPROVAL.—

14 “(A) IN GENERAL.—The Secretary shall
15 promulgate regulations under which the Sec-
16 retary may withdraw the approval of an accred-
17 itation body if the Secretary determines that
18 the accreditation body does not meet the stand-
19 ards under subparagraph (B) of paragraph (1),
20 the requirements of clauses (i) through (vi) of
21 subparagraph (C) of paragraph (1), or the re-
22 quirements of paragraph (4).

23 “(B) EFFECT OF WITHDRAWAL.—If the
24 Secretary withdraws the approval of an accredi-
25 tation body under subparagraph (A), the certifi-

1 cate of any facility accredited by the body shall
2 continue in effect until the expiration of a rea-
3 sonable period, as determined by the Secretary,
4 for such facility to obtain another accreditation.

5 “(3) ACCREDITATION.—To be accredited by an
6 approved accreditation body a facility shall meet—

7 “(A) the standards described in paragraph
8 (1)(B) which the Secretary determines are ap-
9 plicable to the facility, and

10 “(B) such other standards which the ac-
11 creditation body may require.

12 “(4) COMPLIANCE.—To ensure that facilities
13 accredited by an accreditation body will continue to
14 meet the standards of the accreditation body, the ac-
15 creditation body shall—

16 “(A) make onsite visits of the facilities ac-
17 credited by the body of a sufficient number and
18 of such frequency to allow a reasonable esti-
19 mate of the performance of the body; and

20 “(B) take such additional measures as the
21 Secretary determines to be appropriate.

22 Visits made under subparagraph (A) shall be made
23 after providing such notice as the Secretary may re-
24 quire.

1 “(5) REVOCATION OF ACCREDITATION.—If an
2 accreditation body revokes the accreditation of a fa-
3 cility, the certificate of the facility shall continue in
4 effect until such time as may be determined by the
5 Secretary.

6 “(6) EVALUATION AND REPORT.—

7 “(A) EVALUATION.—The Secretary shall
8 evaluate the performance of each approved ac-
9 creditation body by—

10 “(i) inspecting under subsection (g)(2)
11 a sufficient number of the facilities accred-
12 ited by the body to allow a reasonable esti-
13 mate of the performance of the body; and

14 “(ii) such additional means as the
15 Secretary determines to be appropriate.

16 “(f) QUALITY STANDARDS.—

17 “(1) IN GENERAL.—The standards referred to
18 in subsection (d)(1)(B)(i) are standards established
19 by the Secretary which include—

20 “(A) standards that require establishment
21 and maintenance of a quality assurance and
22 quality control program at each facility that is
23 adequate and appropriate to ensure the reliabil-
24 ity and accuracy of interpretation of fetal
25 ultrasound;

1 “(B) a requirement that personnel who
2 perform ultrasound—

3 “(i)(I) be licensed by a State to per-
4 form ultrasound procedures; or

5 “(II) be certified as qualified to per-
6 form ultrasound procedures by an organi-
7 zation described in paragraph (2)(A); and

8 “(ii) during the 2-year period begin-
9 ning October 1, 1997, meet training stand-
10 ards for personnel who perform
11 ultrasonography or meet experience re-
12 quirements which shall at a minimum in-
13 clude 1 year of experience in the perform-
14 ance of ultrasonography; and

15 “(iii) upon the expiration of such 2-
16 year period meet minimum training stand-
17 ards for personnel who perform fetal
18 ultrasound;

19 “(C) a requirement that ultrasound images
20 be interpreted by a physician who is certified as
21 qualified to interpret fetal ultrasound and who
22 meets training and continuing medical edu-
23 cation requirements as established by the Sec-
24 retary;

1 “(D) a requirement that fetal
2 ultrasonography be performed only when medi-
3 cally necessary.

4 “(E) a requirement that—

5 “(i) a facility that performs any fetal
6 ultrasound maintain a record of such
7 ultrasound in the permanent medical
8 records of the patient—

9 “(I) for a period of not fewer
10 than 5 years, or longer if mandated
11 by State law; or

12 “(II) until such time as the pa-
13 tient should request that the patient’s
14 medical records be forwarded to a
15 medical institution or a physician of
16 the patient;

17 whichever is longer; and

18 “(ii)(I) a facility must assure the
19 preparation of a written report of the re-
20 sults of any fetal ultrasound examination
21 signed by the interpreting physician;

22 “(II) such written report shall be pro-
23 vided to the patient’s physicians (if any);

24 “(III) if such a physician is not avail-
25 able or if there is no such physician, the

1 written report shall be sent directly to the
2 patient; and

3 “(IV) if such report is sent to the pa-
4 tient, the report shall include a summary
5 written in terms easily understood by a lay
6 person.

7 Subparagraph (E) shall not be construed to limit a
8 patient’s access to the patient’s medical records.

9 “(2) CERTIFICATION OF PERSONNEL.—The
10 Secretary shall by regulation—

11 “(A) specify organizations eligible to cer-
12 tify individuals to perform fetal ultrasound as
13 required by paragraph (1)(B); and

14 “(B) establish standards for a program to
15 certify physicians described in paragraph
16 (1)(C).

17 “(g) INSPECTIONS.—

18 “(1) INSPECTIONS.—

19 “(A) IN GENERAL.—The Secretary may
20 enter and inspect certified facilities to deter-
21 mine compliance with the standards established
22 under subsection (f). The Secretary shall, if fea-
23 sible, delegate to a State agency the authority
24 to make such inspections.

1 “(B) IDENTIFICATION.—The Secretary, or
2 State agency acting on behalf of the Secretary,
3 may conduct inspections only on presenting
4 identification to the owner, operator, or agent
5 in charge of the facility to be inspected.

6 “(C) SCOPE OF INSPECTION.—In conduct-
7 ing inspections, the Secretary or State agency
8 acting on behalf of the Secretary—

9 “(i) shall have access to all equip-
10 ment, materials, records, and information
11 that the Secretary or State agency consid-
12 ers necessary to determine whether the fa-
13 cility is being operated in accordance with
14 this section; and

15 “(ii) may copy, or require the facility
16 to submit to the Secretary or the State
17 agency, any of the materials, records, or
18 information.

19 “(D) QUALIFICATIONS OF INSPECTORS.—
20 Qualified individuals, as determined by the Sec-
21 retary, shall conduct all inspections. The Sec-
22 retary may request that a State agency acting
23 on behalf of the Secretary designate a qualified
24 officer or employee to conduct the inspections,
25 or designate a qualified Federal officer or em-

1 ployee to conduct inspections. The Secretary
2 shall establish minimum qualifications and ap-
3 propriate training for inspectors and criteria
4 for certification of inspectors in order to inspect
5 facilities for compliance with subsection (f).

6 “(E) FREQUENCY.—The Secretary or
7 State agency acting on behalf of the Secretary
8 shall conduct inspections under this paragraph
9 of each facility as frequently as needed to as-
10 sure that facilities are in compliance with this
11 section, but no more frequently than once every
12 2 years.

13 “(F) RECORDS AND ANNUAL REPORTS.—
14 The Secretary or a State agency acting on be-
15 half of the Secretary which is responsible for in-
16 specting ultrasound facilities shall maintain
17 records of inspections required under this para-
18 graph for a period as prescribed by the Sec-
19 retary. Such a State agency shall annually pre-
20 pare and submit to the Secretary a report con-
21 cerning the inspections carried out under this
22 paragraph. Such reports shall include a descrip-
23 tion of the facilities inspected and the results of
24 such inspections.

1 “(2) INSPECTION OF ACCREDITED FACILI-
2 TIES.—The Secretary shall inspect annually a suffi-
3 cient number of the facilities accredited by an ac-
4 creditation body to provide the Secretary with a rea-
5 sonable estimate of the performance of such body.

6 “(3) INSPECTION OF FACILITIES INSPECTED BY
7 STATE AGENCIES.—The Secretary shall inspect an-
8 nually facilities inspected by State agencies acting
9 on behalf of the Secretary to assure a reasonable
10 performance by such State agencies.

11 “(4) TIMING.—The Secretary, or State agency,
12 may conduct inspections under paragraphs (1), (2),
13 and (3), during regular business hours or at a mutu-
14 ally agreeable time and after providing such notice
15 as the Secretary may prescribe, except that the Sec-
16 retary may waive such requirements if the continued
17 performance of ultrasonography at such facility
18 threatens the public health.

19 “(5) LIMITED REINSPECTION.—Nothing in this
20 section limits the authority of the Secretary to con-
21 duct limited reinspections of facilities found not to
22 be in compliance with this section.

23 “(h) SANCTIONS.—

24 “(1) IN GENERAL.—In order to promote vol-
25 untary compliance with this section, the Secretary

1 may, in lieu of taking the actions authorized by sub-
2 section (i), impose one or more of the following sanc-
3 tions:

4 “(A) Directed plans of correction which af-
5 ford a facility an opportunity to correct viola-
6 tions in a timely manner.

7 “(B) Payment for the cost of onsite mon-
8 itoring.

9 “(2) CIVIL MONEY PENALTIES.—The Secretary
10 may assess civil money penalties in an amount not
11 to exceed \$10,000 for—

12 “(A) failure to obtain a certificate as re-
13 quired by subsection (b),

14 “(B) each failure by a facility to substan-
15 tially comply with, or each day on which a facil-
16 ity fails to substantially comply with, the stand-
17 ards established under subsection (f) or the re-
18 quirements described in subclauses (I) through
19 (III) of subsection (d)(1)(B)(ii), and

20 “(C) each violation, or for each aiding and
21 abetting in a violation of, any provision of, or
22 regulation promulgated under, this section by
23 an owner, operator, or any employee of a facil-
24 ity required to have a certificate.

1 “(3) PROCEDURES.—The Secretary shall de-
2 velop and implement procedures with respect to
3 when and how each of the sanctions is to be imposed
4 under paragraphs (1) and (2). Such procedures shall
5 provide for notice to the owner or operator of the fa-
6 cility and a reasonable opportunity for the owner or
7 operator to respond to the proposed sanctions and
8 appropriate procedures for appealing determinations
9 relating to the imposition of sanctions.

10 “(i) SUSPENSION AND REVOCATION.—

11 “(1) IN GENERAL.—The certificate of a facility
12 issued under subsection (c) may be suspended or re-
13 voked if the Secretary finds, after providing, except
14 as provided in paragraph (2), reasonable notice and
15 an opportunity for a hearing to the owner or opera-
16 tor of the facility, that the owner, operator, or any
17 employee of the facility—

18 “(A) has been guilty of misrepresentation
19 in obtaining the certificate;

20 “(B) has failed to comply with the require-
21 ments of subsection (d)(1)(B)(ii)(III) or the
22 standards established by the Secretary under
23 subsection (f);

24 “(C) has failed to comply with reasonable
25 requests of the Secretary for any record, infor-

1 mation, report, or material that the Secretary
2 concludes is necessary to determine the contin-
3 ued eligibility of the facility for a certificate or
4 continued compliance with the standards estab-
5 lished under subsection (f);

6 “(D) has refused a reasonable request of
7 the Secretary, any Federal officer or employee
8 duly designated by the Secretary, or any State
9 officer or employee duly designated by the
10 State, for permission to inspect the facility or
11 the operations and pertinent records of the fa-
12 cility in accordance with subsection (g);

13 “(E) has violated or aided and abetted in
14 the violation of any provision of, or regulation
15 promulgated under, this section; or

16 “(F) has failed to comply with a sanction
17 imposed under subsection (h).

18 “(2) ACTION BEFORE A HEARING.—

19 “(A) IN GENERAL.—The Secretary may
20 suspend the certificate of the facility before
21 holding a hearing required by paragraph (1) if
22 the Secretary makes the finding described in
23 paragraph (1) and determines that—

24 “(i) the failure of a facility to comply
25 with the standards established by the Sec-

1 retary under subsection (f) presents a seri-
2 ous risk to human health; or

3 “(ii) a facility has engaged in an ac-
4 tion described in subparagraph (D) or (E)
5 of paragraph (1).

6 “(B) HEARING.—If the Secretary suspends
7 a certificate under subparagraph (A), the Sec-
8 retary shall provide an opportunity for a hear-
9 ing to the owner or operator of the facility not
10 later than 60 days from the effective date of the
11 suspension. The suspension shall remain in ef-
12 fect until the decision of the Secretary made
13 after the hearing.

14 “(3) INELIGIBILITY TO OWN OR OPERATE FA-
15 CILITIES AFTER REVOCATION.—If the Secretary re-
16 vokes the certificate of a facility on the basis of an
17 act described in paragraph (1), no person who
18 owned or operated the facility at the time of the act
19 may, within 2 years of the revocation of the certifi-
20 cate, own or operate a facility that requires a cer-
21 tificate under this section.

22 “(j) INJUNCTIONS.—If the Secretary determines
23 that—

24 “(1) continuation of any activity related to the
25 provision of fetal ultrasonography by a facility would

1 constitute a serious risk to human health, the Sec-
2 retary may bring suit in the district court of the
3 United States for the district in which the facility
4 is situated to enjoin continuation of the activity; and

5 “(2) a facility is operating without a certificate
6 as required by subsection (b), the Secretary may
7 bring suit in the district court of the United States
8 for the district in which the facility is situated to en-
9 join the operation of the facility.

10 Upon a proper showing, the district court shall grant a
11 temporary injunction or restraining order against continu-
12 ation of the activity or against operation of a facility, as
13 the case may be, without requiring the Secretary to post
14 a bond, pending issuance of a final order under this sub-
15 section.

16 “(k) JUDICIAL REVIEW.—

17 “(1) PETITION.—If the Secretary imposes a
18 sanction on a facility under subsection (h) or sus-
19 pends or revokes the certificate of a facility under
20 subsection (i), the owner or operator of the facility
21 may, not later than 60 days after the date the action
22 of the Secretary becomes final, file a petition with
23 the United States court of appeals for the circuit in
24 which the facility is situated for judicial review of
25 the action. As soon as practicable after receipt of the

1 petition, the clerk of the court shall transmit a copy
2 of the petition to the Secretary or other officer des-
3 ignated by the Secretary. As soon as practicable
4 after receipt of the copy, the Secretary shall file in
5 the court the record on which the action of the Sec-
6 retary is based, as provided in section 2112 of title
7 28, United States Code.

8 “(2) ADDITIONAL EVIDENCE.—If the petitioner
9 applies to the court for leave to adduce additional
10 evidence, and shows to the satisfaction of the court
11 that the additional evidence is material and that
12 there were reasonable grounds for the failure to ad-
13 duce such evidence in the proceeding before the Sec-
14 retary, the court may order the additional evidence
15 (and evidence in rebuttal of the additional evidence)
16 to be taken before the Secretary, and to be adduced
17 upon the hearing in such manner and upon such
18 terms and conditions as the court may determine to
19 be proper. The Secretary may modify the findings of
20 the Secretary as to the facts, or make new findings,
21 by reason of the additional evidence so taken, and
22 the Secretary shall file the modified or new findings,
23 and the recommendations of the Secretary, if any,
24 for the modification or setting aside of the original

1 action of the Secretary with the return of the addi-
2 tional evidence.

3 “(3) JUDGMENT OF COURT.—Upon the filing of
4 the petition referred to in paragraph (1), the court
5 shall have jurisdiction to affirm the action, or to set
6 the action aside in whole or in part, temporarily or
7 permanently. The findings of the Secretary as to the
8 facts, if supported by substantial evidence, shall be
9 conclusive.

10 “(4) FINALITY OF JUDGMENT.—The judgment
11 of the court affirming or setting aside, in whole or
12 in part, any action of the Secretary shall be final,
13 subject to review by the Supreme Court of the Unit-
14 ed States upon certiorari or certification, as provided
15 in section 1254 of title 28, United States Code.

16 “(1) INFORMATION.—

17 “(1) IN GENERAL.—Not later than October 1,
18 1999, and annually thereafter, the Secretary shall
19 compile and make available to physicians and the
20 general public information that the Secretary deter-
21 mines is useful in evaluating the performance of fa-
22 cilities, including a list of facilities—

23 “(A) that have been convicted under Fed-
24 eral or State laws relating to fraud and
25 abuse, false billings, or kickbacks;

1 “(B) that have been subject to sanctions
2 under subsection (h), together with a statement
3 of the reasons for the sanctions;

4 “(C) that have had certificates revoked or
5 suspended under subsection (i), together with a
6 statement of the reasons for the revocation or
7 suspension;

8 “(D) against which the Secretary has
9 taken action under subsection (j), together with
10 a statement of the reasons for the action;

11 “(E) whose accreditation has been revoked,
12 together with a statement of the reasons of the
13 revocation;

14 “(F) against which a State has taken ad-
15 verse action; and

16 “(G) that meet such other measures of
17 performance as the Secretary may develop.

18 “(2) DATE.—The information to be compiled
19 under paragraph (1) shall be information for the cal-
20 endar year preceding the date the information is to
21 be made available to the public.

22 “(3) EXPLANATORY INFORMATION.—The infor-
23 mation to be compiled under paragraph (1) shall be
24 accompanied by such explanatory information as

1 may be appropriate to assist in the interpretation of
2 the information compiled under such paragraph.

3 “(m) STATE LAWS.—Nothing in this section shall be
4 construed to limit the authority of any State to enact and
5 enforce laws relating to the matters covered by this section
6 that are at least as stringent as this section or the regula-
7 tions issued under this section.

8 “(n) CONSULTATIONS.—In carrying out this section,
9 the Secretary shall consult with appropriate Federal agen-
10 cies within the Department of Health and Human Services
11 for the purposes of developing standards, regulations,
12 evaluations, and procedures for compliance and oversight.

13 “(o) STATE PROGRAM.—

14 “(1) IN GENERAL.—The Secretary may, upon
15 application, authorize a State—

16 “(A) to carry out, subject to paragraph
17 (2), the certification program requirements
18 under subsections (b), (c), (d), (g)(1), (h), (i),
19 and (j) (including the requirements under regu-
20 lations promulgated pursuant to such sub-
21 sections), and

22 “(B) to implement the standards estab-
23 lished by the Secretary under subsection (f),
24 with respect to ultrasound facilities operating within
25 the State.

1 “(2) APPROVAL.— The Secretary may approve
2 an application under paragraph (1) if the Secretary
3 determines that—

4 “(A) the State has enacted laws and issued
5 regulations relating to ultrasound facilities
6 which are the requirements of this section (in-
7 cluding the requirements under regulations pro-
8 mulgated pursuant to such subsections), and

9 “(B) the State has provided satisfactory
10 assurances that the State—

11 “(i) has the legal authority and quali-
12 fied personnel necessary to enforce the re-
13 quirements of and the regulations promul-
14 gated pursuant to this section (including
15 the requirements under regulations pro-
16 mulgated pursuant to such subsections),

17 “(ii) will devote adequate funds to the
18 administration and enforcement of such re-
19 quirements, and

20 “(iii) will provide the Secretary with
21 such information and reports as the Sec-
22 retary may require.

23 “(3) AUTHORITY OF STATE.—In a State with
24 an approved application—

1 “(A) the State shall carry out the Sec-
2 retary’s functions under subsections (e) and (f);

3 “(B) the State may take action under sub-
4 sections (h), (i), and (j); and

5 “(C) the State shall conduct oversight
6 functions under subsections (g)(2) and (g)(3).

7 “(4) WITHDRAWAL OF APPROVAL.—

8 “(A) IN GENERAL.—The Secretary may,
9 after providing notice and opportunity for cor-
10 rective action, withdraw the approval of a
11 State’s authority under paragraph (1) if the
12 Secretary determines that the State does not
13 meet the requirements of such paragraph. The
14 Secretary shall promulgate regulations for the
15 implementation of this subparagraph.

16 “(B) EFFECT OF WITHDRAWAL.—If the
17 Secretary withdraws the approval of a State
18 under subparagraph (A), the certificate of any
19 facility accredited by the State shall continue in
20 effect until the expiration of a reasonable pe-
21 riod, as determined by the Secretary, for such
22 facility to obtain certification by the Secretary.

23 “(p) FUNDING.—

24 “(1) FEES.—

1 “(A) IN GENERAL.—The Secretary shall,
2 in accordance with this paragraph assess and
3 collect fees from persons described in subsection
4 (d)(1)(A) (other than persons who are govern-
5 mental entities, as determined by the Secretary)
6 to cover the costs of inspections conducted
7 under subsection (g)(1) by the Secretary or a
8 State acting under a delegation under subpara-
9 graph (A) of such subsection. Fees may be as-
10 sessed and collected under this paragraph only
11 in such manner as would result in an aggregate
12 amount of fees collected during any fiscal year
13 which equals the aggregate amount of costs for
14 such fiscal year for inspections of facilities of
15 such persons under subsection (g)(1). A per-
16 son’s liability for fees shall be reasonably based
17 on the proportion of the inspection costs which
18 relate to such person.

19 “(B) DEPOSIT AND APPROPRIATIONS.—

20 “(i) DEPOSIT AND AVAILABILITY.—

21 Fees collected under subparagraph (A)
22 shall be deposited as an offsetting collec-
23 tion to the appropriations for the Depart-
24 ment of Health and Human Services as
25 provided in appropriation Acts and shall

1 remain available without fiscal year limita-
2 tion.

3 “(ii) APPROPRIATIONS.—Fees col-
4 lected under subparagraph (A) shall be col-
5 lected and available only to the extent pro-
6 vided in advance in appropriation Acts.

7 “(2) AUTHORIZATION OF APPROPRIATIONS.—
8 There are authorized to be appropriated for the Sec-
9 retary to carry out activities which are not sup-
10 ported by fees authorized and collected under para-
11 graph (1), such sums as may be necessary for fiscal
12 years 1997 through 2001.”.

13 **SEC. 403. DATA SURVEY.**

14 The Institute of Medicine, by itself or with the Na-
15 tional Institutes of Health, shall survey the data collected
16 on the prevalence of the use of fetal ultrasound and the
17 interaction between physicians and consumers that may
18 be driving the use of fetal ultrasound. The survey should
19 begin with data collected after the report in 1984 by the
20 National Institutes of Health on a consensus development
21 conference on diagnostic ultrasound imaging in pregnancy.

22 **SEC. 404. OUTREACH.**

23 The Secretary of Health and Human Services shall
24 establish a program to provide educational outreach to
25 medical practitioners and the public regarding the appro-

1 priateness of fetal ultrasound for the health of mothers
2 and fetuses.

3 **SEC. 405. REPORT.**

4 No later than January 1, 1999, the Secretary shall
5 report to the Committee on Labor and Human Resources
6 of the Senate and the Committee on Commerce of the
7 House of Representatives on whether this program has re-
8 sulted in improvement of the quality of fetal ultrasound,
9 and a reduction in nonmedically indicated fetal
10 ultrasonography, without affecting access to medically
11 necessary services or unnecessarily burdening health care
12 providers.

13 **SEC. 406. TECHNICAL AMENDMENT.**

14 Section 354(q)(3) of the Public Health Service Act
15 (42 U.S.C. 263b(q)(3)) is amended by striking “Sec-
16 retary” each place it occurs and inserting “State”.

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