I

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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Safe Motherhood Act of 1996''.

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

TITLE I—EPIDEMIOLOGICAL AND EDUCATIONAL ACTIVITIES REGARDING PREGNANCY-RELATED COMPLICATIONS

SEC. 101. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Pregnancy-Related Morbidity and Mortality Surveillance and Research Act''.

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

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

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

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

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

(4) The state of medical knowledge can be improved by improving the systems for collecting data, and by using the data as a basis for research on the prevention and treatment of pregnancy-related complications.

SEC. 102. CENTERS FOR DISEASE CONTROL AND PREVENTION; EPIDEMIOLOGICAL DATA AND PUBLIC EDUCATION.

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

''EPIDEMIOLOGICAL DATA AND PUBLIC EDUCATION REGARDING PREGNANCY-RELATED COMPLICATIONS

''SEC. 317G. (a) TECHNICAL ASSISTANCE TO STATES FOR COLLECTION OF DATA.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide technical assistance to the States for the purpose of assisting with the following activities:

''(1) Collecting data on the incidence and prevalence of pregnancy-related complications.

''(2) Identifying and reporting the risk factors associated with such complications.

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

''(b) PUBLIC EDUCATION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out activities to educate health professionals and the public on the prevention of pregnancy-related complications and the treatments available for such complications.

''(c) DEFINITION.—For purposes of this section, the term 'pregnancy-related complication' means a disease, disorder, or other medical condition that is related to pregnancy.

''(d) AUTHORIZATION OF APPROPRIATIONS.—

''(1) TECHNICAL ASSISTANCE FOR COLLECTION OF DATA.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $25,000,000.

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

SEC. 103. COMPREHENSIVE EPIDEMIOLOGICAL REPORT TO CONGRESS.

(a) STUDY.—

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

(A)(i) The national incidence and prevalence of each of ectopic pregnancy, preeclampsia, placenta previa, abruptio placentae, all hypertensive disorders of pregnancy, and such other pregnancy-related complications as the Secretary determines to be appropriate.

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

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

(C)(i) The national incidence and prevalence of cases in which pregnancy-related complications were a contributing factor in the death of the patients involved, including a specification of the incidence and prevalence of such cases according to the type of complication involved.

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

(D) The extent of the effectiveness of Federal and State activities for the collection of epidemiological data on pregnancy-related complications, including consideration of the extent to which cases of such complications are not being identified.

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

(2) RECOMMENDATIONS OF SECRETARY.—In addition to the determinations required in paragraph (1), the study under such paragraph shall include the recommendations of the Secretary for the following:

(A) Improving the effectiveness of Federal and State activities for the collection of the epidemiological data described in paragraph (1), including developing and implementing a uniform system for collecting and exchanging the data.

(B) An agenda for the conduct and support by the Federal Government of research on preventing and treating pregnancy-related complications, including the following:

(i) Research to determine whether there is a significant relationship between the development of such complications and multiple births, unintended pregnancy, treatments for infertility, sexually transmitted diseases, and the lack of access to health care.

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

(C) Statutory or administrative modifications to the program of education established in section 317G(b) of the Public Health Service Act (as added by section 102 of this Act).

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

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

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

(1) The term ''pregnancy-related complication'' means a disease, disorder, or other medical condition that is related to pregnancy.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

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

TITLE II—PUBLIC EDUCATION REGARDING FOLIC ACT AS DIETARY SUPPLEMENT

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Folic Acid Public Education Act''.

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

(1) Folic acid, a vitamin of the B complex, is effective in preventing the serious, common birth defects spina bifida and anencephaly, but only if the woman involved consumes the vitamin daily before she becomes pregnant and during the initial days after she becomes pregnant.

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

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

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

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

TITLE III—NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT OF 1996

SEC. 301. SHORT TITLE OF TITLE.

This title may be cited as the ''Newborns' and Mothers' Health Protection Act of 1996''.

SEC. 302. FINDINGS.

Congress finds that—

(1) the length of post-delivery inpatient care should be based on the unique characteristics of each mother and her newborn child, taking into consideration the health of the mother, the health and stability of the newborn, the ability and confidence of the mother and father to care for the newborn, the adequacy of support systems at home, and the access of the mother and newborn to appropriate follow-up health care; and

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

SEC. 303. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOLLOWING BIRTH.

(a) IN GENERAL.—Except as provided in subsection (b), a health plan or an employee health benefit plan that provides maternity benefits, including benefits for childbirth, shall ensure that coverage is provided with respect to a mother who is a participant, beneficiary, or policyholder under such plan and her newborn child for a minimum of 48 hours of inpatient length of stay following a normal vaginal delivery, and a minimum of 96 hours of inpatient length of stay following a caesarean section,

without requiring the attending provider to obtain authorization from the health plan or employee health benefit plan.

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

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

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

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

(a) IN GENERAL.—

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

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

(A) the home, a provider's office, a hospital, a birthing center, an intermediate care facility, a federally qualified health center, a federally qualified rural health clinic, or a State health department maternity clinic; or

(B) another setting determined appropriate under regulations promulgated by the Secretary, in consultation with the Secretary of Health and Human Services;

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

(2) CONSIDERATIONS BY SECRETARY.—In promulgating regulations under paragraph (1)(B), the Secretary shall consider telemedicine and other innovative means to provide follow-up care and shall consider care in both urban and rural settings.

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

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

(2) in a manner that meets the health care needs of the mother and her newborn child, that provides for the appropriate monitoring of the conditions of the mother and child, and that occurs not later than the 72-hour period immediately following discharge.

(c) CONSISTENCY WITH STATE LAW.—The Secretary shall, with respect to regulations promulgated under subsection (a) concerning appropriate post-delivery care settings, ensure that, to the extent practicable, such regulations are consistent with State licensing and practice laws.

SEC. 305. PROHIBITIONS.

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

(1) deny enrollment, renewal, or continued coverage to a mother and her newborn child who are participants, beneficiaries or policyholders based on compliance with this title;

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

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided treatment in accordance with this title; or

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide treatment to an individual policyholder, participant, or beneficiary in a manner inconsistent with this title.

SEC. 306. NOTICE.

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

(b) HEALTH PLAN.—A health plan shall provide notice to each policyholder regarding coverage required under this title. Such notice shall be in writing, prominently positioned, and be transmitted—

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

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

SEC. 307. APPLICABILITY.

(a) CONSTRUCTION.—

(1) IN GENERAL.—A requirement or standard imposed under this title on a health plan shall be deemed to be a requirement or standard imposed on the health plan issuer. Such requirements or standards shall be enforced by the State insurance commissioner for the State involved or the official or officials designated by the State to enforce the requirements of this title. In the case of a health plan offered by a health plan issuer in connection with an employee health benefit plan, the requirements or standards imposed under this title shall be enforced with respect to the health plan issuer by the State insurance commissioner for the State involved or the official or officials designated by the State to enforce the requirements of this title.

(2) LIMITATION.—Except as provided in section 308(c), the Secretary shall not enforce the requirements or standards of this title as they relate to health plan issuers or health plans. In no case shall a State enforce the requirements or standards of this title as they relate to employee health benefit plans.

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

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

(c) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to require that a mother who is a participant, beneficiary, or policyholder covered under this title—

(1) give birth in a hospital; or

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

SEC. 308. ENFORCEMENT.

(a) HEALTH PLAN ISSUERS.—Each State shall require that each health plan issued, sold, renewed, offered for sale or operated in such State by a health plan issuer meet the standards established under this title. A State shall submit such information as required by the Secretary demonstrating effective implementation of the requirements of this title.

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

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

(c) FAILURE TO ENFORCE.—In the case of the failure of a State to substantially enforce the standards and requirements set forth in this title with respect to health plans, the Secretary, in consultation with the Secretary of Health and Human Services, shall enforce the standards of this title in such State. In the case of a State that fails to substantially enforce the standards set forth in this title, each health plan issuer operating in such State shall be subject to civil enforcement as provided for under sections 502, 504, 506, and 510 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132, 1134, 1136, and 1140). The civil penalties contained in paragraphs (1) and (2) of section 502(c) of such Act (29 U.S.C. 1132(c) (1) and (2)) shall apply to any information required by the Secretary to be disclosed and reported under this section.

(d) REGULATIONS.—The Secretary, in consultation with the Secretary of Health and Human Services, may promulgate such regulations as may be necessary or appropriate to carry out this title.

SEC. 309. DEFINITIONS.

As used in this title:

(1) ATTENDING PROVIDER.—The term ''attending provider'' shall include—

(A) the obstetrician-gynecologists, pediatricians, family physicians, and other physicians primarily responsible for the care of a mother and newborn; and

(B) the nurse midwives and nurse practitioners primarily responsible for the care of a mother and her newborn child in accordance with State licensure and certification laws.

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

(3) EMPLOYEE HEALTH BENEFIT PLAN.—

(A) IN GENERAL.—The term ''employee health benefit plan'' means any employee welfare benefit plan, governmental plan, or church plan (as defined under paragraphs (1), (32), and (33) of section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002 (1), (32), and (33))) that provides or pays for health benefits (such as provider and hospital benefits) for participants and beneficiaries whether—

(i) directly;

(ii) through a health plan offered by a health plan issuer as defined in paragraph (4); or

(iii) otherwise.

(B) RULE OF CONSTRUCTION.—An employee health benefit plan shall not be construed to be a health plan or a health plan issuer.

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

(i) Coverage only for accident, or disability income insurance, or any combination thereof.

(ii) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act).

(iii) Coverage issued as a supplement to liability insurance.

(iv) Liability insurance, including general liability insurance and automobile liability insurance.

(v) Workers compensation or similar insurance.

(vi) Automobile medical payment insurance.

(vii) Coverage for a specified disease or illness.

(viii) Hospital or fixed indemnity insurance.

(ix) Short-term limited duration insurance.

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

(xi) A health insurance policy providing benefits only for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

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

(5) HEALTH PLAN.—

(A) IN GENERAL.—The term ''health plan'' means any group health plan or individual health plan.

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

(C) INDIVIDUAL HEALTH PLAN.—The term ''individual health plan'' means any contract, policy, certificate or other arrangement offered to individuals by a health plan issuer that provides or pays for health benefits (such as provider and hospital benefits) and that is not a group health plan.

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

(i) Coverage only for accident, or disability income insurance, or any combination thereof.

(ii) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act).

(iii) Coverage issued as a supplement to liability insurance.

(iv) Liability insurance, including general liability insurance and automobile liability insurance.

(v) Workers compensation or similar insurance.

(vi) Automobile medical payment insurance.

(vii) Coverage for a specified disease or illness.

(viii) Hospital or fixed indemnity insurance.

(ix) Short-term limited duration insurance.

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

(xi) A health insurance policy providing benefits only for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(E) CERTAIN PLANS INCLUDED.—Such term includes any plan or arrangement not described in any clause of subparagraph (D) which provides for benefit payments, on a periodic basis, for—

(i) a specified disease or illness, or

(ii) a period of hospitalization,

without regard to the costs incurred or services rendered during the period to which the payments relate.

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

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

(8) SECRETARY.—The term ''Secretary'' unless otherwise specified means the Secretary of Labor.

SEC. 310. PREEMPTION.

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

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

(2) that requires health plans to provide coverage for at least 48 hours of inpatient length of stay following a normal vaginal delivery, and at least 96 hours of inpatient length of stay following a caesarean section;

(3) that requires health plans to provide coverage for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations; or

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

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

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

SEC. 311. REPORTS TO CONGRESS CONCERNING CHILDBIRTH.

(a) FINDINGS.—Congress finds that—

(1) childbirth is one part of a continuum of experience that includes prepregnancy, pregnancy and prenatal care, labor and delivery, the immediate postpartum period, and a longer period of adjustment for the newborn, the mother, and the family;

(2) health care practices across this continuum are changing in response to health care financing and delivery system changes, science and clinical research, and patient preferences; and

(3) there is a need to—

(A) examine the issues and consequences associated with the length of hospital stays following childbirth;

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

(C) identify appropriate health care practices and procedures with regard to the hospital discharge of newborns and mothers;

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

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

(b) ADVISORY PANEL.—

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

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

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

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

developed under subparagraph (B) if any, including the reasons for not reaching such a consensus.

(2) PARTICIPATION.—

(A) DEPARTMENT REPRESENTATIVES.—The Secretary of Health and Human Services shall ensure that representatives from within the Department of Health and Human Services that have expertise in the area of maternal and child health or in outcomes research are appointed to the advisory panel established under paragraph (1).

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

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

(I) Patient care.

(II) Patient education.

(III) Quality assurance.

(IV) Outcomes research.

(V) Consumer issues.

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

(I) Health care practitioners.

(II) Health plans.

(III) Hospitals.

(IV) Employers.

(V) States.

(VI) Consumers.

(c) STUDIES.—

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

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

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

(C) the diversity of negative or positive outcomes affecting mothers, infants, and families;

(D) the manner in which post natal care has changed over time and the manner in which that care has adapted or related to changes in the length of hospital stay, taking into account—

(i) the types of post natal care available and the extent to which such care is accessed; and

(ii) the challenges associated with providing post natal care to all populations, including vulnerable populations, and solutions for overcoming these challenges; and

(E) the financial incentives that may—

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

(ii) influence the clinical decisionmaking of health care providers.

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

(d) REPORTS.—

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

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

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

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

(D) limitations on the databases in existence on the date of enactment of this Act.

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

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

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

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

(e) TERMINATION OF PANEL.—The advisory panel shall terminate on the date that occurs 60 days after the date on which the last report is submitted under this section.

SEC. 312. EFFECTIVE DATE.

Except as otherwise provided for in this title, the provisions of this title shall apply as follows:

(1) With respect to health plans, such provisions shall apply to such plans on the first day of the contract year beginning on or after January 1, 1997.

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

TITLE IV—ULTRASOUND

SEC. 401. SHORT TITLE.

This title may be cited as the ''Ultrasound Quality Standards Act of 1996''.

SEC. 402. CERTIFICATION OF ULTRASOUND FACILITIES.

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

''Subpart 4—Ultrasonography Facilities

''SEC. 355. CERTIFICATION OF ULTRASOUND FACILITIES.

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

''(1) ACCREDITATION BODY.—The term 'accreditation body' means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit ultrasound facilities.

''(2) CERTIFICATE.—The term 'certificate' means the certificate described in subsection (b)(1).

''(3) FACILITY.—

''(A) IN GENERAL.—The term 'facility' means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts fetal ultrasound activities screening.

''(B) ACTIVITIES.—For the purposes of this section, the activities of a facility include the operation of ultrasound equipment, the interpretation of the ultrasound, and any production of a permanent record of such ultrasonography, including videotapes.

''(4) INSPECTION.—The term 'inspection' means an onsite evaluation of the facility by the Secretary or State agency on behalf of the Secretary.

''(5) FETAL ULTRASOUND.—The term 'fetal ultrasound' means ultrasonography performed on a pregnant woman for purposes of viewing the fetus.

''(b) CERTIFICATE REQUIREMENT.—

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

''(A) a certificate—

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

''(ii) that is applicable to the examination or procedure to be conducted; and

''(iii) that is displayed prominently in such facility; or

''(B) a provisional certificate—

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

''(ii) that is applicable to the examination or procedure to be conducted; and

''(iii) that is displayed prominently in such facility.

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

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

''(A) operate ultrasound equipment that is used to image the fetus;

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

''(C) provide for the processing of film or videotape of the ultrasound images produced.

''(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

''(1) IN GENERAL.—The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

''(2) PROVISIONAL CERTIFICATE.—The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clause (iii) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued,

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

''(d) APPLICATION FOR CERTIFICATE.—

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

''(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

''(i) a description of the manufacturer, model, and type of each instrument used in the performance of fetal ultrasonography by the facility;

''(ii) a description of the procedures currently used to provide fetal ultrasonography at the facility, including—

''(I) the types of procedures performed and the number of such procedures performed in the prior 12 months; and

''(II) the names and qualifications (educational background, training, and experience) of the personnel performing fetal ultrasonography and interpreting the ultrasound images;

''(iii) proof of accreditation in such manner as the Secretary shall prescribe; and

''(B) the person or agent submits to the Secretary—

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

''(ii) a satisfactory assurance that the facility will—

''(I) permit inspections under subsection (g);

''(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

''(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

''(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

''(2) APPEAL.—If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

''(A) a statement of the grounds on which the denial is based, and

''(B) an opportunity for an appeal in accordance with the procedures set forth in regu-

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

''(3) EFFECT OF DENIAL.—If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

''(e) ACCREDITATION.—

''(1) APPROVAL OF ACCREDITATION BODIES.—

''(A) IN GENERAL.—The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iii) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

''(B) STANDARDS.—The Secretary shall establish standards for accreditation bodies, including—

''(i) standards that prohibit individuals conducting the reviews from maintaining any financial relationship to the facility

undergoing review which would constitute a conflict of interest;

''(ii) standards that limit the imposition of fees for accreditation to reasonable amounts;

''(iii) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

''(iv) such additional standards as the Secretary may require.

''(C) ASSURANCES.—The accrediting body shall provide the Secretary satisfactory assurances that the body will—

''(i) comply with the standards as described in subparagraph (B);

''(ii) comply with the requirements described in paragraph (4);

''(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

''(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

''(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

''(vi) provide such other additional information as the Secretary may require.

''(D) REGULATIONS.—Not later than 9 months after the date of the enactment of this section, the Secretary shall promulgate regulations under which the Secretary may approve one or more accreditation bodies.

''(2) WITHDRAWAL OF APPROVAL.—

''(A) IN GENERAL.—The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

''(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certifi-

cate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

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

''(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

''(B) such other standards which the accreditation body may require.

''(4) COMPLIANCE.—To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

''(A) make onsite visits of the facilities accredited by the body of a sufficient number and of such frequency to allow a reasonable estimate of the performance of the body; and

''(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

''(5) REVOCATION OF ACCREDITATION.—If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

''(6) EVALUATION AND REPORT.—

''(A) EVALUATION.—The Secretary shall evaluate the performance of each approved accreditation body by—

''(i) inspecting under subsection (g)(2) a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

''(ii) such additional means as the Secretary determines to be appropriate.

''(f) QUALITY STANDARDS.—

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

''(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability and accuracy of interpretation of fetal ultrasound;

"(B) a requirement that personnel who perform ultrasound—

"(i)(I) be licensed by a State to perform ultrasound procedures; or

"(II) be certified as qualified to perform ultrasound procedures by an organization described in paragraph (2)(A); and

"(ii) during the 2-year period beginning October 1, 1997, meet training standards for personnel who perform ultrasonography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of ultrasonography; and

"(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform fetal ultrasound;

"(C) a requirement that ultrasound images be interpreted by a physician who is certified as qualified to interpret fetal ultrasound and who meets training and continuing medical education requirements as established by the Secretary;

"(D) a requirement that fetal ultrasonography be performed only when medically necessary.

"(E) a requirement that—

"(i) a facility that performs any fetal ultrasound maintain a record of such ultrasound in the permanent medical records of the patient—

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

"(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and

"(ii)(I) a facility must assure the preparation of a written report of the results of any fetal ultrasound examination signed by the interpreting physician;

"(II) such written report shall be provided to the patient's physicians (if any);

"(III) if such a physician is not available or if there is no such physician, the

written report shall be sent directly to the patient; and

''(IV) if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person.

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

''(2) CERTIFICATION OF PERSONNEL.—The Secretary shall by regulation—

''(A) specify organizations eligible to certify individuals to perform fetal ultrasound as required by paragraph (1)(B); and

''(B) establish standards for a program to certify physicians described in paragraph (1)(C).

''(g) INSPECTIONS.—

''(1) INSPECTIONS.—

''(A) IN GENERAL.—The Secretary may enter and inspect certified facilities to determine compliance with the standards established under subsection (f). The Secretary shall, if feasible, delegate to a State agency the authority to make such inspections.

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

"(C) SCOPE OF INSPECTION.—In conducting inspections, the Secretary or State agency acting on behalf of the Secretary—

"(i) shall have access to all equipment, materials, records, and information that the Secretary or State agency considers necessary to determine whether the facility is being operated in accordance with this section; and

"(ii) may copy, or require the facility to submit to the Secretary or the State agency, any of the materials, records, or information.

"(D) QUALIFICATIONS OF INSPECTORS.—Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or em-

ployee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

''(E) FREQUENCY.—The Secretary or State agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility as frequently as needed to assure that facilities are in compliance with this section, but no more frequently than once every 2 years.

''(F) RECORDS AND ANNUAL REPORTS.—The Secretary or a State agency acting on behalf of the Secretary which is responsible for inspecting ultrasound facilities shall maintain records of inspections required under this paragraph for a period as prescribed by the Secretary. Such a State agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

''(2) INSPECTION OF ACCREDITED FACILITIES.—The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

''(3) INSPECTION OF FACILITIES INSPECTED BY STATE AGENCIES.—The Secretary shall inspect annually facilities inspected by State agencies acting on behalf of the Secretary to assure a reasonable performance by such State agencies.

''(4) TIMING.—The Secretary, or State agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of ultrasonography at such facility threatens the public health.

''(5) LIMITED REINSPECTION.—Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

''(h) SANCTIONS.—

''(1) IN GENERAL.—In order to promote voluntary compliance with this section, the Secretary

may, in lieu of taking the actions authorized by subsection (i), impose one or more of the following sanctions:

"(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

"(B) Payment for the cost of onsite monitoring.

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

"(A) failure to obtain a certificate as required by subsection (b),

"(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii), and

"(C) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

''(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) and (2). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

''(i) SUSPENSION AND REVOCATION.—

''(1) IN GENERAL.—The certificate of a facility issued under subsection (c) may be suspended or revoked if the Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

''(A) has been guilty of misrepresentation in obtaining the certificate;

''(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) or the standards established by the Secretary under subsection (f);

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

mation, report, or material that the Secretary concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f);

''(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State officer or employee duly designated by the State, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

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

''(F) has failed to comply with a sanction imposed under subsection (h).

''(2) ACTION BEFORE A HEARING.—

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

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

retary under subsection (f) presents a serious risk to human health; or

"(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1).

"(B) HEARING.—If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the facility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

"(3) INELIGIBILITY TO OWN OR OPERATE FACILITIES AFTER REVOCATION.—If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

"(j) INJUNCTIONS.—If the Secretary determines that—

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

constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

''(2) a facility is operating without a certificate as required by subsection (b), the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

''(k) JUDICIAL REVIEW.—

''(1) PETITION.—If the Secretary imposes a sanction on a facility under subsection (h) or suspends or revokes the certificate of a facility under subsection (i), the owner or operator of the facility may, not later than 60 days after the date the action of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the

petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

''(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original

action of the Secretary with the return of the additional evidence.

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

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

''(l) INFORMATION.—

''(1) IN GENERAL.—Not later than October 1, 1999, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

''(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

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

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

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

"(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

"(F) against which a State has taken adverse action; and

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

"(2) DATE.—The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

"(3) EXPLANATORY INFORMATION.—The information to be compiled under paragraph (1) shall be accompanied by such explanatory information as

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

''(m) STATE LAWS.—Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

''(n) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of developing standards, regulations, evaluations, and procedures for compliance and oversight.

''(o) STATE PROGRAM.—

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

''(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) (including the requirements under regulations promulgated pursuant to such subsections), and

''(B) to implement the standards established by the Secretary under subsection (f),

with respect to ultrasound facilities operating within the State.

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

''(A) the State has enacted laws and issued regulations relating to ultrasound facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

''(B) the State has provided satisfactory assurances that the State—

''(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

''(ii) will devote adequate funds to the administration and enforcement of such requirements, and

''(iii) will provide the Secretary with such information and reports as the Secretary may require.

''(3) AUTHORITY OF STATE.—In a State with an approved application—

"(A) the State shall carry out the Secretary's functions under subsections (e) and (f);

"(B) the State may take action under subsections (h), (i), and (j); and

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

"(4) WITHDRAWAL OF APPROVAL.—

"(A) IN GENERAL.—The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Secretary shall promulgate regulations for the implementation of this subparagraph.

"(B) EFFECT OF WITHDRAWAL.—If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility accredited by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

"(p) FUNDING.—

"(1) FEES.—

"(A) IN GENERAL.—The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

"(B) DEPOSIT AND APPROPRIATIONS.—

"(i) DEPOSIT AND AVAILABILITY.—Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall

remain available without fiscal year limitation.

''(ii) APPROPRIATIONS.—Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

''(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the Secretary to carry out activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1997 through 2001.''.

SEC. 403. DATA SURVEY.

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

SEC. 404. OUTREACH.

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

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

SEC. 405. REPORT.

No later than January 1, 1999, the Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on whether this program has resulted in improvement of the quality of fetal ultrasound, and a reduction in nonmedically indicated fetal ultrasonography, without affecting access to medically necessary services or unnecessarily burdening health care providers.

SEC. 406. TECHNICAL AMENDMENT.

Section 354(q)(3) of the Public Health Service Act (42 U.S.C. 263b(q)(3)) is amended by striking ''Secretary'' each place it occurs and inserting ''State''.

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