numbered subchapter C of chapter V of the Federal Food, Drug, and Cosmetic Act, by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779, and is classified to part C (§ 360hh et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs.

§ 263b. Certification of mammography 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) of this section to accredit mammography facilities.

(2) Certificate

The term ''certificate'' means the certificate described in subsection (b)(1) of this section.

(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 breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) Activities

For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f) of this section.

(4) Inspection

The term ''inspection'' means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) Mammogram

The term ''mammogram'' means a radiographic image produced through mammography.

(6) Mammography

The term ''mammography'' means radiography of the breast.

(7) Survey

The term ''survey'' means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E) of this section.

(8) Review physician

The term ''review physician'' means a physician as prescribed by the Secretary under subsection (f)(1)(D) of this section who meets such additional requirements as may be established by an accreditation body under subsection (e) of this section and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) of this section on behalf of the accreditation body.

(b) Certificate requirement

(1) Certificate

No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs[1] (1) or (2) of subsection (c) of this section;

(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 or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c) of this section;

(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 temporary renewal certificate, provisional certificate, or a limited provisional certificate.

(2) Examination or procedure

A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(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) of this section meets the applicable requirements of subsection (d)(1) of this section with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) Temporary renewal certificate

The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

[1] So in original. Probably should be ''paragraph''.

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) Limited provisional certificate

The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) 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) of this section, except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A) of this section. 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 mammography 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) of this section.

(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 x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

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

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

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E) of this section; and

(iv) 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) of this section to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g) of this section;

(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 regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(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)(iv) of this section 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 require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

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

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) of this section to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1) of this section;

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) of this section which are relevant to accreditation as determined by the Secretary; and

(vii) 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 October 27, 1992, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(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 certificate 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 on an annual basis of a sufficient number of the facilities accredited by the body 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 annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) of this section 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.

(B) Report

The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the

House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) Quality standards

(1) In general

The standards referred to in subsection (d)(1)(B)(i) of this section 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, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

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

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

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

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

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after October 27, 1992, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography 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) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) 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 radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) Inspections

(1) Annual inspections

(A) In general

The Secretary may enter and inspect facilities to determine compliance with the certification requirements under subsection (b) of this section and the standards established under subsection (f) of this section. The Secretary shall, if feasible, delegate to a State or local agency the authority to make such inspections.

(B) Identification

The Secretary, or State or local agency acting on behalf of the Secretary, may con-

duct 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 or local agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State or local 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 or local 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 or local agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee 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) of this section.

(E) Frequency

The Secretary or State or local agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually, subject to paragraph (6).

(F) Records and annual reports

The Secretary or a State or local agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State or local 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 or local agencies

The Secretary shall inspect annually facilities inspected by State or local agencies acting on behalf of the Secretary to assure a reasonable performance by such State or local agencies.

(4) Timing

The Secretary, or State or local 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 mammography 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.

(6) Demonstration program

(A) In general

The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) Requirements

Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f) of this section. The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(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) of this section, 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) Patient information

If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c) of this section) was so inconsistent with the quality standards established pursu-

ant to subsection (f) of this section as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

(3) 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) of this section,

(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) of this section or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii) of this section,

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

(D) 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.

(4) 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) through (3). 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) of this section 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) of this section or the standards established by the Secretary under subsection (f) of this section;

(C) has failed to comply with reasonable requests of the Secretary (or of an accreditation body approved pursuant to subsection (e) of this section) for any record, information, report, or material that the Secretary (or such accreditation body or State carrying out certification program requirements pursuant to subsection (q) of this section) concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f) of this section;

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

(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) of this section.

(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 has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

(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 mammography 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) of this section, 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) of this section or suspends or revokes the certificate of a facility under subsection (i) of this section, 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.

(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.

(*l*) Information

(1) In general

Not later than October 1, 1996, 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) of this section, together with a statement of the reasons for the sanctions;

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

(D) against which the Secretary has taken action under subsection (j) of this section, 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 meets 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) National Advisory Committee

(1) Establishment

In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the ''Advisory Committee'').

(2) Composition

The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

(A) physicians,

(B) practitioners, and

(C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, at least 2 industry representatives with expertise in mammography equipment, and at least 2 practicing physicians who provide mammography services.

(3) Functions and duties

The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;

(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;

(C) advise the Secretary in the development of regulations with respect to sanctions;

(D) assist in developing procedures for monitoring compliance with standards under subsection (f) of this section;

(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;

(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) of this section on access to the services of such facilities in such areas;

(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E) of this section;

(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and

(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) Meetings

The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least annually.

(5) Chairperson

The Secretary shall appoint a chairperson of the Advisory Committee.

(*o*) 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.

(p) Breast cancer screening surveillance research grants

(1) Research

(A) Grants

The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) Use of funds

Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) Grant application

To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) Report

A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) Establishment

The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) Standards and procedures

The Secretary shall establish standards and procedures for the operation of the breast cancer screening surveillance system, including procedures to maintain confidentiality of patient records.

(4) Information

The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5.

(q) 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) of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f) of this section,

with respect to mammography 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 mammography 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 Secretary

In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f) of this section;

(B) the Secretary may take action under subsections (h), (i), and (j) of this section; and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3) of this section.

(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 certified 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.

(r) 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) of this section (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) of this section 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) of this section. 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 to carry out this section—

(A) to award research grants under subsection (p) of this section, such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

(July 1, 1944, ch. 373, title III, § 354, as added Pub. L. 102–539, § 2, Oct. 27, 1992, 106 Stat. 3547; amended Pub. L. 105–248, §§ 2–13, Oct. 9, 1998, 112 Stat. 1864–1867; Pub. L. 108–365, §§ 2–4, Oct. 25, 2004, 118 Stat. 1738–1740.)

PRIOR PROVISIONS

A prior section 263b, act July 1, 1944, ch. 373, title III, § 354, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1173; amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), 104 Stat. 4529; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779, set forth Congressional declaration of purpose, prior to repeal by Pub. L. 101–629, § 19(a)(3), Nov. 28, 1990, 104 Stat. 4530.

Sections 263c to 263n, act July 1, 1944, ch. 373, title III, §§ 355–360F, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174, and amended, which related to electronic product radiation control, were renumbered sections 531 to 542, respectively, of the Federal Food, Drug, and Cosmetic Act by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, and are classified to sections 360hh to 360ss, respectively, of Title 21, Food and Drugs.

AMENDMENTS

2004—Subsec. (b)(1). Pub. L. 108–365, § 2(1)(C), substituted ''temporary renewal certificate, provisional

certificate, or a limited provisional certificate'' for ''provisional certificate'' in concluding provisions.

Subsec. (b)(1)(A). Pub. L. 108–365, § 2(1)(A), inserted ''or a temporary renewal certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (1) or (2) of subsection (c)'' for ''subsection (c)(1)'' in cl. (i).

Subsec. (b)(1)(B). Pub. L. 108–365, § 2(1)(B), inserted ''or a limited provisional certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (3) and (4) of subsection (c)'' for ''subsection (c)(2)'' in cl. (i).

Subsec. (c)(2) to (4). Pub. L. 108–365, § 2(2), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (n)(2). Pub. L. 108–365, § 3(1), reenacted subpar. (C) without change, added concluding provisions, and struck out former concluding provisions which read as follows: ''whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least 2 practicing physicians who provide mammography services.''

Subsec. (n)(4). Pub. L. 108–365, § 3(2), substituted ''annually'' for ''biannually''.

Subsec. (r)(2). Pub. L. 108–365, § 4, substituted ''2007'' for ''2002'' in subpars. (A) and (B).

1998—Subsec. (a)(4). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State''.

Subsec. (a)(8). Pub. L. 105–248, § 4(b), added par. (8).

Subsec. (d)(2)(B). Pub. L. 105–248, § 3, substituted ''part 498 of title 42, Code of Federal Regulations'' for ''42 C.F.R. 498 and in effect on October 27, 1992''.

Subsec. (e)(1)(B)(i)(I), (II). Pub. L. 105–248, § 4(a)(1), substituted ''review physicians'' for ''practicing physicians''.

Subsec. (e)(1)(B)(ii). Pub. L. 105–248, § 4(a)(2), substituted ''relationship'' for ''financial relationship''.

Subsec. (f)(1)(G)(i). Pub. L. 105–248, § 5, added cl. (i) and struck out former cl. (i) which read as follows: ''a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

''(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, 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''.

Subsec. (f)(1)(G)(ii)(IV). Pub. L. 105–248, § 6, added subcl. (IV) and struck out former subcl. (IV) which read as follows: ''if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and''.

Subsec. (g)(1). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State'' wherever appearing.

Subsec. (g)(1)(A). Pub. L. 105–248, § 7, in first sentence, struck out ''certified'' before ''facilities'' and inserted ''the certification requirements under subsection (b) of this section and'' after ''compliance with''.

Subsec. (g)(1)(E). Pub. L. 105–248, § 8(1), inserted '', subject to paragraph (6)'' before period at end.

Subsec. (g)(3). Pub. L. 105–248, § 9(1), (2), inserted ''or local'' after ''State'' in heading and in two places in text.

Subsec. (g)(4). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State''.

Subsec. (g)(6). Pub. L. 105–248, § 8(2), added par. (6).

Subsec. (h)(2). Pub. L. 105–248, § 10(a), added par. (2) and redesignated former par. (2) as (3).

Subsec. (h)(3). Pub. L. 105–248, § 10(a)(1), (b), redesignated par. (2) as (3), added subpar. (C), and redesignated former subpar. (C) as (D). Former par. (3) redesignated (4).

Subsec. (h)(4). Pub. L. 105–248, § 10(a)(1), (c), redesignated par. (3) as (4) and substituted ''paragraphs (1) through (3)'' for ''paragraphs (1) and (2)''.

Subsec. (i)(1)(C). Pub. L. 105–248, § 11, inserted ''(or of an accreditation body approved pursuant to subsection (e) of this section)'' after ''of the Secretary'' and inserted ''(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q) of this section)'' after ''that the Secretary''.

Subsec. (i)(1)(D). Pub. L. 105–248, § 9(3), inserted ''or local'' after ''any State'' and ''or local agency'' after ''by the State''.

Subsec. (i)(2)(A). Pub. L. 105–248, § 12, substituted ''has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—'' and cls. (i) and (ii) for ''makes the finding described in paragraph (1) and determines that—

''(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) of this section 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).''

Subsec. (q)(4)(B). Pub. L. 105–248, § 13, substituted ''certified'' for ''accredited''.

Subsec. (r)(2)(A). Pub. L. 105–248, § 2, substituted ''subsection (p)'' for ''subsection (q)'' and ''2002'' for ''1997''.

Subsec. (r)(2)(B). Pub. L. 105–248, § 2, substituted ''fiscal years'' for ''fiscal year'' and ''2002'' for ''1997''.

Change of Name

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Termination of Advisory Committees

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

Regulations

Pub. L. 103–183, title VII, § 707, Dec. 14, 1993, 107 Stat. 2241, provided that: ''The Secretary of Health and Human Services is authorized to issue interim final regulations—

''(1) under which the Secretary may approve accreditation bodies under section 354(e) of the Public Health Service Act (42 U.S.C. 263b(e)); and

''(2) establishing quality standards under section 354(f) of the Public Health Service Act (42 U.S.C. 263b(f)).''

Study

Section 3 of Pub. L. 102–539 directed Comptroller General of United States to conduct a study of the certifi-

cation program authorized by this section to determine if the program has resulted in improvement of quality and accessibility of mammography services, and if the program has reduced the frequency of poor quality mammography and improved early detection of breast cancer, with Comptroller General, not later than 3 years from Oct. 27, 1992, submit to Congress an interim report of results of study and, not later than 5 years from such date to submit a final report.

PART G—QUARANTINE AND INSPECTION

§ 264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[1].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d) of this section, regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term ''State'' includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term ''qualifying stage'', with respect to a communicable disease, means that such disease—

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

(July 1, 1944, ch. 373, title III, § 361, 58 Stat. 703; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–624, § 29(c), July 12, 1960, 74 Stat. 419; Pub. L. 94–317, title III, § 301(b)(1), June 23, 1976, 90 Stat. 707; Pub. L. 107–188, title I, § 142(a)(1), (2), (b)(1), (c), June 12, 2002, 116 Stat. 626, 627.)

AMENDMENTS

2002—Pub. L. 107–188, § 142(a)(1), (2), (b)(1), and (c), which directed certain amendments to section 361 of the Public Health Act, was executed by making the amendments to this section, which is section 361 of the Public Health Service Act, to reflect the probable intent of Congress. See below.

Subsec. (b). Pub. L. 107–188, § 142(a)(1), substituted ''Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,'' for ''Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General''.

Subsec. (d). Pub. L. 107–188, § 142(a)(2), (b)(1), substituted in first sentence ''Regulations'' for ''On recommendation of the National Advisory Health Council, regulations'', ''in a qualifying stage'' for ''in a communicable stage'' in two places, designated existing text as par. (1) and substituted ''(A)'' and ''(B)'' for ''(1)'' and ''(2)'', respectively, and added par. (2).

Subsec. (e). Pub. L. 107–188, § 142(c), added subsec. (e).

1976—Subsec. (d). Pub. L. 94–317 inserted provision defining ''State'' to include, in addition to the several States, only the District of Columbia.

1960—Subsec. (c). Pub. L. 86–624 struck out reference to Territory of Hawaii.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by

[1] So in original. Comma probably should not appear.