FIFTEENTH CONGRESS OF THE REPUBLIC)
OF THE PHILIPPINES)
First Regular Session)

SENATE
S. No. 1888

Introduced by Senator Miriam Defensor Santiago

EXPLANATORY NOTE

Breast cancer is one of the most common forms of cancer among women. Medical reports show that three-quarters of all breast cancers occur in women over age 50. Though rare, men can also develop breast cancer. The best protection against breast cancer is to detect it at its earliest stage. Hence, regular mammographs starting from the age of 40 is necessary for early detection and prompt treatment. Unlike in the United States, there is no law in the Philippines providing for uniform quality standards for mammography. The key features of the bill are: (1) certification by the Secretary of Health or a government officer or employee duly authorized by the Secretary of Health that the mammography facility provides quality mammography services; (2) accreditation by a government-approved non-profit or government accreditation body; (3) application of the facility to an accreditation body approved by the Secretary of Health, periodic review of its clinical images, annual survey by a medical physicist and compliance with government-developed quality standards of personnel qualifications, quality assurance programs, record-keeping and reporting; and (4) annual inspection conducted by trained and certified government personnel.[1]

MIRIAM DEFENSOR SANTIAGO

[1] This bill was originally filed during the Fourteenth Congress, First Regular session.

SENATE
OFFICE OF THE SECRETARY

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RECEIVED BY

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AN ACT
ESTABLISHING QUALITY STANDARDS IN MAMMOGRAPHY

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. *Definitions* - For the purposes of this Act:

(1) "Accreditation Body" means a body that has been approved by the Secretary of Health under Section *(5)* (1) (A) of this Act to accredit mammography facilities.

(2) "Certificate" means the certificate described in Section (2) (1).

(3) "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 of Health, that conducts breast cancer screening or diagnosis through mammography activities.

(4) "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 standard described in subsection (6) of this section.

(5) "Inspection" means an on-site evaluation of the facility by the Secretary of Health, or official duly authorized by the Secretary of Health.

(6) "Survey" means an on-site physical consultation and evaluation performed by medical physicist as described in Section ***6*** of this Act.

SECTION 2. *Certificate Requirements.* -

(1) Certificate - No facility may conduct an examination or procedure described in, subsection 2 of this section involving mammography after the passage of this Act, unless the facility obtains -

(A) a certificate - (i) that is issued, and if applicable, renewed, by the Secretary in accordance with Section (3) (1) of this Act; (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 Section (3) (2) of this Act;

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

(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 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.

SECTION 3. *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 Section (4) (1) (A) of this Act meets the applicable requirements of Section (4) (1) of this Act with respect to the facility. The Secretary of Health may issue or renew a certificate under this paragraph for not more than three (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 Section (4) (1) of this Act, except providing information required by clause (iii) and (iv) of Section (4)(1)(A). A provisional certificate may be in effect no longer than six (6)

months form the date it was issued, except that it may be extended once for a period of not more than ninety (90) days if the owner, lessor, or agent of the facility demonstrates to the Secretary of Health, 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 Section (2)(1) of this Act.

SECTION 4. *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 unauthorized agent of the person, submits to the Secretary, in such form and manner as the Secretary of Health 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 - (a) the types of procedures performed and the number of such procedures performed in the prior twelve (12) months; (b) the methodologies for mammography; and (c) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the qualified medical physicist as described in Section (6)(1)(E) of this Act and

(iii) proof of accreditation in such manner as the Secretary of Health may prescribe;

(B) the person or agent submits to the Secretary of Health –

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary of Health under Section 6 of this Act to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will - (I) permit inspections under Section 7 of this Act; (E) make such reports, to the Secretary of Health as he she may require; and

(iii) update the information submitted under subparagraph A o f this section or assurances submitted under this subparagraph on a timely basis as required by the Secretary of Health; and

(iv) such other information as the Secretary of Health may require.

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

(2) Appeal - If the Secretary of Health denies an application for the certification of a facility submitted under subsection (l)(A) of this section, 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 of Health.

(3) Effect of Denial - If the application for 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 subsection (2)(B) of this section.

SECTION 5. *Accreditation.* -

(1) Approval of Accreditation Bodies

(A) In general - The Secretary of Health may approve a private non-profit organization or government health agency to accredit facilities for purposes of Section (4)(1)(A)(iv) of this Act if the accreditation body meets the standards for accreditation established by the Secretary of Health as described in paragraph (E) and provides the assurances required by paragraph (C).

(B) Standards - The Secretary shall establish standards for accreditation bodies, including-

(i) standards that require an accreditation body to perform (a) a review of clinical images from each facility accredited by such body of not less than every three (3) years which review will be made by qualified practicing physicians; and (b) a review of a random sample of clinical images from such facilities in each three-year period from the date this Act is passed, which review will be made by qualified practicing physicians;

(ii) standards that prohibit individuals conducting reviews described in clause (a) from maintaining any financial 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 this Act to ensure that the facility meets the standards described in Section (6)(I)(E) of this Act;

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

(vi) standards that are equal to standards established under Section **6** of this Act which are so relevant to accreditation as determined by the Secretary of Health; and accreditation as determined by the Secretary of Health, and

(vii) such additional standards as the Secretary may require.

(C) Assurances - The accrediting body shall provide the Secretary of Health satisfactory assurances that the. body will –

(i) comply with the standards as described in paragraph (B) of this section;

(ii) comply with the requirements described in subsection (4) of this section;

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

(iv) notify the Secretary of Health 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 of Health withdraws approval of the accreditation body under subsection 2 of this section in a timely manner; and

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

(D) Regulations -Not later than nine (9) months after the passage of this Act, the Secretary of Health shall promulgate regulations under which the Secretary of Health may approve an accreditation body.

(2) Withdrawal of Approval

(A) In general - The Secretary of Health shall promulgate regulations under which the Secretary of Health may withdraw approval of an accreditation body if the Secretary of Health determines that the accreditation body does not meet the standards under subsection (B) the requirements of subparagraphs (i) through (vi) of subsection (C) of subsection (l), 'or the requirements of subsection (l), or the requirements of subsection 4 of this section.

(B) Effect of Withdrawal - If the Secretary of Health withdraws the approval of an accreditation body under paragraph (A) of this section, 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 of Health, 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 subsection (I) (B) of this section 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 on-site 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 of Health determines to be appropriate. Visits made under shall be made after providing such notice as the Secretary of Health 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 of Health.

(6) Evaluation and Report -

(A) Evaluation - The Secretary of Health shall evaluate annually the performance of each approved accreditation body by - (i) inspecting under Section (7)(2) of this Act 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 of Health determines to he appropriate.

(B) Report - The Secretary of Health shall annually prepare and submit to the Committee on Labor, Employment, and Human Resources Development and the Committee on Trade and Commerce a report that describes the results of the evaluation conducted in accordance with paragraph (A).

SECTION 6. *Quality Standards.* -

(1) In general - The standards referred to in Section (4)(1)(B)(i) of this Act are standards established by the Secretary of Health 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) (a) be licensed by a State to perform radiological procedures; or (b) be certified as qualified to perform radiological procedures by an organization described in subsection (2)(A) of this section; and (ii) during the two-year period from the time this Act is passed, meet training standards for personnel who perform mammography or meet experience requirements which shall meet at a minimum include one (1) year of experience in the performance of mammography; and (iii) upon the expiration of such two-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) by a board described in subsection (2)(B); or

(ii) by a program that complies with the standards described in subsection (2)(C) of this section; and

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

(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 to perform such surveys by a board as described in subsection (2)(D) of this section; or

(iii) in the first five **(5)** years after this Act is passed, who meet other criteria established by the Secretary of Health which are comparable to the criteria described in subparagraph (i) or (ii).

(F) a requirement that a medical physicist who is qualified in mammography as described in paragraph (E) of this section survey mammography equipment and oversee quality assurance practices at each facility.

(G) a requirement that - (i) a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient - (a) for a period of not less

than five (5) years, or not less than ten (10) years if no additional mammograms of such patient *are* performed at the facility, or longer if mandated by law; or (b) 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)(a) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician; (b) such written report shall be provided to the patient's physicians (if any); (c) if such a physician is not available or if there is no physician, the written report is sent to the patient, the report shall include a summary written 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 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 subsection (1) (C);

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

(C) establish standards for a program to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

SECTION 7. *Inspections.* -

(1) Annual inspections -

(A) In general - The Secretary of Health may enter and inspect certified facilities to determine compliance with the standards established under Section 6 of this Act. The Secretary of Health shall, if feasible, delegate to a local agency the authority to make such inspections.

(B) Identification - The Secretary of Health or Government agency acting on behalf of the Secretary of Health, 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 of Health or local agency acting on behalf of the Secretary of Health - (i) shall have access to all equipment, materials, records, and information that the Secretary of Health or local agency considers necessary to determine whether the facility is being operated in accordance with this Act; and (ii) may copy, or require the facility to submit to the Secretary of Health or the government agency, any of the materials, records, or

(D) Qualifications of inspectors - Qualified individuals, as determined by the Secretary of Health, may request that a local agency acting on behalf of the Secretary of Health designate a qualified officer or employee of the Department of Health to conduct the inspections, or designate a qualified officer or employee of the Department of Health in Manila to conduct inspections. The Secretary of Health shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with Section

(E) Frequency - The Secretary of Health or local agency acting on behalf of the Secretary of Health shall conduct inspections under this paragraph of each facility no less often than annually.

(F) Records and annual reports - The Secretary of Health or local agency acting on behalf of the Secretary of Health which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this subsection for a period as prescribed by the Secretary of Health. Such a local agency shall annually prepare and submit to the Secretary of Health a report concerning the inspections carried out under this subsection. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) Inspection of accredited facilities - The Secretary of Health shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with the reasonable estimate of the performance of such body.

(3) Inspection of facilities inspected by local government agencies - The Secretary of Health shall inspect annually facilities inspected by local government agencies acting on behalf of the Secretary of Health to assure a reasonable performance by such local agencies.

(4) Timing - The Secretary of Health, or local government agency, may conduct inspections under subsections (l), (2), or (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary of Health may prescribe, except that the Secretary of Health may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) Limited re-inspection - Nothing in this section limits the authority of the Secretary of Health to conduct limited re-inspections of facilities found not to be in compliance with is section.

SECTION 8. *Penalties.* -

(1) In general - In order to promote voluntary compliance with this Act, the Secretary of Health may, in compliance of taking the actions authorized by Section 9 of this Act, 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) The Secretary of Health may assess civil money penalties in an amount not to exceed Ten Thousand Pesos (Pl0,000.00) for -

(A) failure to obtain a certificate as required by Section 2 of this Act;

(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 Section 6 or the requirements described in clauses (a) through (c) of Section 4(1)(B)(ii) of this Act; 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 of Health shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under subsections (1) and (2) of this section. 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 appropriate sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

SECTION 9. *Suspension and Revocation.* -

(1) In general - The certificate of a facility issued under Section 3 of this Act may be suspended or revoked if the Secretary of Health finds, after providing, except as provided in subsection 2, reasonable notice and an opportunity for a hearing to the owner or operator of this 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 Section 4(l)(B)(ii)(c) of this Act or the standards established by the Secretary of Health under Section 6 of this Act.

(C) has failed to comply with reasonable requests of the Secretary of Health for any record, information, report, or material that the Secretary of Health for any record, information, report, or material that the Secretary of Health concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under Section 6.

(D) has refused a reasonable request of the Secretary of Health or any government officer or employee duly designated by the Secretary of Health, for permission to inspect the facility of the operations and pertinent records in accordance with Section 7 of this Act;

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

(F) has failed to comply with a sanction imposed under Section 8 of this Act.

(2) Action before a hearing -

(A) In general - The Secretary of Health may suspend the certificate of the facility before holding a hearing required by subsection (1) if the Secretary makes the finding described in subsection (1) and determines that - (i) the failure of a facility to comply with the standards established by the Secretary of Health under subsection (1) of this Act presents a serious risk to human health; or (ii) a facility has engaged in action described in paragraph (D) of subsection (I) of this section.

(B) Hearing - If the Secretary of Health suspends a certificate under subsection (1) of this section, the Secretary shall provide an opportunity for a hearing to the owner

or operator of the facility not later than sixty (60) days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary of Health made after the hearing.

(3) Ineligibility to own or operate facilities after revocation - If the Secretary of Health revokes the certificate of a facility on the basis of an act described in subsection (l), no person who owned or operated the facility at the time of the act may, within two (2) years of the revocation of the certificate, own or operate a facility that requires a certificate under this Act.

SECTION 10. *Injunctions.* - If the Secretary of Health 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 of Health may bring suit to enjoin continuation of the activity; and (2) a facility is operating without a certificate as required by Section 2 of this Act, the Secretary may bring suit to enjoin operation of the facility.

Upon a proper showing, the 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.

SECTION 11. *Information.* -

(1)In general -Not later than two (2) years after the passage of this Act, and annually thereafter, the Secretary of health shall compile and make available to physicians and the general public information that the Secretary of Health determines is useful in evaluating the performance of facilities, including a list of facilities –

(A) that have been convicted for fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under Section 8 of this Act, together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under Section 9 together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary of Health has taken action under Section 9 of this Act, together with a statement of the reasons for the action;

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

(F) against which a local government unit has taken adverse action; and

(G) that meets such other measures of performance as the Secretary of Health may develop.

(2) Date - The information to be complied under subsection (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 complied under subsection (1) shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the interpretation compiled under such paragraph.

SECTION 12. *National Advisory Committee.* -

(1) Establishment - In carrying out this section, the Secretary of Health shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter referred to as the "Advisory Committee").

(2) Composition - The Advisory Committee shall be composed of not fewer than thirteen (13) nor more than nineteen (19) individuals who are not officers or employees of the government. The Secretary of Health shall make appointment to the Advisory Committee from among -

(A) physicians;

(B) practitioners;

(C) other health professionals; whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary of Health shall appoint at least four (4) individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least two (2) practicing physicians who provide mammography services.

(3) Functions and duties - The Advisory committee shall -

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

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

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

(D) assist in developing procedures for monitoring compliance with standards under Section 6 of this Act;

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

(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 Section 6 of this Act on access to the services of such facilities in such areas;

(H) determine whether there still exists a sufficient number of medical physicists seven (7) years after the passage of this Act, to assure compliance with the requirements of Section 6(1)(E) of this Act;

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

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

The Advisory Committee shall report the findings made under paragraphs (G) and (I) to the Secretary of Health and Congress not later than one (I) year after the passage of this Act.

(4) Meetings - The Advisory Committee shall meet not less than quarterly for the first three (3) years of the program and thereafter, at least biannually.

(5) Chairperson - The Secretary shall appoint a chairperson of the Advisory Committee.

SECTION 13. *Consultations.* - In carrying out this Act, the Secretary of Health shall consult with appropriate government agencies within the Department of Health for the purposes of developing standards, regulations, evaluations, and procedures for compliance and oversight.

SECTION 14. *Separability Clause.* - If any person, or part hereof, is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SECTION 15. *Repealing Clause.* - Any law, presidential decree, or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with, the provisions of this Act is hereby repealed or amended accordingly.

SECTION 16. *Effectivity clause.* - This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.

Approved,