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

Senate
Office of the Secretary

'13 OCT -3 P6 :01

SENATE
S. No. 1819

RECEIVED BY:

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.*

MIRIAM DEFENSOR SANTIAGO

acs

* This bill was originally filed during the Fourteenth Congress, First Regular Session.

Senate
Office of the Secretary

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

'13 OCT -3 P6 :01

SENATE
S. No. 1819

RECEIVED BY:

Introduced by Senator Miriam Defensor Santiago

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 this Act to accredit mammography facilities;

(2) "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;

(3) "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 under this Act;

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

(5) "Survey" means an on-site physical consultation and evaluation performed by medical physicist as provided for under 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 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 this Act; (ii) that is applicable to the examination or procedure to be conducted; and (iii) that is displayed prominently in such facility. The reference to a certificate in this section includes a provisional certificate.

(2) Examination or Procedure - A facility shall obtain a certificate in order to -

(A) Operate 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 facility meets the applicable requirements of this Act. 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. 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 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 authorized 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; 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 this Act to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will permit inspections pursuant to this Act and make such reports to the Secretary of Health as the Secretary may require; and

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

(2) Appeal - If the Secretary of Health denies an application for the certification of a facility submitted under 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 to be issued by the Secretary.

SECTION 5. *Quality Standards.* -

(1) In general - The Secretary of Health shall establishing the following standards -

(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 be licensed to perform radiological procedures;

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

(E) A requirement that individuals who survey mammography facilities be medical physicists –

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

(ii) certified in diagnostic radiological physics or certified to perform such surveys; or

(iii) *in the first five (5) years after this Act is passed, who meet other criteria established by the Secretary of Health.*

(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.

SECTION 6. *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 5 of this Act.

(B) Identification - The Secretary of Health or the Secretary's authorized representative, 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 the Secretary's authorized representative - (i) shall have access to all equipment, materials, records, and information that the Secretary of Health or the Secretary's authorized representative 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 Secretary's authorized representative, any of the said equipment, materials, records, or information.

(D) Frequency - The Secretary of Health or the Secretary's authorized representative shall conduct inspections of each facility no less often than annually.

(E) Records and Annual Reports - The Secretary of Health shall maintain records of annual inspections required under this Section for a period of not less than five (5) years. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) Timing - The Secretary of Health or the Secretary's authorized representative may conduct inspections under this Section 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.

(3) 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 this section.

SECTION 7. *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 8 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) Civil penalties - The Secretary of Health may assess civil money penalties in an amount not to exceed One Hundred Thousand Pesos (P100,000.00) for the following:

(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 5 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 Act 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 8. *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 of this Act or the standards established by the Secretary of Health under Section 5 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 5.

(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 6 of this Act;

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

(F) has failed to comply with a sanction imposed under Section 7 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 9. *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 Section.

SECTION 10. *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 7 of this Act, together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under Section 8 together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary of Health has taken action under Section 8 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 11. *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 5 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 5 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 5 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 (1) 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 12. *Consultations.* - In carrying out this Act, the Secretary of Health shall consult with appropriate government agencies for the purpose of developing standards, regulations, evaluations, and procedures for compliance and oversight.

SECTION 13. *Separability Clause.* - If any provision 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 14. *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, modified, 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,