

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1393 Session of
1991

INTRODUCED BY SCHWARTZ, PETERSON, O'PAKE, FUMO, BRIGHTBILL,
JONES, BELAN, AFFLERBACH, LYNCH, FATTAH, ANDREZESKI, LINCOLN,
BORTNER, REIBMAN, STAPLETON, MUSTO, JUBELIRER, MELLOW, STOUT,
LEWIS, PORTERFIELD, CORMAN, SALVATORE, ARMSTRONG, HELFRICK,
RHOADES, BELL, HART, FISHER, HOLL, GREENLEAF, MADIGAN,
LAVALLE, DAWIDA, WILLIAMS, SCANLON, HOPPER AND SHUMAKER,
OCTOBER 29, 1991

SENATOR TILGHMAN, APPROPRIATIONS, RE-REPORTED AS AMENDED,
MAY 12, 1992

AN ACT

1 ~~Providing for the authorization by the Department of Health of~~ <—
2 ~~radiation machines used to perform mammography; specifying~~
3 ~~application and inspection procedures; providing for~~
4 ~~withdrawal and reinstatement of authorization; and imposing a~~
5 ~~penalty.~~

6 ~~The General Assembly finds as follows:~~

7 ~~(1) Breast cancer is the most common cancer and the~~
8 ~~second leading cause of cancer deaths in the United States.~~

9 ~~(2) It is estimated that there will be 10,300 new cases~~
10 ~~of breast cancer in this Commonwealth in 1991, and 2,600~~
11 ~~breast cancer deaths.~~

12 ~~(3) One of every ten women can expect to develop breast~~
13 ~~cancer in her lifetime.~~

14 ~~(4) Early detection of breast cancer is the most~~
15 ~~effective means to reduce breast cancer mortality.~~

16 ~~(5) Periodic screening mammography, in conjunction with~~

~~good health care and monthly self examination, can reduce a woman's risk of dying from breast cancer by 30%.~~

~~(6) A mammogram is among the radiographic images most difficult to read thus requiring adherence to strict quality standards to insure optimal clarity.~~

~~(7) If a mammogram image quality is poor or the interpretation is faulty, the interpreter may miss cancerous lesions which could delay treatment and result in avoidable mastectomy or death.~~

PROVIDING FOR LICENSURE OF SCREENING MAMMOGRAPHY SERVICE

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PROVIDERS; PRESCRIBING POWERS AND DUTIES OF THE DEPARTMENT OF HEALTH; ESTABLISHING RADIATION MACHINE AND FACILITY INSPECTION PROCEDURES; PROVIDING FOR LICENSURE REVOCATION AND NONRENEWAL; AND IMPOSING PENALTIES.

THE GENERAL ASSEMBLY FINDS AS FOLLOWS:

(1) BREAST CANCER IS THE MOST COMMON CANCER AND THE SECOND LEADING CAUSE OF CANCER DEATHS IN THE UNITED STATES.

(2) THERE WERE APPROXIMATELY 10,300 NEW CASES OF BREAST CANCER IN THIS COMMONWEALTH IN 1991 AND 2,600 BREAST CANCER DEATHS.

(3) ONE OF EVERY TEN WOMEN CAN EXPECT TO DEVELOP BREAST CANCER IN HER LIFETIME.

(4) EARLY DETECTION OF BREAST CANCER IS THE MOST EFFECTIVE MEANS TO REDUCE BREAST CANCER MORTALITY.

(5) PERIODIC SCREENING MAMMOGRAPHY, IN CONJUNCTION WITH GOOD HEALTH CARE AND MONTHLY SELF-EXAMINATION, CAN REDUCE A WOMAN'S RISK OF DYING FROM BREAST CANCER BY 30%.

(6) A MAMMOGRAM IS AMONG THE RADIOGRAPHIC IMAGES MOST DIFFICULT TO READ THUS REQUIRING ADHERENCE TO STRICT QUALITY STANDARDS TO INSURE OPTIMAL CLARITY.

(7) IF A MAMMOGRAM IMAGE QUALITY IS POOR OR THE
INTERPRETATION IS FAULTY, THE INTERPRETER MAY MISS CANCEROUS
LESIONS WHICH COULD DELAY TREATMENT AND RESULT IN AVOIDABLE
MASTECTOMY OR DEATH.

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The General Assembly of the Commonwealth of Pennsylvania
hereby enacts as follows:

~~Section 1. Short title.~~

~~This act shall be known and may be cited as the Mammography
Quality Assurance Act.~~

~~Section 2. Definitions.~~

~~The following words and phrases when used in this act shall
have the meanings given to them in this section unless the~~

~~context clearly indicates otherwise:~~

~~"Department."—The Department of Health of the Commonwealth.~~

~~"Mammography system."—The radiation machine used for
mammography; automatic exposure control devices; films, screens
and cassettes; image processors; darkrooms; and viewboxes.~~

~~"Qualified radiation physicist."—An individual certified by
the American Board of Radiology in Radiological Physics or
Diagnostic Radiological Physics.~~

~~"Radiation machine."—Any device that emits ionizing
radiation.~~

~~"Radiation technologist."—An individual certified by the
American Registry of Radiological Technologists.~~

~~Section 3.—Authorization by department.~~

~~(a)—General rule.—A person shall not use a radiation
machine to perform mammography unless the radiation machine is
specifically authorized by the department under this act for use
for mammography.~~

~~(b)—Standards.—The department shall authorize a radiation
machine for use for mammography if the following requirements
are met:~~

~~(1)—The radiation machine meets the criteria for the
American College of Radiology accreditation program as
adopted in June 1987, including subsequent amendments, by the
American College of Radiology. The department shall make
available copies of those criteria to the public and may by
rule adopt modified criteria, so long as the criteria are not
less stringent than the criteria established by the American
College of Radiology.~~

~~(2)—The radiation machine is specifically designed to
perform mammography.~~

~~(3) The radiation machine is used in a facility that does all of the following:~~

~~(i) At least annually has a qualified radiation physicist calibrate the radiation machine and provide onsite consultation to the facility, including, but not limited to, a complete evaluation of the entire mammography system to ensure compliance with this act and the rules promulgated under this act.~~

~~(ii) Maintains for at least seven years records of the consultation required in subparagraph (i) and the findings of the consultation.~~

~~(iii) Establishes a quality control program which meets the criteria for the American College of Radiology mammography accreditation program.~~

~~(iv) Retains and makes available to patients original mammograms for a period of at least five years.~~

~~(4) The radiation machine is operated by a radiation technologist who meets the criteria for the American College of Radiology mammography accreditation program.~~

~~(5) The interpreting physician meets certification, training and continuing education requirements for the American College of Radiology accreditation program.~~

~~Section 4. Temporary authorization.~~

~~The department may issue a nonrenewable temporary authorization for a radiation machine for use for mammography if additional time is needed for submission of evidence satisfactory to the department that the radiation machine meets the standards set forth in section 3(b) for approval for mammography. A temporary authorization granted under this section during the first 18 months following the effective date~~

~~1 of this act shall be effective for no more than six months. A~~
~~2 temporary authorization granted under this section after 18~~
~~3 months following the effective date of this act shall be~~
~~4 effective for no more than three months. The department may~~
~~5 withdraw a temporary authorization prior to its expiration if~~
~~6 the radiation machine does not meet one or more of the standards~~
~~7 set forth in section 3(b).~~

~~8 Section 5.— Application.~~

~~9 (a) General rule.— To obtain authorization from the~~
~~10 department to use a radiation machine for mammography, the~~
~~11 person who owns or leases the radiation machine or an authorized~~
~~12 agent of the person shall apply to the department for~~
~~13 mammography authorization on an application form provided by the~~
~~14 department and shall provide all of the information required by~~
~~15 the department as specified on the application form.~~

~~16 (b) Multiple machines.— A person who owns or leases more~~
~~17 than one radiation machine used for mammography shall obtain~~
~~18 authorization for each radiation machine.~~

~~19 (c) Department response.— The department shall process and~~
~~20 respond to an application within 30 days after the date of~~
~~21 receipt of the application.~~

~~22 (d) Certificate of registration.— Upon determining to grant~~
~~23 mammography authorization for a radiation machine, the~~
~~24 department shall issue a certificate of registration specifying~~
~~25 mammography authorization for each authorized radiation machine.~~
~~26 A mammography authorization is effective for three years.~~

~~27 Section 6.— Inspections.~~

~~28 (a) Initial inspection.— No later than 60 days after initial~~
~~29 mammography authorization of a radiation machine under this act,~~
~~30 the department shall inspect the radiation machine. However,~~

~~during the first year following the effective date of this act,
the department may conduct the initial inspection later than 60
days after the initial mammography authorization.~~

~~(b) Subsequent inspection. After the initial inspection,
the department shall annually inspect the radiation machine and
may inspect the radiation machine more frequently. The
department shall make reasonable efforts to coordinate the
inspections under this section with the department's other
inspections of the facility in which the radiation machine is
located.~~

~~(c) Inspection certificate. After each satisfactory
inspection by the department, the department shall issue a
certificate of radiation machine inspection or a similar
document identifying the facility and radiation machine
inspected and providing a record of the date the radiation
machine was inspected. The facility shall post the certificate
or other document near the inspected radiation machine.~~

~~Section 7. Alternate authorization procedure.~~

~~In lieu of the application requirements of section 5 and the
inspection requirements of section 6, documentation of American
College of Radiology accreditation may be submitted on an annual
basis as evidence of compliance with section 3.~~

~~Section 8. Withdrawal of authorization.~~

~~(a) General rule. The department may withdraw the
mammography authorization for a radiation machine if it does not
meet one or more of the standards set forth in section 3(b).~~

~~(b) Hearing. The department shall provide an opportunity
for a hearing in accordance with 2 Pa.C.S. (relating to
administrative law and procedure) in connection with a denial or
withdrawal of mammography authorization.~~

~~(c) Emergency. Upon a finding that a deficiency in a radiation machine used for mammography or a violation of this act or the rules promulgated under this act seriously affects the health, safety and welfare of individuals upon whom the radiation machine is used for mammography, the department may issue an emergency order summarily withdrawing the mammography authorization of the radiation equipment. The department shall incorporate its findings in the order and shall provide an opportunity for a hearing within five working days after issuance of the order. The order shall be effective during the proceedings.~~

~~(d) Reinstatement. If the department withdraws the mammography authorization of a radiation machine, the radiation machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization under section 5, except that the department shall not issue a reinstated certificate of mammography registration until the department inspects the radiation machine and determines that it meets the standards set forth in section 3(b). The department shall conduct an inspection required under this subsection no later than 60 days after receiving a proper application for reinstatement of a mammography authorization.~~

~~Section 9. Penalty.~~

~~If a person violates this act, the department may impose a fine of not more than \$500 for each calendar week in which a mammography is performed in violation of this act against the owner of the radiation machine or, if a lessee of the radiation machine has effective control of the radiation machine, the lessee. If a person continues to violate this act for a period~~

1 ~~of two weeks after a fine is imposed under this section, the~~
2 ~~department shall post a conspicuous notice on the unauthorized~~
3 ~~radiation machine and at the entry to the facility where the~~
4 ~~radiation machine is located warning the public that the~~
5 ~~facility is performing mammography using a radiation machine~~
6 ~~that is a substantial hazard to public health.~~

7 ~~Section 10. Regulations.~~

8 ~~The department may promulgate rules and regulations to~~
9 ~~administer and enforce this act.~~

10 ~~Section 11. Effective date.~~

11 ~~This act shall take effect in 60 days.~~

12 SECTION 1. SHORT TITLE.

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13 THIS ACT SHALL BE KNOWN AND MAY BE CITED AS THE MAMMOGRAPHY
14 QUALITY ASSURANCE ACT.

15 SECTION 2. DEFINITIONS.

16 THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS ACT SHALL
17 HAVE THE MEANINGS GIVEN TO THEM IN THIS SECTION UNLESS THE
18 CONTEXT CLEARLY INDICATES OTHERWISE:

19 "DEPARTMENT." THE DEPARTMENT OF HEALTH OF THE COMMONWEALTH.

20 "MAMMOGRAPHY SYSTEM." THE RADIATION MACHINE USED FOR
21 MAMMOGRAPHY; AUTOMATIC EXPOSURE CONTROL DEVICES; FILMS, SCREENS
22 AND CASSETTES; IMAGE PROCESSORS; DARKROOMS AND VIEWBOXES.

23 "QUALIFIED RADIATION PHYSICIST." AN INDIVIDUAL CERTIFIED BY
24 THE AMERICAN BOARD OF RADIOLOGY IN RADIOLOGICAL PHYSICS OR
25 DIAGNOSTIC RADIOLOGICAL PHYSICS.

26 "RADIATION MACHINE." ANY DEVICE THAT EMITS IONIZING
27 RADIATION.

28 "RADIATION TECHNOLOGIST." AS DEFINED IN REGULATIONS
29 PROMULGATED UNDER SECTION 4163 OF THE OMNIBUS BUDGET
30 RECONCILIATION ACT OF 1990 (PUBLIC LAW 101-508, 104 STAT. 1388).

1 "SCREENING MAMMOGRAPHY FACILITY." AN INDIVIDUAL,
2 ORGANIZATION, FACILITY, INSTITUTION OR PART THEREOF STAFFED AND
3 EQUIPPED TO PROVIDE SCREENING MAMMOGRAPHY SERVICES.

4 "SCREENING MAMMOGRAPHY SERVICE." A RADIOLOGIC PROCEDURE
5 FURNISHED TO AN ASYMPTOMATIC WOMAN FOR THE PURPOSE OF EARLY
6 DETECTION OF BREAST CANCER. THE TERM INCLUDES A PHYSICIAN'S
7 INTERPRETATION OF THE RESULTS OF THE PROCEDURE.

8 SECTION 3. AUTHORIZATION BY DEPARTMENT.

9 (A) GENERAL RULE.--A PERSON SHALL NOT USE A RADIATION
10 MACHINE TO PERFORM MAMMOGRAPHY UNLESS THE RADIATION MACHINE IS
11 SPECIFICALLY AUTHORIZED BY THE DEPARTMENT UNDER THIS ACT FOR USE
12 FOR MAMMOGRAPHY.

13 (B) STANDARDS.--NO PERSON SHALL MAINTAIN OR OPERATE A
14 SCREENING MAMMOGRAPHY SERVICE WITHOUT FIRST OBTAINING A LICENSE
15 TO OPERATE SUCH A SERVICE, EXCEPT THAT A PROVIDER OF SCREENING
16 MAMMOGRAPHY SERVICES APPROVED BY THE DEPARTMENT UNDER SECTION
17 4163 OF THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990 (PUBLIC
18 LAW 101-508, 104 STAT. 1388) IS EXEMPT FROM THE PROVISIONS OF
19 THIS ACT. SUCH LICENSE SHALL BE BASED ON MEETING THE FOLLOWING
20 REQUIREMENTS:

21 (1) THE RADIATION MACHINE MEETS THE CRITERIA ESTABLISHED
22 BY REGULATIONS PROMULGATED UNDER SECTION 4163 OF THE OMNIBUS
23 BUDGET RECONCILIATION ACT OF 1990. THE DEPARTMENT OF HEALTH
24 MAY CONTRACT WITH THE DEPARTMENT OF ENVIRONMENTAL RESOURCES
25 TO DETERMINE WHETHER THE RADIATION MACHINE MEETS THE REQUIRED
26 CRITERIA.

27 (2) THE RADIATION MACHINE IS SPECIFICALLY DESIGNED TO
28 PERFORM MAMMOGRAPHY.

29 (3) THE PROVIDER OF SCREENING MAMMOGRAPHY SERVICES DOES
30 ALL OF THE FOLLOWING:

1 (I) ESTABLISHES A QUALITY CONTROL PROGRAM, INCLUDING
2 INSPECTIONS BY A QUALIFIED RADIATION PHYSICIST, THAT
3 MEETS THE CRITERIA ESTABLISHED BY REGULATIONS PROMULGATED
4 UNDER SECTION 4163 OF THE OMNIBUS BUDGET RECONCILIATION
5 ACT OF 1990.

6 (II) RETAINS AND MAKES AVAILABLE TO PATIENTS
7 ORIGINAL MAMMOGRAMS AS REQUIRED BY REGULATIONS
8 PROMULGATED UNDER SECTION 4163 OF THE OMNIBUS BUDGET
9 RECONCILIATION ACT OF 1990.

10 (4) A RADIATION TECHNOLOGIST WHO MEETS THE CRITERIA
11 ESTABLISHED BY REGULATIONS PROMULGATED UNDER SECTION 4163 OF
12 THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990 OPERATES THE
13 RADIATION MACHINE.

14 (5) THE INTERPRETING PHYSICIAN MEETS THE CRITERIA
15 ESTABLISHED BY REGULATIONS PROMULGATED UNDER SECTION 4163 OF
16 THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990.

17 SECTION 4. APPLICATION.

18 (A) GENERAL RULE.--TO OBTAIN A LICENSE TO OPERATE SCREENING
19 MAMMOGRAPHY SERVICES, THE PROVIDER OF SCREENING MAMMOGRAPHY
20 SERVICES SHALL APPLY TO THE DEPARTMENT ON AN APPLICATION FORM
21 PROVIDED BY THE DEPARTMENT AND SHALL PROVIDE ALL OF THE
22 INFORMATION REQUIRED BY THE DEPARTMENT AS SPECIFIED ON THE
23 APPLICATION FORM.

24 (B) MULTIPLE MACHINES.--A PROVIDER OF SCREENING MAMMOGRAPHY
25 SERVICES WHO OWNS OR LEASES MORE THAN ONE RADIATION MACHINE USED
26 FOR MAMMOGRAPHY SHALL NOTIFY THE DEPARTMENT OF EACH RADIATION
27 MACHINE.

28 (C) EXPANSION OF SCREENING MAMMOGRAPHY SERVICE.--APPLICATION
29 FOR EXPANSION OF A PREVIOUSLY LICENSED FACILITY SHALL BE MADE ON
30 FORMS FURNISHED BY THE DEPARTMENT.

(D) ISSUANCE OF LICENSE.--

(1) THE DEPARTMENT SHALL ISSUE A LICENSE UPON DETERMINING THAT THE APPLICANT HAS MET THE FOLLOWING CRITERIA:

(I) THE SCREENING MAMMOGRAPHY SERVICE PROVIDER IS A RESPONSIBLE PERSON.

(II) THE LOCATION TO BE USED AS A SCREENING MAMMOGRAPHY FACILITY IS ADEQUATELY CONSTRUCTED, EQUIPPED, MAINTAINED AND OPERATED TO SAFELY AND EFFICIENTLY RENDER THE SERVICES OFFERED.

(III) THE SCREENING MAMMOGRAPHY FACILITY PROVIDES SAFE AND EFFICIENT SERVICES WHICH ARE ADEQUATE FOR THE CARE, TREATMENT AND COMFORT OF THE PATIENTS OF THE FACILITY.

(IV) THERE IS SUBSTANTIAL COMPLIANCE WITH THIS ACT AND ANY RULES AND REGULATIONS ADOPTED BY THE DEPARTMENT UNDER THIS ACT.

(2) IN LIEU OF MEETING THE CRITERIA UNDER PARAGRAPH (1), IF THE SCREENING MAMMOGRAPHY SERVICE PROVIDER SUBMITS TO THE DEPARTMENT ANNUAL DOCUMENTATION OF FULL COMPLIANCE WITH THE AMERICAN COLLEGE OF RADIOLOGY ACCREDITATION PROGRAM, THE DEPARTMENT SHALL ISSUE A LICENSE WHICH SPECIFIES THE NUMBER OF AUTHORIZED RADIATION MACHINES.

(3) EACH LICENSE ISSUED BY THE DEPARTMENT SHALL SPECIFY THE NUMBER OF AUTHORIZED RADIATION MACHINES LOCATED AT A GIVEN SCREENING MAMMOGRAPHY FACILITY. A SCREENING MAMMOGRAPHY FACILITY LICENSE IS EFFECTIVE FOR THREE YEARS. THE FACILITY SHALL POST ITS LICENSE IN A PROMINENT LOCATION.

SECTION 5. INSPECTIONS.

(A) INITIAL INSPECTION.--NO LICENSE TO OPERATE A SCREENING

1 MAMMOGRAPHY FACILITY SHALL BE ISSUED UNTIL THE DEPARTMENT HAS
2 INSPECTED THE FACILITY, INCLUDING EACH RADIATION MACHINE.
3 PREVIOUSLY EXISTING PROVIDERS OF MAMMOGRAPHY SERVICES MAY
4 CONTINUE IN OPERATION UNTIL THE DEPARTMENT CONDUCTS THE INITIAL
5 INSPECTION WHICH SHALL OCCUR NO LATER THAN 60 DAYS FOLLOWING THE
6 EFFECTIVE DATE OF THIS ACT.

7 (B) SUBSEQUENT INSPECTION.--AFTER THE INITIAL INSPECTION,
8 THE DEPARTMENT SHALL ANNUALLY INSPECT THE SCREENING MAMMOGRAPHY
9 FACILITY AND MAY INSPECT THE RADIATION MACHINE MORE FREQUENTLY.
10 THE DEPARTMENT SHALL MAKE REASONABLE EFFORTS TO COORDINATE THE
11 INSPECTIONS UNDER THIS SECTION WITH THE DEPARTMENT'S OTHER
12 INSPECTIONS OF THE FACILITY IN WHICH THE RADIATION MACHINE IS
13 LOCATED.

14 (C) INSPECTION CERTIFICATE.--AFTER EACH INSPECTION BY THE
15 DEPARTMENT WHICH FINDS THE SCREENING MAMMOGRAPHY FACILITY IN
16 FULL COMPLIANCE WITH THE REQUIREMENTS OF THIS ACT, THE
17 DEPARTMENT SHALL ISSUE A CERTIFICATE OF RADIATION MACHINE
18 INSPECTION OR A SIMILAR DOCUMENT IDENTIFYING THE FACILITY AND
19 RADIATION MACHINE INSPECTED AND PROVIDING A RECORD OF THE DATE
20 THE RADIATION MACHINE WAS INSPECTED. THE FACILITY SHALL POST THE
21 CERTIFICATE OR OTHER DOCUMENT NEAR THE INSPECTED RADIATION
22 MACHINE.

23 SECTION 6. REASONS FOR REVOCATION OR NONRENEWAL OF LICENSE.

24 THE DEPARTMENT MAY REFUSE TO RENEW A LICENSE OR MAY SUSPEND
25 OR REVOKE OR LIMIT A LICENSE FOR ALL OR ANY PORTION OF A
26 SCREENING MAMMOGRAPHY FACILITY FOR THE FOLLOWING REASONS:

27 (1) A SERIOUS VIOLATION OF THIS ACT OR OF LICENSURE
28 REGULATIONS ISSUED UNDER THIS ACT. FOR THE PURPOSE OF THIS
29 PARAGRAPH, A SERIOUS VIOLATION IS ONE WHICH POSES A
30 SIGNIFICANT THREAT TO THE HEALTH OF PATIENTS.

1 (2) FAILURE OF A LICENSEE TO SUBMIT A REASONABLE
2 TIMETABLE TO CORRECT DEFICIENCIES.

3 (3) THE EXISTENCE OF A CYCLICAL PATTERN OF DEFICIENCIES
4 OVER A PERIOD OF TWO OR MORE YEARS.

5 (4) FAILURE TO CORRECT DEFICIENCIES IN ACCORDANCE WITH A
6 TIMETABLE SUBMITTED BY THE APPLICANT AND AGREED UPON BY THE
7 DEPARTMENT.

8 (5) FRAUD OR DECEIT IN OBTAINING OR ATTEMPTING TO OBTAIN
9 A LICENSE.

10 (6) LENDING, BORROWING OR USING THE LICENSE OF ANOTHER
11 OR IN ANY WAY KNOWINGLY AIDING OR ABETTING THE IMPROPER
12 GRANTING OF A LICENSE.

13 (7) INCOMPETENCE, NEGLIGENCE OR MISCONDUCT IN OPERATING
14 A SCREENING MAMMOGRAPHY FACILITY OR IN PROVIDING SERVICES TO
15 OR TREATMENT OF PATIENTS.

16 (8) A SERIOUS VIOLATION OF THE LAWS RELATING TO MEDICAL
17 ASSISTANCE OR MEDICARE REIMBURSEMENT.

18 SECTION 7. RIGHT TO ENTER AND INSPECT.

19 FOR THE PURPOSE OF DETERMINING THE SUITABILITY OF THE
20 APPLICANTS AND OF THE PREMISES OR FOR DETERMINING THE ADEQUACY
21 OF THE CARE AND TREATMENT PROVIDED OR THE CONTINUING CONFORMITY
22 OF THE LICENSEES TO THIS ACT AND TO APPLICABLE FEDERAL, STATE
23 AND LOCAL REGULATIONS, ANY AUTHORIZED AGENT OF THE DEPARTMENT
24 MAY ENTER, VISIT AND INSPECT THE BUILDING, GROUNDS, EQUIPMENT
25 AND SUPPLIES OF ANY SCREENING MAMMOGRAPHY FACILITY LICENSED OR
26 REQUIRING A LICENSE UNDER THIS ACT AND SHALL HAVE FULL AND FREE
27 ACCESS TO THE RECORDS OF THE FACILITY AND TO THE PATIENTS AND
28 EMPLOYEES THEREIN AND THEIR RECORDS, AND SHALL HAVE FULL
29 OPPORTUNITY TO INTERVIEW THE PATIENTS AND EMPLOYEES. UPON
30 ENTERING A SCREENING MAMMOGRAPHY FACILITY, THE INSPECTORS SHALL

1 PROPERLY IDENTIFY THEMSELVES TO THE INDIVIDUAL ON THE PREMISES
2 THEN IN CHARGE OF THE FACILITY.

3 SECTION 8. PROVIDER VIOLATIONS.

4 (A) NOTICE OF VIOLATIONS.--WHENEVER THE DEPARTMENT SHALL,
5 UPON INSPECTION, INVESTIGATION OR COMPLAINT, FIND A VIOLATION OF
6 THIS ACT OR REGULATIONS ADOPTED BY THE DEPARTMENT UNDER THIS ACT
7 OR UNDER FEDERAL LAW, IT SHALL GIVE WRITTEN NOTICE THEREOF
8 SPECIFYING THE VIOLATION FOUND TO THE SCREENING MAMMOGRAPHY
9 FACILITY. THE NOTICE SHALL REQUIRE THE SCREENING MAMMOGRAPHY
10 SERVICE PROVIDER TO TAKE ACTION OR TO SUBMIT A PLAN OF
11 CORRECTION WHICH SHALL BRING THE SCREENING MAMMOGRAPHY FACILITY
12 INTO COMPLIANCE WITH APPLICABLE LAW OR REGULATION WITHIN A
13 SPECIFIED TIME. THE PLAN OF CORRECTION MUST BE SUBMITTED WITHIN
14 TEN DAYS OF RECEIPT OF THE WRITTEN NOTICE.

15 (B) APPOINTMENT OF TEMPORARY MANAGEMENT.--WHEN THE SCREENING
16 MAMMOGRAPHY SERVICE PROVIDER HAS FAILED TO BRING THE FACILITY
17 INTO COMPLIANCE WITHIN THE TIME SPECIFIED BY THE DEPARTMENT, OR
18 WHEN THE FACILITY HAS DEMONSTRATED THAT IT IS UNWILLING OR
19 UNABLE TO ACHIEVE COMPLIANCE, SUCH AS WOULD CONVINCE A
20 REASONABLE PERSON THAT ANY CORRECTION OF VIOLATIONS WOULD BE
21 UNLIKELY TO BE MAINTAINED, THE DEPARTMENT MAY PETITION THE
22 COMMONWEALTH COURT OR THE COURT OF COMMON PLEAS OF THE COUNTY IN
23 WHICH THE FACILITY IS LOCATED TO APPOINT TEMPORARY MANAGEMENT
24 DESIGNATED AS QUALIFIED BY THE DEPARTMENT TO ASSUME OPERATION OF
25 THE FACILITY AT THE FACILITY'S EXPENSE TO ASSURE THE HEALTH AND
26 SAFETY OF THE FACILITY PATIENTS UNTIL IMPROVEMENTS ARE MADE TO
27 BRING THE FACILITY INTO COMPLIANCE WITH THE LAWS AND REGULATIONS
28 FOR LICENSURE OR UNTIL THERE IS AN ORDERLY CLOSURE OF THE
29 FACILITY. IN THE ALTERNATE, THE DEPARTMENT MAY PROCEED IN
30 ACCORDANCE WITH THIS ACT.

1 SECTION 9. DEPARTMENTAL ORDERS.

2 ORDERS OF THE DEPARTMENT FROM WHICH NO APPEAL IS TAKEN TO THE
3 STATE HEALTH FACILITY HEARING BOARD AND ORDERS OF THE BOARD FROM
4 WHICH NO TIMELY APPEAL IS TAKEN TO THE COMMONWEALTH COURT ARE
5 FINAL ORDERS AND MAY BE ENFORCED IN COURT.

6 SECTION 10. ACTIONS AGAINST UNLICENSED HEALTH CARE PROVIDERS.

7 (A) ACTIONS IN EQUITY.--WHENEVER A LICENSE IS REQUIRED UNDER
8 THIS ACT TO MAINTAIN OR OPERATE A SCREENING MAMMOGRAPHY
9 FACILITY, THE DEPARTMENT MAY MAINTAIN AN ACTION IN THE NAME OF
10 THE COMMONWEALTH FOR AN INJUNCTION OR OTHER PROCESS RESTRAINING
11 OR PROHIBITING ANY PERSON FROM ESTABLISHING, CONDUCTING OR
12 OPERATING ANY UNLICENSED SCREENING MAMMOGRAPHY FACILITY.

13 (B) PERMANENT INJUNCTION.--SHOULD A PERSON WHO IS REFUSED A
14 LICENSE OR THE RENEWAL OF A LICENSE TO OPERATE OR CONDUCT A
15 SCREENING MAMMOGRAPHY FACILITY, OR WHOSE LICENSE TO OPERATE OR
16 CONDUCT A SCREENING MAMMOGRAPHY FACILITY IS SUSPENDED OR
17 REVOKED, FAIL TO APPEAL, OR SHOULD SUCH APPEAL BE DECIDED
18 FINALLY FAVORABLE TO THE DEPARTMENT, THEN THE COURT SHALL ISSUE
19 A PERMANENT INJUNCTION UPON PROOF THAT THE PERSON IS OPERATING
20 OR CONDUCTING A SCREENING MAMMOGRAPHY FACILITY WITHOUT A LICENSE
21 AS REQUIRED BY THIS ACT.

22 SECTION 11. ACTIONS AGAINST VIOLATION OF LAW, RULES AND
23 REGULATIONS.

24 (A) ACTIONS BROUGHT BY DEPARTMENT.--WHENEVER ANY PERSON,
25 REGARDLESS OF WHETHER SUCH PERSON IS A LICENSEE, HAS VIOLATED
26 ANY OF THE PROVISIONS OF THIS ACT OR THE REGULATIONS ISSUED
27 UNDER THIS ACT, THE DEPARTMENT MAY MAINTAIN AN ACTION IN THE
28 NAME OF THE COMMONWEALTH FOR AN INJUNCTION OR OTHER PROCESS
29 RESTRAINING OR PROHIBITING SUCH PERSON FROM ENGAGING IN SUCH
30 ACTIVITY.

1 (B) CIVIL PENALTY.--ANY PERSON, REGARDLESS OF WHETHER SUCH
2 PERSON IS A LICENSEE, WHO HAS COMMITTED A VIOLATION OF THIS ACT
3 OR ANY REGULATION UNDER THIS ACT, INCLUDING FAILURE TO CORRECT A
4 SERIOUS LICENSURE VIOLATION WITHIN THE TIME SPECIFIED IN A
5 DEFICIENCY CITATION, MAY BE ASSESSED A CIVIL PENALTY BY AN ORDER
6 OF THE DEPARTMENT OF UP TO \$500 FOR EACH DEFICIENCY FOR EACH DAY
7 THAT EACH DEFICIENCY CONTINUES. CIVIL PENALTIES SHALL BE
8 COLLECTED FROM THE DATE THE FACILITY RECEIVES NOTICE OF THE
9 VIOLATION UNTIL THE DEPARTMENT CONFIRMS CORRECTION OF THE
10 VIOLATION.

11 (C) FACILITY CLOSURE FOR THREAT TO HEALTH OR SAFETY.--
12 WHENEVER THE DEPARTMENT DETERMINES THAT DEFICIENCIES POSE AN
13 IMMEDIATE AND SERIOUS THREAT TO THE HEALTH OR SAFETY OF THE
14 PATIENTS SERVED BY A SCREENING MAMMOGRAPHY FACILITY, THE
15 DEPARTMENT MAY DIRECT THE CLOSURE OF THE FACILITY AND THE
16 TRANSFER OF PATIENTS AND THEIR RECORDS TO OTHER LICENSED OR
17 CERTIFIED SCREENING MAMMOGRAPHY FACILITIES.

18 SECTION 12. INJUNCTION OR RESTRAINING ORDER WHEN APPEAL IS
19 PENDING.

20 WHENEVER THE DEPARTMENT SHALL HAVE REFUSED TO GRANT OR RENEW
21 A LICENSE, OR SHALL HAVE SUSPENDED OR REVOKED A LICENSE REQUIRED
22 BY THIS ACT TO OPERATE OR CONDUCT A SCREENING MAMMOGRAPHY
23 FACILITY, OR SHALL HAVE ORDERED THE PERSON TO REFRAIN FROM
24 CONDUCT VIOLATING THE RULES AND REGULATIONS OF THE DEPARTMENT,
25 AND THE PERSON, DEEMING HIMSELF AGGRIEVED BY SUCH REFUSAL OR
26 SUSPENSION OR REVOCATION OR ORDER, SHALL HAVE APPEALED FROM THE
27 ACTION OF THE DEPARTMENT TO THE STATE HEALTH FACILITY HEARING
28 BOARD, OR FROM THE ORDER OF THE BOARD TO THE COMMONWEALTH COURT,
29 THE COURT MAY, DURING PENDENCY OF SUCH APPEAL, ISSUE A
30 RESTRAINING ORDER OR INJUNCTION UPON A SHOWING THAT THE

1 CONTINUED OPERATION OF THE SCREENING MAMMOGRAPHY FACILITY
2 ADVERSELY AFFECTS THE WELL-BEING, SAFETY OR INTEREST OF THE
3 PATIENTS OR THE SCREENING MAMMOGRAPHY FACILITY; OR THE COURT MAY
4 AUTHORIZE CONTINUED OPERATION OF THE FACILITY OR MAKE SUCH OTHER
5 ORDER, PENDING FINAL DISPOSITION OF THE CASE, AS JUSTICE AND
6 EQUITY REQUIRE.

7 SECTION 13. FEES.

8 THE DEPARTMENT MAY PUBLISH AS FINAL REGULATIONS ESTABLISHING
9 A FEE SCHEDULE IN CONNECTION WITH MAMMOGRAPHY AUTHORIZATION. THE
10 FEES SHALL BE PAID TO THE DEPARTMENT FOR DEPOSIT INTO THE STATE
11 TREASURY OF THE COMMONWEALTH. THE FEES ASSESSED BY THE
12 DEPARTMENT SHALL APPROXIMATE, TO THE EXTENT POSSIBLE, THE COSTS
13 REQUIRED TO IMPLEMENT THIS ACT. FEES SHALL BE ASSESSED FOR THE
14 FOLLOWING:

- 15 (1) LICENSURE OF SCREENING MAMMOGRAPHY FACILITIES.
16 (2) INSPECTIONS OF RADIATION MACHINES.

17 SECTION 14. REGULATIONS.

18 THE DEPARTMENT MAY PROMULGATE RULES AND REGULATIONS TO
19 ADMINISTER AND ENFORCE THIS ACT.

20 SECTION 15. EFFECTIVE DATE.

21 THIS ACT SHALL TAKE EFFECT IN 60 DAYS.