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MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 2003

DECEMBER 9, 2003.—Ordered to be printed

Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 1879]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1879) to amend the Public Health Service Act to revise and extend provisions relating to mammography quality standards, having considered the same, reports favorably thereon without amendment and recommends that the bill do pass.

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I. PURPOSE AND NEED FOR LEGISLATION

Breast cancer is the second leading cause of cancer deaths among American women. In 2001, an estimated 192,200 new cases of breast cancer were diagnosed and an estimated 40,200 women died from the disease. The probability of survival increases significantly, however, when breast cancer is discovered in its early stages. Currently, the most effective technique for early detection of breast cancer is screening mammography.

The Mammography Quality Standards Act was originally passed in 1992 to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. The MQSA has had a positive impact on mammography quality. FDA inspection data continue to show overall facility compliance with the national standards to ensure the quality of the x-ray images. Currently, over 60 percent of facilities have no violations, and only 2 percent have noncompliance with at the most serious level. Over 99 percent of all mammography facilities pass the phantom image test during their facility inspection. Experts agree that improving the quality of images should lead to more accurate interpretation by physicians and, therefore the MQSA remains an essential tool for early detection and for combating mortality associated with breast cancer. Moreover, the death rate from cancer in the U.S. has been decreasing about 2 percent annually during the past decade, suggesting that public awareness, early detection and improved therapies are having an impact on the disease.

Congress reauthorized MQSA in 1998, extending the program through 2002. Although MQSA was slated for reauthorization in the 107th Congress, no such action was taken on the bill due to controversy surrounding the best ways to enhance MQSA without causing additional medical litigation or flight from the mammography profession. Reducing the authorization period on a one-time basis from 5 years to 2 years will give the committee additional time to consider the best ways to enhance MQSA without affecting access to quality mammography services.

The Mammography Quality Standards Reauthorization Act of 2003 (S. 1879) is also needed to permit the Secretary to issue a temporary renewal certificate, under certain circumstances that do not affect the quality of mammography services, to allow for the completion of reaccreditation and recertification without a disruption of service that could result in the delay of the diagnosis and treatment of breast cancer. In addition, this legislation will permit the Secretary to issue a limited provisional certificate to allow a facility to perform the screening exam necessary to demonstrate their ability to provide quality mammography during a survey by the accrediting body.

II. SUMMARY

S. 1879 amends the Public Health Service Act to extend funding for the mammography facilities certification program through FY 2005.

The legislation also permits the Secretary of Health and Human Services (the Secretary) to issue two additional types of certificates—temporary renewal and limited provisional certificates—for specific periods of time for circumstances outlined in the legislation. The Secretary may issue a temporary renewal certificate for up to 45 days to facilities seeking reaccreditation that have been awarded an accreditation extension for specified reasons, including inability of the accrediting body to complete the process in time and unforeseen situations which cause the facility to be unable to meet the reaccreditation timeframes, but do not compromise the quality of mammography.

A limited provisional certificate may be issued by the Secretary upon the request of an accreditation body for a limited provisional

certificate—that is valid up to 72 hours—to enable the facility to conduct examinations for educational purposes during an onsite visit by the accreditation body.

III. HISTORY OF LEGISLATION AND VOTES IN COMMITTEE

On April 8, 2003, the HELP Committee held a hearing chaired by Senator Ensign entitled “Mammography Quality Standards Act (MQSA): Patient Access to Quality Health Care.” The hearing focused on ways that the legislation could encourage self-assessment of interpretive skills by radiologists with the goal of reducing the number of missed breast cancers without affecting medical litigation, and without causing flight by radiologists from the profession by contributing to the unique regulatory requirements mandated under the MQSA.

On November 18, 2003, Senator Mikulski, for herself and Senators Ensign, Kennedy, Snowe, Dodd, Murray, Jeffords and Cantwell introduced S. 1879, the Mammography Quality Standards Act of 2003. The bill was referred to the Health, Education, Labor, and Pensions Committee. On November 21, 2003, the committee was polled and unanimously approved S. 1879.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

1. PERIOD OF REAUTHORIZATION

The committee intends for this limited reauthorization to provide additional time to consider the MQSA program. At the expiration of this 2-year reauthorization, the committee intends to return to a 5-year authorization cycle. The committee believes that the shortened reauthorization period is necessary to evaluate different approaches to enhance MQSA without driving dedicated people from the profession. The committee also intends for this reauthorization to signal to mammography professionals our support for the MQSA; FDA runs a strong program that provides quality care to consumers. The committee does not intend to repeat this 2-year reauthorization period but will reauthorize the program in 2005 for a period of 5 years; that will be until 2010 and continue on a 5-year reauthorization cycle.

The committee recognizes that at the present time, mammography is not a perfect science and approximately one of every 10 breast cancers cannot be detected on a mammogram. The committee heard testimony that because the public misperceives that mammography is 100 percent accurate, women frequently resort to medical litigation if breast cancer is diagnosed subsequent to having a mammogram that was interpreted as normal. As a result of this, as well as other factors such as reimbursement, the number of radiologists willing to practice mammography is decreasing. The developing crisis in the availability of mammography service is the greatest threat to quality mammography at the present time, according to testimony before the committee. Therefore, the committee recognizes the difficulty in reaching a balance between enhancing MQSA and the potential consequences of additional regulatory burdens or increasing medical litigation.

2. TEMPORARY RENEWAL CERTIFICATE

Occasionally, circumstances not relating to mammography quality preclude completion of the reaccreditation process prior to expiration of the facility's certificate. The situation can arise, for example, when a facility is unavoidably delayed in the submission of information due to installation of new equipment or unexpected transport delays in transmitting images from place to place. This legislation permits the Secretary to recognize these exceptional circumstances to allow orderly completion of reaccreditation and recertification without a disruption of service and thereby avoiding the possibility of delaying the diagnosis and treatment of women with breast cancer.

3. LIMITED PROVISIONAL CERTIFICATE

This legislation will authorize the Secretary to issue a limited provisional certificate to permit the facility to perform the screening exam necessary to demonstrate their ability to provide quality mammography during a survey by the accrediting body. Under the current statute, mammography facilities that have lost their MQSA accreditation must be able to perform an exam on a woman as part of a supervised, educational on-site survey before it can be reaccredited. As a result, this legislation will avoid the unnecessary closing of facilities and thus avoid possible delays in the diagnosis and treatment of breast cancer.

V. REGULATORY IMPACT STATEMENT

The committee has determined that there will be no increase in the regulatory burden imposed by this bill. The reauthorization of the funding for the program will not impact the regulatory burden under the program. Both the temporary renewal and limited provisional certificates are issued by the Secretary under the appropriate circumstance, thus adding no regulatory burdens to the facility.

VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104-1, the Congressional Accountability Act (CAA), requires a description of the application of this bill to the legislative branch. S. 1879 extends funding for the mammography facilities certification program through FY 2005 and permits the Secretary to issue two additional types of certificates in certain circumstances to permit the continued operation of facilities providing mammography services. As such, it has no application to the legislative branch.

VII. COST ESTIMATE

Due to time constraints the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record at a later time.

VIII. SECTION-BY-SECTION ANALYSIS

S. 1879 amends the Public Health Service Act to revise and extend provisions relating to mammography quality standards.

Sec. 1. Short title

Section 1 entitles the Act the “Mammography Quality Standards Reauthorization Act of 2003”.

Sec. 2. Temporary renewal and limited provisional certificate

Permits the Secretary of Health and Human Services (the Secretary) to issue a temporary certificate to facilities seeking re-accreditation and awarded an accreditation extension for specified reasons, including the inability of the accrediting body to complete the process in time and unforeseen situations which cause the facility to be unable to meet the reaccreditation timeframes, but do not compromise the quality of mammography. The certificate is valid for up to 45 days.

Permits the Secretary to issue upon the request of an accreditation body a limited provisional certificate—that is valid up to 72 hours—to enable the entity to conduct examinations for educational purposes during an onsite visit by the accreditation body.

Sec. 3. Authorization of appropriations

Extends funding for the mammography facilities certification program through FY 2005.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *
Mammography Quality Standards Reauthorization Act of 2003
 * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

Subpart 3—Mammography Facilities

SEC. 354. CERTIFICATION OF MAMMOGRAPHY FACILITIES.

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

- * * * * *
- (b) * * *
- * * * * *
- (A) a certificate or a temporary renewal certificate—
 (i) that is issued, and, if applicable, renewed, by the Secretary in accordance with [subsection (c)(1)] paragraphs (1) or (2) of subsection (c);
- * * * * *
- (B) a provisional certificate or a limited provisional certificate—

- (i) that is issued by the Secretary in accordance with **subsection (c)(2)** paragraphs (3) and (4) of subsection (c);
- (ii) * * *

* * * * *

The reference to a certificate in this section includes a **provisional certificate** temporary renewal certificate, provisional certificate, or a limited provisional certificate;

* * * * *

(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

(1) IN GENERAL.—* * *

(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:

(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).

[(2)](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), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to 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).

* * * * *

(r) FUNDING.—

(1) FEES.—

(A) IN GENERAL.—* * *

(B) * * *

(i) * * *

* * * * *

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(A) to award reseach grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through ~~2002~~2005; 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 ~~2002~~2005.

