108TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
108–694

MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 2004

SEPTEMBER 22, 2004.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 4555]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4555) to amend the Public Health Service Act to revise and extend provisions relating to mammography quality standards, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

AMENDMENT

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Mammography Quality Standards Reauthorization Act of 2004".

SEC. 2. TEMPORARY RENEWAL AND LIMITED PROVISIONAL CERTIFICATE.

Section 354 of the Public Health Service Act (42 U.S.C. 263b) is amended—

(1) in subsection (b)(1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by inserting "or a temporary renewal certificate" after "certificate"; and

(ii) in clause (i), by striking "subsection (c)(1)" and inserting "paragraphs (1) or (2) of subsection (c)";

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by inserting "or a limited provisional certificate" after "certificate"; and

(ii) in clause (i), by striking "subsection (c)(2)" and inserting "paragraphs (3) and (4) of subsection (c)"; and

(C) in the flush matter at the end, by striking "provisional certificate" and inserting "temporary renewal certificate, provisional certificate, or a limited provisional certificate"; and

(2) in subsection (c)—

(A) by redesignating paragraph (2) as paragraph (4); and

(B) by inserting after paragraph (1) the following:

"(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).".

SEC. 3. NATIONAL ADVISORY COMMITTEE.

Section 354(n) of the Public Health Service Act (42 U.S.C. 263b(n)) is amended—

(1) in paragraph (2), by striking subparagraph (C) and all that follows and inserting the following:

"(C) other health professionals,

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

(2) in paragraph (4), by striking "biannually" and inserting "annually".

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

Subparagraphs (A) and (B) of section 354(r)(2) of the Public Health Service Act (42 U.S.C. 263b(r)(2)(A) and (B)) are amended by striking "2002" each place it appears and inserting "2007".

PURPOSE AND SUMMARY

The purpose of H.R. 4555 is to reauthorize the Mammography Quality Standards Act (MQSA).

BACKGROUND AND NEED FOR LEGISLATION

In 1992, Congress enacted the Mammography Quality Standards Act to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. In 1998, Congress reauthorized MQSA through 2002 in the Mammography Quality Standards Reauthorization Act of 1998.

The MQSA provides that screening and diagnostic services must be accredited and certified by the Food and Drug Administration (FDA). When performing this function, the FDA also considers the special circumstances required in ensuring clear, accurate and reliable mammograms of patients with breast implants. As of June 30, 2004, there were 9,039 MQSA-certified facilities in the United States and its territories.

There are four FDA-approved accreditation bodies under MQSA. The period of approval for each of the accreditation bodies is seven years, after which time they need to apply for renewal of their status. The approved bodies are the American College of Radiology, and the States of Arkansas, Iowa, and Texas. FDA reports annually to the Congress about the performance of these accreditation bodies. There is also an annual facility inspection component under the program. Under MQSA, trained FDA inspectors, with state agencies under contract to the FDA, and with states that are certifying agencies, perform annual MQSA inspections. Only FDA performs annual inspections of Federal facilities. Forty-eight States and jurisdictions have contracted with FDA to perform these inspections.

Inspectors perform science-based inspections to (1) determine the radiation dose for the standard mammography; (2) assess image quality using a standard image quality phantom; (3) empirically evaluate the quality of the facility's film processing; (4) and, evaluate the facility's equipment. In addition to the science-based inspections, the inspectors review the facility's medical reports, lay summaries, and medical audits to ensure the facility's procedures meet MQSA requirements. MQSA requires FDA to collect fees from facilities to cover the cost of their annual facility inspections.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On June 15, 2004 the Subcommittee on Health met in open markup session and approved H.R. 4555 for Full Committee consideration by a voice vote. On June 24, 2004, the Committee on Energy and Commerce met in open markup session and approved H.R. 4555, as amended, by a voice vote.

COMMITTEE VOTES

There were no record votes taken in connection with ordering H.R. 4555 reported. A motion by Mr. Pickering to order H.R. 4555 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to continue the improvement in the quality of mammograms nationwide.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4555, the Mammography Quality Standards Reauthorization Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 7, 2004.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4555, the Mammography Quality Standards Reauthorization Act of 2004.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

H.R. 4555—Mammography Quality Standards Reauthorization Act of 2004

Summary: H.R. 4555 would reauthorize funding for programs carried out under the Mammography Quality Standards Act (MQSA) of 1992. (The program was last reauthorized in 1998.) Authorizations for the program expired at the end of fiscal year 2002 for activities not supported by user fees. The bill would authorize the appropriation of such sums as necessary through fiscal year

2007. Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 4555 would cost $10 million in 2005 and $51 million over the 2005–2009 period. Enacting the bill would not affect direct spending or receipts.

H.R. 4555 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 4555 is shown in the following table. The costs fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2004	2005	2006	2007	2008	2009
SPENDING SUBJECT TO APPROPRIATION						
MQSA spending under current law:						
Estimated budget authority [1]	16	0	0	0	0	0
Estimated outlays	16	7	2	0	0	0
Proposed changes:						
Estimated authorization level	0	17	17	18	0	0
Estimated outlays	0	10	15	17	7	2
MQSA spending under H.R. 4555:						
Estimated authorization level [1]	16	17	17	18	0	0
Estimated outlays	16	17	17	17	7	2

[1] The 2004 level is the amount appropriated in that year for activities authorized under the Mammography Quality Standards Act but not supported by user fees.

Basis of estimate: For this estimate, CBO assumes that the bill will be enacted in fiscal year 2004, that the necessary appropriations will be provided near the start of each fiscal year, and that outlays will not follow historical spending patterns for the MQSA program.

H.R. 4555 would authorize the appropriation of such sums as necessary through 2007 for the Food and Drug Administration (FDA) to carry out MQSA activities that are not supported by user fees. Such activities include establishing and enforcing standards for mammography facilities, accreditation bodies, equipment, personnel, and quality assurance; inspecting facilities run by governmental entities; and providing consumer education. The bill also would allow the Secretary of Health and Human Services to issue a temporary renewal certificate and a limited provisional certificate to facilities seeking reaccreditation under certain circumstances. CBO estimates that these activities could be carried out with funding set at the 2004 appropriation level, adjusted for inflation. We estimate that these activities would cost $8 million in 2005 and $33 million over the 2005–2009 period.

H.R. 4555 would modify composition of the National Mammography Quality Assurance Advisory Committee to include two industry representatives with expertise in mammography equipment. CBO assumes that this requirement would effectively add two new members to the committee. The bill also would cut back the committee's meeting schedule by directing the committee to convene only once each year instead of meeting biannually as required under current law. We estimate that implementing those changes, on balance, would have a negligible effect on FDA's costs associated with the advisory committee.

In addition, H.R. 4555 would reauthorize the breast cancer screening surveillance research grant program, administered by the

National Cancer Institute. The bill would authorize the appropriation of such sums as necessary for that program, at an estimated cost of $2 million in 2005 and $18 million over the 2005–2009 period. The program funds research to determine the effectiveness of screening programs in reducing breast cancer mortality.

Intergovernmental and private-sector impact: H.R. 4555 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Previous cost estimate: On March 9, 2004, CBO transmitted a cost estimate for S. 1879, the Mammography Quality Standards Act of 2003, as passed by the Senate on February 2, 2004. The main difference between the bills is that H.R. 4555 would reauthorize the MQSA program (including the breast cancer screening surveillance research grants) through fiscal year 2007, while S. 1879 would reauthorize MQSA activities through 2005. H.R. 4555 also would make administrative changes to the National Mammography Quality Assurance Advisory Committee; S. 1879 does not contain a similar provision. Our cost estimates reflect those differences.

Estimate prepared by: Federal Costs: Julia Christenson. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on Private Sector: Meena Fernandes.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short Title

Section 1 designates the short title of the bill as "The Mammography Quality Standards Reauthorization Act of 2004."

Section 2. Temporary Renewal and Limited Provisional Certificate

Section 2 amends section 354 of the Public Health Service Act to authorize the Secretary of Health and Human Services (HHS) to issue a temporary renewal certificate, for a period not to exceed 45 days, to any facility seeking reaccreditation under MQSA. In order for a facility to receive a temporary renewal certificate from the Secretary, the facility must have been issued an accreditation certificate not to exceed 45 days. In order to be issued a temporary renewal certificate by the Secretary, a facility needs to meet any of the following criteria: (1) if the facility has met the established time frames for submitting materials to the accreditation body for reaccreditation, but the accreditation body is unable to complete the process before the certificate expires; (2) if the facility acquires additional or replacement equipment, has a low volume of mammography, or has significant personnel changes which prohibit the facility from meeting the accreditation time frames; (3) or, if there are other unforeseen circumstances that keep the facility from meeting the reaccreditation time frames, but at the same time have not compromised the quality of mammography in the opinion of the accreditation body.

Section 2 also allows the Secretary to issue, upon the request of an accreditation body, a limited provisional certificate, for a period not to exceed 72 hours, to allow an entity to conduct examination for educational purposes while an onsite visit from an accreditation body is in progress.

Finally, section 2 permits the Secretary to appoint individuals with expertise in mammography equipment to the National Mammography Quality Assurance Advisory Committee and grants the Advisory Committee greater flexibility in how many times the Committee must meet annually.

Section 3. Authorization of Appropriations

Section 3 authorizes the appropriations of such sums as necessary through fiscal year 2007.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (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):

SECTION 354 OF THE PUBLIC HEALTH SERVICE ACT

SEC. 354. CERTIFICATION OF MAMMOGRAPHY FACILITIES.

(a) * * *

(b) CERTIFICATE REQUIREMENT.—

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

(A) a certificate *or a temporary renewal certificate—*

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with [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)*;

* * * * * * *

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) * * *

(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 signifi-

cantly 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).

* * * * * * *

(n) NATIONAL ADVISORY COMMITTEE.—

(1) * * *

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

(A) * * *

* * * * * * *

[(C) other health professionals,

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

(C) other health professionals,

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

* * * * * * *

(4) MEETINGS.—The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least [biannually] *annually*.

* * * * * * *

(r) FUNDING.—

(1) * * *

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

(A) to award research grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through [2002] *2007*; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through [2002] *2007*.

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