

MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION
ACT OF 2002

JULY 22, 2002.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 4888]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4888) to reauthorize the Mammography Quality Standards Act, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are 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 2002”.

SEC. 2. 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)) are each amended by striking “2002” and inserting “2007”.

SEC. 3. TEMPORARY CERTIFICATE.

Section 354(c) of the Public Health Service Act (42 U.S.C. 263b) is amended by redesignating paragraph (2) as paragraph (3) and inserting after paragraph (1) the following:

“(2) TEMPORARY ISSUANCE OF A CERTIFICATE.—The Secretary may issue a temporary renewal certificate for a period not to exceed 45 days to a facility seeking reaccreditation if the accreditation body for the facility has issued an accreditation extension for a period not to exceed 45 days for any of the following reasons:

“(A) The facility has met the established time frames for submitting materials to the accreditation body, but the accreditation body is unable to complete the reaccreditation process before the certificate expires.

“(B) Circumstances such as the facility acquiring additional or replacement equipment, having low volume of mammography, or having significant personnel changes have caused the facility to be unable to meet reaccreditation time frames.

“(C) Other unforeseen situations have caused the facility to be unable to meet reaccreditation time frames, but in the opinion of the accreditation body, have not compromised the quality of mammography.”.

SEC. 4. GAO STUDY.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of the program established by the Mammography Quality Standards Act of 1992 (the program under section 354 of the Public Health Service Act, referred to in this Act as the “MQSA”) to—

(1) evaluate the demonstration program regarding frequency of inspections authorized under section 354(g) of the Public Health Service Act, including the effect of the program on compliance with the MQSA;

(2) evaluate the accessibility of mammography services;

(3) evaluate the role of States in acting as both accreditation bodies and certification bodies under the MQSA; and

(4) identify areas, if any, where the MQSA could be improved to increase access to and quality of mammography services for women.

(b) REPORT.—Not earlier than 3 years, but not later than 4 years after the date of enactment of this section, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study described in subsection (a).

SEC. 5. INSTITUTE OF MEDICINE STUDY.

(a) STUDY.—Not later than one year after the date of enactment of this section, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall request the Institute of Medicine to enter into an agreement under which such Institute conducts a study for the purpose of making recommendations regarding the following:

(1) Ways to encourage more radiologists to be adequately trained in mammography interpretation.

(2) Ways to ensure enough adequately trained personnel at all levels to ensure the quality and availability of mammography services to women.

(3) Whether interventional mammography procedures should be subject to the requirements of the MQSA.

(4) Ways to improve continuing medical education requirements, such as including an assessment of interpretive skills, for physicians interpreting mammograms.

(5) Other areas, if any, where the MQSA could be improved to increase the quality of mammography services for women.

(b) REPORT.—The Secretary shall ensure that, not later than 18 months after the date on which the Secretary enters into the agreement under subsection (a), the study under such subsection is completed and a report on the study is submitted to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

Amend the title so as to read:

A bill to amend the Public Health Service Act to extend the program established by the Mammography Quality Standards Act of 1992, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 4888 is to reauthorize the Mammography Quality Standards Act (“MQSA”).

BACKGROUND AND NEED FOR LEGISLATION

In 1992, Congress enacted the Mammography Quality Standards Act (“MQSA”) 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). As of 2001, there were 9,646 MQSA-certified mammography facilities in the United States and its territories. Of these, 9,331 facilities are fully certified. The remaining facilities are in the process of becoming accredited.

FDA has approved five accreditation bodies under MQSA, each of which can last no longer than three years. The approved bodies are the American College of Radiology, and the States of Arkansas, California, 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-five States and jurisdictions have contracted with FDA to perform these inspections.

Inspectors perform science-based inspections to determine the radiation dose for the standard Mammography; to assess image quality using a standard image quality phantom; to empirically evaluate the quality of the facility’s film processing; and to 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.

The Committee expects the FDA to promulgate final regulations establishing quality standards and accreditation criteria specific to full field digital mammography and permit mammography facilities to be certified to offer and maintain full field digital mammography systems exclusively if they so desire. It is the Committee’s understanding that an entity has submitted an application to become the accrediting body for full field digital mammography, and that this application contains proposed quality standards relating to full

field digital mammography. The Committee expects the FDA to continue its review of these proposed standards and, if these standards are appropriate, issue final regulations allowing facilities to offer this technology exclusively and meet MQSA requirements.

HEARINGS

The Committee on Energy and Commerce did not hold hearings on the legislation.

COMMITTEE CONSIDERATION

On Thursday, June 13, 2002, the Full Committee met in open markup session and favorably ordered reported H.R. 4888, as amended, by voice vote, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4888 reported. A motion by Mr. Tauzin to order H.R. 4888 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. 4888, the Mammography Quality Standards Reauthorization Act of 2002, 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 22, 2002.

Hon. W.J. "BILLY" TAUZIN,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed estimate of H.R. 4888, the Mammography Quality Standards Reauthorization Act of 2002.

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

Sincerely,

STEVEN M. LIEBERMAN
(For Dan L. Crippen, Director).

Enclosure.

H.R. 4888—Mammography Quality Standards Reauthorization Act of 2002

Summary: H.R. 4888 would reauthorize funding for programs carried out under the Mammography Quality Standards Act (MQSA) of 1992. (The program was last reauthorized in 1998.) Current authorizations expire after fiscal year 2002 for activities not supported by user fees. The bill would authorize the appropriation of such sums as necessary for fiscal years 2003 through 2007. Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 4888 would cost \$12 million in 2003 and \$77 million over the 2003–2007 period. (That estimate assumes annual appropriations are adjusted for inflation. Without such adjustment, the five-year total would be \$72 million.) The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 4888 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. 4888 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Million of Dollars—					
	2002	2003	2004	2005	2006	2007
SPENDING SUBJECT TO APPROPRIATION						
Spending under current law:						
Estimated authorization level ¹	15	0	0	0	0	0
Estimated outlays	15	4	1	0	0	0
Proposed changes: ²						
Estimated authorization level	0	16	16	16	17	17
Estimated outlays	0	12	15	16	17	17
Spending under H.R. 4888:						
Estimated authorization level ¹	15	16	16	16	17	17
Estimated outlays	15	16	16	16	17	17

¹The 2000 level is the amount appropriated for that year for activities authorized under the Mammography Quality Standards Act but not supported by user fees.

²The amounts shown reflect annual adjustments for anticipated inflation for those activities for which the bill would authorize such sums as necessary. Without such inflation adjustments, the five-year changes in authorization levels would total \$77 million (instead of \$82 million) and the changes in outlays would total \$72 million (instead of \$77 million).

Basis of estimate: H.R. 4888 would authorize the appropriation of such sums as necessary for 2003 through 2007 for the Food and

Drug Administration to carry out MQSA activities that are not supported by user fees. Those 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 to facilities seeking reaccreditation under certain circumstances. CBO estimates that these activities could be carried out with the 2002 appropriation levels adjusted for inflation. We estimate that these activities would cost \$7 million in 2003 and \$45 million over the 2003–2007 period.

In addition, H.R. 4888 would reauthorize the breast cancer screening surveillance research grant program, administered by the National Cancer Institute. The bill would authorize such sums as necessary for that program, at an estimated cost of \$5 million in 2003 and \$30 million over the 2003–2007 period. The program funds research to determine the effectiveness of screening programs in reducing breast cancer mortality. CBO's estimate assumes continued funding at the 2002 level adjusted for inflation.

H.R. 4888 would require the General Accounting Office and the Institute of Medicine to conduct studies on the MQSA program and the related issues surrounding the quality of mammography services. CBO estimates that the cost of those studies would be less than \$500,000 in 2003 and would total less than \$1 million over the 2003–2007 period.

For this estimate, CBO assumes that the bill would have an effective date of October 1, 2002. We also assume that the necessary appropriations would be provided at the start of each fiscal year and that outlays would follow historical spending patterns for this program.

Pay-as-you-go considerations: None.

Intergovernmental and private-sector impact: H.R. 4888 contains no intergovernmental or private-sector impact as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Julia Christenson; Impact on state, local, and tribal governments: Leo Lex; impact on the private sector; Jennifer Bowman.

Estimate approved by: Robert A. Sunshine, 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 establishes the short title as the “Mammography Quality Standards Reauthorization Act of 2002.”

Section 2. Authorization of Appropriations

Section 2 extends the authorization of appropriations for section 354(r)(2) of the Public Health Service Act until 2007.

Section 3. Temporary Certificate

Section 3 allows 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 prohibits the facility from meeting the accreditation time frames; (3) or if there are other unforeseen circumstances that cause 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 4. GAO Study

Section 4 requires the General Accounting Office (GAO) to conduct a study of the demonstration program established by MQSA. In the study, GAO will (1) evaluate the program regarding the frequency of inspections authorized under the Public Health Service Act, including the effect of the program on compliance with MQSA; (2) evaluate the accessibility of mammography services; (3) evaluate the role of states in acting as both accreditation bodies and certification bodies under the MQSA; and, (4) identify areas where the MQSA could be improved to increase access to and the quality of mammography services for women.

Section 5. Institute of Medicine Study

Section 5 directs the Secretary of HHS to enter into an agreement with the Institute of Medicine for the purpose of conducting a study and making recommendations to the Secretary. In the

study, the Institute of Medicine will examine (1) ways to encourage more radiologist to be adequately trained in mammography interpretation; (2) ways to ensure enough adequately trained personnel at all levels to ensure the quality and availability of mammography services to women; (3) whether interventional mammography procedures should be subject to the requirements of the MQSA; (4) ways to improve continuing medical education requirements, such as including an assessment of interpretive skills, for physicians interpreting mammograms; and, (5) other areas where the MQSA could be improved to increase the quality of mammography services for women.

The Secretary will submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House, a report on the study conducted in this section within 18 months after the date on which the Secretary enters into an agreement with the Institute of Medicine.

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) * * *

* * * * *

(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

(1) * * *

(2) *TEMPORARY ISSUANCE OF A CERTIFICATE.*—*The Secretary may issue a temporary renewal certificate for a period not to exceed 45 days to a facility seeking reaccreditation if the accreditation body for the facility has issued an accreditation extension for a period not to exceed 45 days for any of the following reasons:*

(A) *The facility has met the established time frames for submitting materials to the accreditation body, but the accreditation body is unable to complete the reaccreditation process before the certificate expires.*

(B) *Circumstances such as the facility acquiring additional or replacement equipment, having low volume of mammography, or having significant personnel changes have caused the facility to be unable to meet reaccreditation time frames.*

(C) *Other unforeseen situations have caused the facility to be unable to meet reaccreditation time frames, but in the opinion of the accreditation body, have not compromised the quality of mammography.*

[(2)] (3) **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 sub-

section (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) * * *

(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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