

REPEAL AN UNNECESSARY MEDICAL DEVICE REPORTING  
REQUIREMENT

NOVEMBER 7, 1995.—Committed to the Committee of the Whole House on the State  
of the Union and ordered to be printed

Mr. ARCHER, from the Committee on Ways and Means,  
submitted the following

REPORT

[To accompany H.R. 2366]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 2366) to repeal an unnecessary medical device reporting requirement, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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## I. INTRODUCTION

### A. PURPOSE AND SUMMARY

The purpose of the bill is to repeal the Cardiac Pacemaker Registry established in 1984 by section 1862(h) of the Social Security Act (42 U.S.C. 1395y(h)). The bill strikes the subsection (h) that establishes the requirement for the Registry.

### B. BACKGROUND AND NEED FOR LEGISLATION

Section 1862(h) of the Social Security Act (42 U.S.C. 1395y(h)) requires doctors and hospitals receiving Medicare funds to provide information upon implementation, removal or replacement of pacemakers devices and pacemaker leads. These requirements became redundant in 1990 with passage of the amendments to the Federal Food, Drug and Cosmetic Act that established a more comprehensive system for reporting on medical devices. The legislation is needed to eliminate the unnecessary burden on the health care system, the Health Care Financing Administration and the Food and Drug Administration.

### C. LEGISLATIVE HISTORY

H.R. 2366 was introduced on September 19th by Mrs. Vucanovich. On November 1, 1995, the Full Committee met in open session and ordered H.R. 2366 reported to the House, without amendment, by a voice vote, a quorum being present.

## II. SECTION-BY-SECTION SUMMARY OF THE BILL, JUSTIFICATION, AND COMPARISON WITH PRESENT LAW

### SECTION 1: REPEAL

#### *Present law*

Section 1862(h) of the Social Security Act creates a registry of all cardiac pacemaker devices and pacemaker leads paid for by Medicare. This section requires doctors and hospitals receiving Medicare payments to provide information upon implementation, removal or replacement of pacemakers. Reports must be filed with two separate agencies, the Health Care Financing Administration and the Food and Drug Administration.

#### *Explanation of provision*

The provision would repeal the cardiac pacemaker registry established by section 1862(h) (42 U.S.C. 1395y(h)).

#### *Reason for change*

The Registry imposes an unnecessary burden on doctors and hospitals on reporting identical information to two separate agencies and the reporting is now redundant with passage of separate amendments to the Food, Drug and Cosmetic Act that established a more comprehensive reporting system on medical devices.

#### *Effective date*

Upon enactment.

### III. VOTES OF THE COMMITTEE

In compliance with clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives, the following statement is made relative to the votes of the Committee in its consideration of the bill, H.R. 2366:

#### MOTION TO REPORT THE BILL

The bill, H.R. 2366, was ordered favorably reported to the House, without amendment, by voice vote, with a quorum present.

### IV. BUDGET EFFECTS OF THE BILL

#### A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 7(a) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of this bill, H.R. 2366, as reported: The Committee agrees with the cost estimate furnished by the Congressional Budget Office which appears below.

#### B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee states that H.R. 2366 would result in no new or increased budget authority or tax expenditures or revenues.

#### C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with subdivision (C) of clause 2(l)(3) of rule XI of the Rules of the House of Representatives, requiring a cost estimate prepared by the Congressional Budget Office (CBO), the following report prepared by CBO is provided:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, November 7, 1995.*

Hon. BILL ARCHER,  
*Chairman, Committee on Ways and Means,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office and the Joint Committee on Taxation (JCT) have reviewed H.R. 2494, as ordered reported by the House Committee on Ways and Means on November 1, 1995. The JCT estimates that this bill would increase receipts by \$69 million in fiscal year 1996 and by \$696 million over fiscal years 1996 through 2002. CBO concurs with the estimate.

H.R. 2494 addresses the tax treatment of thrift institutions in two ways. First, the bill would repeal the reserve method of accounting allowed under section 593 of the Internal Revenue Code for the bad debts of thrifts. A thrift institution would be required to include in taxable income over a six-year period some portion of its post-1987 additions to its bad debt reserve. The inclusion in income would be suspended during years in which the institution made qualifying residential loans in excess of specified base amount. Second, the bill would provide that a special assessment

paid by thrifts, established in H.R. 2491 (the "Seven-Year Balanced Budget Reconciliation Act of 1995"), passed by the House of Representatives on October 26, 1995, would be allowed as a deduction in computing taxable income. No direct revenue effect is estimated for this second provision.

CBO understands that the JCT estimate represents the effects of H.R. 2494 on governmental receipts (revenue) under the assumption that it is a stand-alone bill, as well as the combined effect on governmental receipts of H.R. 2494 and the thrift provisions of H.R. 2491. As discussed in my letter to Chairman Leach dated October 6, 1995, the reconciliation provisions of the House Committee on Banking and Financial Services, included in H.R. 2491, could cause many federal thrifts to reorganize as banks, which could affect future corporate income tax revenues. The JCT estimates, however, that any such effect from H.R. 2491 would be dominated by the effect of H.R. 2494 if it were included in H.R. 2491. The revenue effects of H.R. 2494 are summarized below:

REVENUE EFFECTS OF H.R. 2494  
[By fiscal year, in millions of dollars]

	1996	1997	1998	1999	2000	2001	2002
Changes in Revenues .....	69	106	103	105	106	107	100

If you wish further details, please feel free to contact me or your staff may wish to contact Mark Booth.

Sincerely,

JAMES L. BLUM  
(For June E. O'Neill, *Director*).

## V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

### A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to subdivision (A) of clause 2(l)(3) of rule XI of the Rules of the House, the Committee advises that it was a result of the Committee's oversight activities concerning the Medicare program that the Committee concluded that it is appropriate to enact the provisions contained in the bill.

### B. SUMMARY OF FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

With respect to subdivision (D) of clause 2(l)(3) of rule XI of the Rules of the House of Representatives (relating to oversight findings), the Committee advises that no oversight findings or recommendations have been submitted to this Committee by the Committee on Government Reform and Oversight with respect to the provisions contained in this bill.

### C. INFLATIONARY IMPACT STATEMENT

In compliance with clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee states that the provisions of the bill are not expected to have an overall inflationary impact on prices or costs in the operation of the national economy.

**VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED**

In compliance with clause 3 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, existing law in which no change is proposed is shown in roman):

**SECTION 1862 OF THE SOCIAL SECURITY ACT**

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) \* \* \*

\* \* \* \* \*

[(h)(1)(A) The Secretary shall, through the Commissioner of the Food and Drug Administration, provide for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title.

[(B) Such registry shall include the manufacturer, model, and serial number of each such device or lead, the name of the recipient of such device or lead, the date and location of the implantation or removal of the device or lead, the name of the physician implanting or removing such device or lead, the name of the hospital or other provider billing for such procedure, any express or implied warranties associated with such device or lead under contract or State law (and any amount paid to a provider under any such warranty), and such other information as the Secretary deems to be appropriate.

[(C) Each physician and provider of services performing the implantation or replacement of pacemaker devices and leads for which payment is made or requested to be made under this title shall, in accordance with regulations of the Secretary, submit information respecting such implantation or replacement for the registry.

[(D) Such registry shall be for the purposes of assisting the Secretary in determining when payments may properly be made under this title, in tracing the performance of cardiac pacemaker devices and leads, in determining when inspection by the manufacturer of such a device or lead may be necessary under paragraph (3), in determining the amount subject to repayment under paragraph (2)(C), and in carrying out studies with respect to the use of such devices and leads. In carrying out any such study, the Secretary may not reveal any specific information which identifies any pacemaker device or lead recipient by name (or which would otherwise identify a specific recipient).

[(E) Any person or organization may provide information to the registry with respect to cardiac pacemaker devices and leads other than those for which payment is made under this title.

[(2) The Secretary may, by regulation, require each provider of services—

[(A) to return, to the manufacturer of the device or lead for testing under paragraph (3), any cardiac pacemaker device or lead which is removed from a patient and payment for the implantation or replacement of which was made or requested by such provider under this title,

[(B) not to charge any beneficiary for replacement of such a device or lead if the device or lead has not been returned in accordance with subparagraph (A), and

[(C) to make repayment to the Secretary of amounts paid under this title to the provider with respect to any cardiac pacemaker device or lead which has been replaced by the manufacturer, or for which the manufacturer has made payment to the provider, under an express or implied warranty.

[(3) The Secretary may, by regulation, require the manufacturer of a cardiac pacemaker device or lead (A) to test or analyze each pacemaker device or lead for which payment is made or requested under this title and which is returned to the manufacturer by a provider of services under paragraph (2), and (B) to provide the results of such test or analysis to that provider, together with information and documentation with respect to any warranties covering such device or lead. In any case where the Secretary has reason to believe, based upon information in the pacemaker registry or otherwise available to him, that replacement of a cardiac pacemaker device or lead for which payment is or may be requested under this title is related to the malfunction of a device or lead, the Secretary may require that personnel of the Food and Drug Administration be present at the testing of such device by the manufacturer, to determine whether such device was functioning properly.

[(4) The Secretary may deny payment under this title, in whole or in part and for such period of time as the Secretary determines to be appropriate, with respect to the implantation or replacement of a pacemaker device or lead of a manufacturer performed by a physician and provider of services after the Secretary determines (in accordance with the procedures established under subsections (c), (f), and (g) of section 1128) that—

[(A) the physician or provider of services has failed to submit information to the registry as required under paragraph (1)(C),

[(B) the provider of services has failed to return devices and leads as required under paragraph (2)(A), has improperly charged beneficiaries as prohibited under paragraph (2)(B), or has failed to make repayment to the Secretary as required under paragraph (2)(C), or

[(C) the manufacturer of the device or lead has failed to perform and to report on the testing of devices and leads returned to it as required under paragraph (3).]

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