

REPEAL AN UNNECESSARY MEDICAL DEVICE REPORTING
REQUIREMENT

NOVEMBER 7, 1995.—Ordered to be printed

Mr. BLILEY, from the Committee on Commerce,
submitted the following

REPORT

[To accompany H.R. 2366]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, 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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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.

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 pacemaker devices and pacemaker leads. These requirements became redundant in 1990 with enactment of 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.

On October 12, 1995, the Speaker's Advisory Group on Corrections, a bipartisan task force, recommended to the Speaker that H.R. 2366 be placed on the House Corrections Calendar.

HEARINGS

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

COMMITTEE CONSIDERATION

On October 30, 1995, the Subcommittee on Health and Environment met in open markup session and approved H.R. 2366 for Full Committee consideration, without amendment, by a voice vote. On November 1, 1995, the Full Committee met in open markup session and ordered H.R. 2366 reported to the House, without amendment, by a voice vote, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and on amendments thereto. There were no recorded votes taken in connection with ordering H.R. 2366 reported. A motion by Mr. Bilirakis to order H.R. 2366 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House, the Committee has not held oversight or legislative hearings on this legislation.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

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.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

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

Hon. THOMAS J. BLILEY, Jr.,
*Chairman, Committee on Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed H.R. 2366, a bill to repeal the pacemaker registry reporting requirement, as reported by the Committees on Commerce and Ways and Means on November 1, 1995. Pay-as-you-go procedures would not apply because the bill would not affect direct spending or receipts.

H.R. 2366 would repeal Section 1862(h) of the Social Security Act, which establishes, through the Commissioner of the Food and Drug Administration, a registry of cardiac pacemakers and pacemaker leads for which payment is made under Medicare. The Secretary of Health and Human Services uses registry data to determine payment for pacemakers and leads under Medicare and for tracking the performance of these devices.

Providers requesting reimbursement for the implant or replacement of pacemakers or leads are required to report various data to the registry, including the manufacturer of the device, the model and serial number of each device, the recipient's name, the location and date of the procedure, and any warrantees associated with the device. Under current law, providers billing Medicare for the replacement of a pacemaker or lead must return the device to its manufacturer for testing; the manufacturer is required to conduct these tests and to report the results to the provider. If a provider fails to return a replaced device for testing, it is prohibited from charging the beneficiary for the procedure. Finally, providers of covered services must repay to the Secretary any amounts received from manufacturer warrantees or device replacements.

The Secretary can deny payment for the implantation or replacement of pacemakers or leads for several reasons: if the physician or provider fails to submit the requisite data; if the provider neglects to return the device or lead to the manufacturer, charges patients when it failed to return the replaced device, or fails to repay funds received under warrantees; or if the manufacturer fails to perform or report the results of the requisite tests on returned devices.

CBO estimates that H.R. 2366 would have no budgetary impact. In 1995, the FDA implemented pacemaker device and lead tracking

regulations that eliminated the need for the pacemaker registry. Additionally, the Health Care Financing Administration has established other mechanisms that better allow the agency to make payment determinations for pacemakers and leads. Thus, the registry has become obsolete.

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

Sincerely,

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

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the bill would have no inflationary impact.

ADVISORY COMMITTEE STATEMENT

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

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1 amends section 1862 of the Social Security Act (41 U.S.C. 1395y) by striking subsection (h).

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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