wishing to present oral statements should notify the Executive Director of CTAC no later than the day before the meeting. Any member of the public may present a written statement to the Subcommittee at any time.

FOR FURTHER INFORMATION CONTACT: Mr. M.D. Morrissette or Lieutenant J.J. Ocken, U.S. Coast Guard Headquarters (G-MTH-1), 2100 Second Street, SW., Washington, DC 20593, (202) 267-1577.

Dated: July 20, 1987.

N.W. Lemley,

Acting Executive Director, Chemical Transportation Advisory Committee.

[FR Doc. 87-16764 Filed 7-22-87; 8:45 am]

BILLING CODE 4910-14-M

Urban Mass Transportation Administration

Environmental Impact Statement and Cost-Effectiveness Analysis; Miami Metromover Project

AGENCY: Urban Mass Transportation, DOT.

ACTION: Notice of draft environmental impact statement and cost-effectiveness analysis.

SUMMARY: The Urban Mass Transportation Administration (UMTA) announces the issuance of the draft environmental impact statement and the cost-effectiveness analysis for the proposed Metromover extensions in Miami, Florida. This Notice supplements the Enviornmental Protection Agency's Notice of Availability which appeared in the Federal Register on July 17, 1987.

DATE: Comments on the draft environmental impact statement must be received on or before August 31, 1987.

ADDRESS: Comments should be submitted to Mr. Peter N. Stowell, Urban Mass Transportation Administration, Region 4, 1720 Peachtree Road NW., Suite 400, Atlanta, Georgia 30309.

FOR FURTHER INFORMATION CONTACT: Donald J. Emerson, Office of Planning Assistance, Urban Mass Transportation Administration, 400 Seventh Street SW., Washington, DC 20590, (202) 366-0096.

SUPPLEMENTARY INFORMATION: UMTA and the Metro-Dade Transit Agency (MDTA) have completed a draft environmental impact statement that evalutates alternative transit improvements linking downtown Miami with the Omni and Brickell activity centers north and south of downtown. Two alternatives are considered: a No-Build alternative in which current bus services are continued, and a Build alternative in which the MDTA's existing downtown people mover system ("Metromover") is extended to Omni and Brickell. The draft EIS describes these alternatives and assesses their transportation, social, economic, and environmental effects. It also presents a comparative evaluation of the alternatives in terms of local goals and objectives.

Interested citizens and agencies are invited to review and comment on the draft environmental impact statement. Copies of the statement can be obtained by writing to Mr. James Moreno, Metromover Project Manager, Metro-Dade Transit Agency, 111 NW. First Street, Miami, Florida 33128, or by calling (305) 375-5902.

On August 18, 1987, the MDTA will be holding a public hearing on the Metromover extensions to Omni and Brickell. The hearing will be held at the Metro-Dade Center, Rooms A and B (Terrace Level), 111 NW. First Street, Miami, Florida. The hearing will include both an afternoon session beginning at 3:00 p.m., and an evening session beginning at 7:00 p.m.

UMTA and MDTA have also prepared separate cost-effectiveness analyses which focus on the investment-worthiness of the proposed Metromover extensions. These analyses are not part of the environmental impact statement, but are available for review by interested agencies and the public. Copies can be obtained from the Metro-Dade Transit Agency at the above address, or from UMTA's Office of Planning Assistance (UGM-22), 400 7th Street SW., Washington, DC 20590, (202) 366-0096.

Issued on: July 20, 1987.

Joseph A. LaSala,

Chief Counsel, Urban Mass Transportation Administration.

[FR Doc. 87-16720 Filed 7-22-87; 8:45 am]

BILLING CODE 4910-57-M

VETERANS ADMINISTRATION

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains an extension and lists the following information: (1) The department of staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) a description of the need and its use, (5) how often the form must be filled out, (6) who will be required or asked to report, (7) an estimate of the number of responses, (8) an estimate of the total number of hours needed to fill out the form, and (9) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESSES: Copies of the forms and supporting documents may be obtained from Patti Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Elaina Norden, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: July 17, 1987.

By direction of the Administrator.

Jack J. Sharkey,

Director, Office of Systems and Telecommunications.

Extension

1. Department of Veterans Benefits.
2. Application for Annual Clothing Allowance.
3. VA Form 21-8678.
4. This information is needed to determine the veteran's eligibility to receive an annual clothing allowance.
5. On occasion.
6. Individuals or households.
7. 6,720 responses.
8. 1,120 hours.
9. Not applicable.

[FR Doc. 87-16682 Filed 7-22-87; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 52, No. 141
Thursday, July 23, 1987

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONSUMER PRODUCT SAFETY COMMISSION

"FEDERAL REGISTER" ANNOUNCEMENT OF PREVIOUS CITATION: Vol. 52, No. 138 (July 20, 1987), p. 27284.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: July 23, 1987, 10:00 a.m.

CHANGES: Time and date changed to July 24, 1987, 10:00 a.m.

Listed Below is the Revised Agenda

Commission Meeting, Friday, July 24, 1987, 10:00 a.m.
Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, MD.

Open to the Public

FY 89 Budget

The Commission will consider the proposed fiscal year 1989 budget.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: 301–492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, MD. 20207, 301–492–6800.

Sheldon D. Butts,

Deputy Secretary.

July 21, 1987.

[FR Doc. 87–16840 Filed 7–21–87; 2:46 pm]

BILLING CODE 6355-01-M

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 2:30 p.m., Thursday, July 23, 1987.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Md.

STATUS: Closed to the Public.

MATTERS TO BE CONSIDERED:

Enforcement Matter OS # 3373

The staff will brief the Commission on issues related to OS # 3373.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: 301–492–5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 301–492–6800.

Sheldon D. Butts,

Deputy Secretary.

July 21, 1987.

[FR Doc. 87–16841 Filed 7–21–87; 2:46 pm]

BILLING CODE 6355-01-M

FEDERAL ELECTION COMMISSION

"FEDERAL REGISTER" NO.: 87–16275.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, July 23, 1987, 10:00 a.m.

THE FOLLOWING ITEM HAS BEEN ADDED TO THE AGENDA:

Draft Advisory Opinion 1987–15—James F. Schoener on behalf of Kemp for President Committee.

DATE AND TIME: Tuesday, July 28, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.
Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, July 30, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of Dates for future Meetings.
Correction and Approval of Minutes.
Eligibility Report for Candidates to Receive Presidential Primary Matching Funds.
Response to Hypothetical Inquiry from Senate Select Committee on Ethics.
Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Information Officer, Telephone: 202–376–3155.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 87–16853 Filed 7–21–87; 3:18 pm]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, July 29, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: July 21, 1987.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 87–16893 Filed 7–21–87; 3:54 pm]

BILLING CODE 6210-01-M

Corrections

Federal Register
Vol. 52, No. 141
Thursday, July 23, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

International Trade Administration

Order Amending Denial of Permission To Apply for or Use Export Licenses; Werner Ernst Gregg

Correction

In notice document 87-15874 appearing on page 26368 in the issue of Tuesday, July 14, 1987, make the following correction:

In the second column, at the end of the document, the signature date should read "July 8, 1987".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 79P-0055 et al.]

Approved Variances for Laser Light Shows; Availability

Correction

In notice document 87-15289 appearing on page 25472 in the issue of Tuesday, July 7, 1987, make the following corrections:

1. On page 25472, in the second column, under **ADDRESS**, in the fourth line, "HFT" should read "HFA".

2. On the same page, in the second column of the table, in the fourth line from the bottom, after "Pennsylvania" and before the period, insert "17603"; and in the third column of the table, in the 15th line from the bottom, "S-800 B" should read "S-8000B".

BILLING CODE 1505-01-D

federal register

Thursday
July 23, 1987

Part II

Department of Health and Human Services

Food and Drug Administration
Health Care Financing Administration

21 CFR Part 805

42 CFR Parts 400, 409, 410, 489 and 498

Cardiac Pacemaker Registry; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 805

Health Care Financing Administration

42 CFR Parts 400, 409, 410, 489, and 498

[Docket Nos. 85N-0322 and BERC-324-F]

Cardiac Pacemaker Registry

AGENCIES: Food and Drug Administration and Health Care Financing Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA) are issuing jointly a final rule to establish a national cardiac pacemaker registry, as required by the Deficit Reduction Act of 1984. This action is based on a proposed rule that was published in the **Federal Register** of May 6, 1986 (51 FR 16792). The final rule requires that certain information be submitted to FDA for inclusion in the registry from physicians and providers of services requesting or receiving Medicare payment for an implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads. The final rule permits HCFA to deny Medicare payment to physicians and providers who fail to submit the required information to the registry.

EFFECTIVE DATE: September 21, 1987. This final rule applies to permanent cardiac pacemakers and leads implanted or removed on or after the effective date.

FOR FURTHER INFORMATION CONTACT:

For FDA information: Les Weinstein, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

For Medicare information: Barton McCann, Bureau of Eligibility, Reimbursement and Coverage, Health Care Financing Administration, Rm. 489, East High Rise Bldg., 6325 Security Blvd., Baltimore, MD 21207, 301-594-9370.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Deficit Reduction Act of 1984 (Pub. L. 98-369), which was enacted on July 18, 1984, amends title XVIII of the Social Security Act (the Act) and requires the establishment of a national pacemaker registry. The purpose of the final rule being issued jointly by FDA and HCFA is to implement the requirements of Pub. L. 98-369.

Highlights of the final rule may be summarized as follows:

(1) The rule provides for an FDA registry of all permanent cardiac pacemakers and leads for which Medicare payment is requested of or made by HCFA; specifies the information that is required to be submitted to the registry, and when, how, and by whom it is to be submitted; and authorizes withholding of Medicare payments to physicians and providers when information is not supplied to the registry, when required.

(2) The rule requires physicians and providers of services who request or receive payment from Medicare for the implantation, removal, or replacement of permanent pacemakers and pacemaker leads for which payment is made or requested under Medicare, to supply specified information for the pacemaker registry for each procedure performed. The information is to be submitted in the form and manner provided under general instructions of the Medicare program.

(3) The rule authorizes denial of Medicare payment to physicians and providers who fail to submit the required information for the registry. The affected physician or provider will be provided 45 days notice of denial of Medicare payment and may appeal the denial.

(4) The rule amends HCFA's existing Medicare regulations governing provider agreements to ensure that patients are not charged (except for coinsurance and deductible amounts) by providers for covered services furnished in connection with the implantation, removal, or replacement of a pacemaker or pacemaker lead in any case in which HCFA denies payment for failure to submit the required information to the registry. However, if the provider later submits the appropriate information required by FDA, payment will be made if the provider resubmits the claim in a timely manner.

The information to be submitted to the registry is as follows: the name of the manufacturer; the model and serial number of the pacemaker or pacemaker lead; the expiration date of any express or implied warranties associated with the pacemaker or lead under contract or State law; the patient's name and health insurance claim number (HICN), the provider number, the date of the procedure, the name and identification number of the physician who ordered the procedure, and the name and identification number of the operating physician. In addition, if the procedure about which the submission to the registry is being made was the removal or replacement of a pacemaker or lead, the following data elements would also have to be submitted: the date the device was initially implanted, if known; whether the device that was replaced was left in the body and, if not so left, whether the device was returned to the manufacturer.

FDA plans to use the data from the registry to monitor the performance of pacemakers and leads to allow the agency to identify generic failures of or defects in pacemakers. This information will be made available to HCFA and accessible to other Department of Health and Human Services (HHS) components in connection with their statutory responsibilities. FDA will notify HCFA of risks associated with any particular device and, if necessary, HCFA will make appropriate adjustments in Medicare coverage of the device. Also, the information generated by examination of pacemaker data may lead FDA to issue regulations that would set forth criteria for requesting that certain types of pacemakers and leads be returned to the manufacturers for testing. If FDA issues any such regulations, HCFA will issue regulations to deny payment for failure to comply with FDA requirements.

The agencies are prohibited from releasing any specific information that identifies by name a recipient of any pacemaker device or lead or that would otherwise identify a specific recipient. Public disclosure of all other information reported to the registry will be governed by the Freedom of Information Act, the Privacy Act of 1974, and the public information regulations of HHS, FDA, and HCFA.

II. Background

In the **Federal Register** of May 6, 1986 (51 FR 16792), FDA and HCFA jointly issued proposed regulations to establish a national cardiac pacemaker registry. Interested persons were given until July 7, 1986, to submit written comments on the proposal; 17 persons did so. Comments were received from hospitals, hospital associations, physicians, physician associations, pacemaker manufacturers, a medical device manufacturers' association, a Medicare Part B carrier, and individuals. Of the 17 letters submitted, 12 were received before the close of the comment period. FDA considered all 17 comments in developing its portion of the final rule, while HCFA, in accordance with its usual practice, limited its analysis and response to the 12 timely comments. A summary and analysis of the comments

received on the proposal and the agencies' responses to them follow.

The agencies also advise that, in the Federal Register of November 14, 1986 (51 FR 41332), HCFA issued a final rule that conformed certain of its regulations to statutory changes enacted since the regulations were published. The November 14, 1986, final rule also recodified certain parts of Title 42. Specifically, §§ 405.232 and 405.252 were moved to a new Part 410. As a result, the agencies have consolidated the proposed amendments to 42 CFR 405.180, 405.232, 405.252, and 405.380 into §§ 409.19 (for Medicare Part A benefits), 410.10 and 410.64 (for Medicare Part B benefits). Further, in the Federal Register of June 12, 1987 (52 FR 22444), HCFA issued a final rule with comment period that recodified Part 405, Subpart O of Title 42 to a new Part 498 of Title 42. As a result, the proposed amendment to § 405.1502 has been redesignated as an amendment to § 498.3.

III. Summary and Analysis of Comments

A. General Comments

1. One comment asked if the final rule will apply to temporary as well as permanent pacemaker devices.

The agencies advise that the final rule will apply only to permanent pacemaker devices (compare, e.g., 21 CFR 870.3600 and 870.3610). Final § 805.1(a) of FDA's rule providing for the registry (21 CFR 805.1(a)) and §§ 409.19(a) and 410.64(a) of HCFA's rule (42 CFR 409.19(a) and 410.64(a)) have been revised accordingly. A temporary pacemaker is used until a permanent pacemaker is implanted or another therapeutic modality is decided upon. It is used for periods generally measured only in weeks. A malfunction of a temporary pacemaker would be reported under FDA's Medical Device Reporting (MDR) requirements (21 CFR Part 803). Because the pacemaker registry will provide FDA with a mechanism for monitoring and evaluating the long-term performance of pacemakers, submission of data on temporary pacemakers, which are used only for the short-term, would serve no useful purpose. Moreover, information is to be submitted to the registry upon implantation, removal, or replacement of a pacemaker. Temporary pacemakers are not implanted but are external to the body.

2. Two comments suggested modifying proposed § 805.1 to provide that, to monitor the performance of pacemakers and leads, FDA may use the registry data in conjunction with other FDA data sources such as the MDR regulations under 21 CFR Part 803, records maintained to comply with current good manufacturing practice (CGMP) regulations under 21 CFR Part 820, and annual reports under 21 CFR Part 814 governing premarket approval of medical devices.

FDA believes that it is not necessary to include this language in the final rule. It is FDA's policy to integrate, coordinate, and utilize all data submitted to the agency by various reporting procedures to monitor devices.

3. One comment inquired whether the proposed rule would apply to the antitachyarrhythmia defibrillator and the automatic implantable defibrillator, neither of which, the comment argued, is a pacemaker.

The agencies acknowledge that the definitions of pacemaker or pacemaker device in § 805.3(c) of the final rule, or the definition of pacemaker lead in § 805.3(d), do not apply to the antitachyarrhythmia defibrillator or to the automatic implantable defibrillator. As advances are made in pacemaker technology, however, the definition of pacemaker device will be revised as necessary for purposes of Medicare coverage.

4. Three comments on § 805.10(h) believe that the date of initial implantation of a removed pacemaker is often unknown to the physician or provider treating a patient with a pacemaker failure, especially if the original implantation was done by a different physician and by a different provider. The agencies recognize that there may be instances where the date of initial implantation is not known. For this reason, final § 805.10(h) has been revised to require reporting of the date of initial implantation only "if known."

5. One comment requested that an upgrade of a pacemaker system from a single-chamber to a dual-chamber be exempt from the requirement of § 805.10(h) to report "if the procedure involved a lead implant, whether a former lead was left in the body." The comment explained that in such an upgrade a lead is left in the body when another lead is implanted, but it should not be necessary to report this fact to the registry.

The agencies reject the comment. The purpose of the registry is to acquire data on pacemaker devices including leads. In order for the data on leads to be comprehensive, the agencies have decided not to exempt from submission information on former leads being left in the body when the pacemaker system is upgraded from a single-chamber to a dual-chamber unit.

Also, regarding § 805.10(h), the agencies, on their own initiative, deleted the latter part of proposed § 805.10(h) that would have required submission of the following: "if the pulse generator was removed or replaced, whether a lead also was removed or replaced; and, if the procedure involved a lead implant, whether a former lead was left in the body." This information would have been redundant because the first part of § 805.10(h) requires that the same information be submitted for "each device." Pursuant to §§ 805.3(c) and 805.10(h), each "device" means pulse generator, atrial lead, or ventricular lead.

6. One comment expressly approved of the data elements that proposed § 805.10 would require to be submitted to the registry. Another comment suggested that, for the purpose of reporting on the removal or replacement of a device, the agencies should also require under § 805.10(h) the submission of information respecting the underlying rhythm or condition that initially required implantation of a pacemaker, a hard copy of the data indicating pacemaker malfunction (e.g., electrocardiogram strips, recording, or numerical test data), the type of monitoring used for the patient in which the device was removed or replaced, and whether any significant problems occurred with the patient because of the failure of the device removed or replaced.

Although section 1862(h)(1)(B) of the Act permits the agencies to include in the registry any information they deem appropriate, the agencies do not believe at this time that the additional data elements suggested by the comment are necessary for the purposes for which the registry is being established. To keep the information-reporting burden at a minimum, the agencies reject the suggested additional data elements as nonessential.

7. One comment suggested that proposed § 405.180 (§ 409.19 in the final rule) be amended by deleting the word "removal." This would mean that information on cases in which a pacemaker or lead is removed but not replaced with another pacemaker or lead would not be collected by the registry.

The agencies do not accept this comment because they believe that to do so would compromise the purpose of the registry as described in the Act. Failure to collect information on pacemakers and leads that are removed would not only increase the number of "lost" devices in the registry, but would also overlook potential serious abuse in the area of implantation by not reporting situations in which the device may not have been medically necessary in the first place.

8. One comment stated that the final rule should include a provision that would allow a manufacturer of pacemakers or leads, in addition to the physician or provider, to provide warranty or other information to the registry. The comment argued that such a provision would express in part the congressional intent behind section 1862(h)(1)(E) of the Act.

Section 1862(h)(1)(E) of the Act states, "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" (emphasis added). It is clear that Congress' intent was to allow, but not to require, the submission to the registry of information regarding implants and explants of non-Medicare patients in addition to those of Medicare patients. There is not any similar requirement that any "person or organization" be allowed to submit information on Medicare cases. Indeed, section 1862(h)(1)(C) of the Act specifies that the "physician and provider of services" for which payment is made or requested under Medicare is to be the source of the information. The agencies believe that, in light of the requirements in these regulations for physician and provider submissions of information, additional submissions would not be necessary for the purposes of the registry.

9. One comment recommended that the agencies add to the final rule a provision that neither the submission to the registry, or release by the agencies, of information constitutes a conclusion or admission that a pacemaker or lead has failed to operate within its performance specifications. The comment expressed concern that, "with the growing number of medical malpractice and product liability cases," the registry data could be used to wrongfully imply liability.

The agencies have revised § 805.1 to make clear that submission or release of data does not necessarily reflect a conclusion or admission that a device has failed to operate within its performance specifications. A submitter need not admit, and may deny, that the information constitutes an admission that the device failed to operate within performance specifications.

FDA's position on this matter was stated in the agency's responses to two comments in the preamble of the MDR final rule (49 FR 36329 and 36338) as well as in the agency's response to a request for clarification of this position from Johnson & Johnson. (See 49 FR 48272).

10. A Medicare Part B carrier requested that a program be established between local Part B carriers and Part A intermediaries so that the carriers could more efficiently deny payment to physicians if the necessary information was not submitted for the registry.

HCFA has been collecting registry information for more than a year and has identified so few instances in which physicians have been responsible for failing to submit information that HCFA does not believe it is necessary to establish such a program at this time. However, the agency is prepared to develop such a program if noncompliance becomes a serious problem.

B. Method of Information Reporting

11. One comment expressed concern that because two agencies, FDA and HCFA, will be involved in the operation of the registry, there might be two separate reporting systems, one for submitting claims data to HCFA and another for submitting registry data to FDA. The comment asked if this "additional requirement" of submitting registry data will delay payment of Medicare claims. The comment also asked if those providers that transmit claims data electronically to their fiscal intermediary will also be able to transmit registry information electronically.

The agencies advise that there will not be two separate reporting systems; providers will submit the required registry information to their fiscal intermediary at the same time they submit the bill for services; providers will not be required to transmit information directly to FDA. Providers may transmit this information electronically to the intermediary if the provider and the intermediary each have that capability. In fact, the agencies encourage providers and intermediaries to pursue all cost-reducing and burden-reducing initiatives. A provider that submits the required information with the bill will not experience any delay in payment of the provider's claim. As noted in paragraph 10 of this preamble, providers have been submitting registry information for more than a year; to date, there have not been any delays in payment.

C. Reporting Responsibilities

12. One comment recommended that proposed § 405.232(k) (§§ 409.19 and 410.64 in the final rule) be changed to limit the reporting obligation to those physicians directly engaged in the implant procedure. The comment argued that §§ 409.19 and 410.64 may encompass cardiologists, referring physicians, or members of a surgical team who do not have access to information that is to be reported to the registry.

The agencies believe that the language in proposed § 405.232(k) may be unclear. Accordingly, the agencies have changed §§ 409.19 and 410.64 of the final rule such that all proposed references to physicians and providers of services "*engaged* in the implantation * * *" now refer to physicians or providers of services that "*request or receive payment from Medicare* for the implantation * * *" (emphasis added). This reference to "physicians" means the surgeon or other physician who performs the implant, replacement, or removal. It is not intended to encompass other physicians such as cardiologists, referring physicians, or members of the surgical team. Also, this revision in final §§ 409.19 and 410.64 makes all references in Title 42 concerning who must report to the registry consistent with § 805.10. In most cases, the provider of services will coordinate the submission of information that must be reported. However, if the provider fails to submit the required information, any physician who requests or receives payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers or pacemaker leads is required to submit information to the registry.

13. Two comments recommended that data about the pacemakers and leads (including warranty information) should be obtained from manufacturers of the devices, or from the representative of the manufacturer that is present during surgery, rather than from physicians and providers, so as not to unduly burden physicians and providers.

As discussed at length in the preamble to the proposal (51 FR 16792), section 1862(h)(1)(C) of the Act provides that physicians and providers (not manufacturers) shall submit all the required information to the registry. The agencies, thus, may not issue regulations requiring either manufacturers or any manufacturer's representative to submit the information (see also paragraph 9 of this preamble).

14. One comment argued that the proposed rule should be more explicit about the specific information that is to be reported to the registry by the attending physician and by the surgeon.

The agencies believe there is no need to specify within the regulation itself which information will be collected from which physicians. Any physician who requests or receives Medicare payment for the implantation, removal, or replacement of a pacemaker or lead is required to provide his or her Medicare physician identification number (used

by Utilization and Quality Control Peer Review Organizations) to the provider. (See § 805.10(e) of the final rule.) Any additional information that a particular physician will be required to submit, such as manufacturer, model, and serial number of the implanted or removed pacemaker or lead, will be determined by the method the provider chooses to use to obtain that information and will be requested in accordance with Medicare program instructions.

D. Manufacturers' Warranties

15. Two comments objected to the proposed definition of "warranty" in § 805.3(h). One of the comments argued that the references in the proposed definition to "implied guarantee" and to "State law" should be deleted on the ground that they are outside the practical scope of the registry. Moreover, the comment argued that implied warranties may vary among States and often arise as a result of judicial case law rather than through legislation. For this reason, there may be questions as to which State's law applies—the State where the manufacturer is located or the State where the explant or implant is performed.

Section 1862(h)(1)(B) of the Act states that the "registry shall include * * * any express or implied warranties associated with such device or lead under contract or State law, and such other information as the Secretary deems to be appropriate." Thus, although the Act gives the agencies the discretion to require that physicians and providers submit information in addition to that specified by the Act, it does not permit the agencies to delete information that the Act requires to be submitted.

Neither the Act nor the final rule creates any warranties but merely recites that warranties may arise under contract or State law. Issues such as variation in warranties from State to State and which State's law applies are beyond the intent and scope of the Act and the final rule.

The agencies recognize that warranties may vary from State to State. However, there is nothing in either the Act or the legislative history to indicate that Congress intended to alter that variability or to place with either FDA or HCFA the responsibility to decide which State's law is controlling. Indeed, the Act calls for the registry to include "*any* express or implied warranties * * * under contract or State law (emphasis added)." Similarly, the legislative history contemplates the inclusion of "*any* express or implied warranties *associated* with the device." (H. Rept. 98-861, 98th Cong., 2d sess.; 1322 (1984)) (emphasis added). Accordingly, it is possible that a pacemaker device may have more than one applicable warranty, and may have a certain warranty, either express or implied, in one State, but a different warranty in another State. In an effort to keep the registry requirements to a minimum, the registry asks only for the applicable warranty expiration dates.

16. One comment urged that the agencies change the definition of "warranty" from "an express or implied guarantee, under contract or State law, of the integrity of a pacemaker device or pacemaker lead and of the manufacturer's responsibility for the repair or replacement of defective parts of a pacemaker device or pacemaker lead," to "* * * an express written affirmation or statement of the integrity of a pacemaker device or pacemaker lead and of the manufacturer's responsibility to refund, repair, replace, or take other remedial action in the event that the pacemaker device or pacemaker lead fails to meet the representations set forth in the statement."

The agencies reject the suggested change to the definition of "warranty." The definition in the proposed rule is adequate for the purposes of the registry and reflects section 1862(h)(1)(B) of the Act, in that it makes clear that a warranty may be either an express warranty or an implied warranty and may arise either by contract or State law. As stated previously, neither the Act nor the final rule actually creates any warranties. Accordingly, the definition remains the same in the final rule.

17. Two comments suggested that the agencies revise proposed § 805.10(g) to provide for the submission of "warranty duration" information rather than "warranty expiration date." The comments argued that the determination of a warranty expiration date might be a cause of delay or inaccuracy.

The agencies recognize that warranty terms and conditions vary. However, because providers are in the best position to calculate or interpret the term of the warranty and to determine the warranty expiration date, the agencies do not believe that such determinations will cause any significant inaccuracy in the information provided to the registry. As noted in paragraph 11 of this preamble, registry information has been collected for more than a year; to date, there have not been any delays in payment. The inclusion of a warranty expiration date, rather than a duration description, will make it easier for the agencies to use registry data to determine whether any warranty might be applicable to a replaced pacemaker. A duration description, by itself, would not indicate when the warranty will expire.

18. Several comments on proposed § 805.10(h) noted the difficulties associated with determining the date of expiration of the warranty for a pacemaker device or lead in a case in which the procedure about which the information for the registry is being collected is a removal or replacement.

The agencies agree that the warranty expiration date for a removed device may not be known by the physician or the provider of services. The agencies did not intend that the physician or provider would be obligated to report this information if the physician or provider does not know it. For this reason, final § 805.10(h) has been revised to require that the warranty expiration date is to be submitted to HCFA for inclusion in the registry only "if known."

19. One comment suggested that the agencies add a new provision in the final rule to require each manufacturer or importer of pacemakers or pacemaker leads to submit to the registry, every year, copies of warranties on all models of currently implanted pacemakers and leads in the United States.

The agencies do not believe that it is necessary for the purposes of the registry to impose such a reporting burden on manufacturers and importers of pacemakers or pacemaker leads. The agencies prefer to request copies of warranties on an as needed basis. In any case, as noted in paragraph 13 of this preamble, section 1862(h) of the Act does not provide any authority to impose such requirements on manufacturers or importers.

20. One comment suggested that where the warranty provides a choice between payment to the patient for uninsured medical expenses, or a new replacement pacemaker without charge, HCFA should insist on a full warranty credit toward a new replacement pacemaker.

HCFA has not accepted this comment. Because the warranty is made to the patient, not to HCFA, the choice would therefore lie with the patient, not HCFA.

E. Denial and Appeal Procedures

21. One comment recommended that proposed § 405.180(a) (§§ 409.19(b) and 410.64(b) in the final rule), dealing with denial of Medicare payment, be revised to provide that payment "may be" rather than "will be" denied in the event that a physician or provider does not meet the reporting requirements of the rule. The

comment argued that the latter wording changes the discretionary authority of the Secretary and is beyond the scope of the Act.

Section 1862(h)(4) of the Act gives the Secretary the discretion to deny Medicare payments to physicians and providers for failure to comply with the registry reporting requirements. HCFA has decided to exercise its authority to deny entire payments to ensure compliance with the reporting requirements. Sections 409.19(b) and 410.64(b) of the final rule reflect HCFA's policy to deny entire payments.

22. One comment on proposed § 405.180(a) recommended that the provisions dealing with denial of Medicare payment in cases of noncompliance (§§ 409.19(b) and 410.64(b) in the final rule) be amended to provide that payment would be withheld "in whole or in part" rather than entirely.

As discussed in response to comment 21, section 1862(h)(4) of the Act gives the Secretary discretionary authority to decide whether payments in whole or in part should be withheld in cases of noncompliance with regulations issued by the agencies. HCFA has decided to exercise its authority to deny whole payments to better ensure compliance with the registry reporting requirements.

23. One comment urged that HCFA establish a time limit of 2 years from the date of implantation of a pacemaker or pacemaker lead to the date for initiating procedures for denial of payment.

HCFA believes that it is unnecessary to set a time frame for initiating denial of Medicare payment. Any initiation of the denial provisions under final § 409.19(b) or § 410.64(b) is expected to occur well within a 2-year period.

24. One comment on HCFA's proposed regulations providing for denial of Medicare payment in cases of noncompliance requested a definition of the word "timely," as used in the preamble to the proposal (51 FR 16793), which stated: "If the provider later submits the appropriate information required by FDA, payment would be made if the provider resubmits the claim timely."

"Timely" means within the time periods specified in § 409.19(c) of the final rule. This section states that HCFA will send a written notice to the affected party 45 days before a determination to deny payment becomes effective. However, before the start of the formal denial process (which begins with the 45-day notice) providers will be given an opportunity to furnish any missing information in a manner similar to the current process their intermediaries use to obtain missing information or to clarify inconsistencies on the bill. Because these processes are usually done prior to payment, HCFA will program the bill processing system to preclude payment until the Part A intermediary receives the required information from the provider. This is consistent with current procedures for collection of missing data, e.g., admission date, discharge date, and condition codes. HCFA believes that this approach will decrease significantly the need for formal denial notices and subsequent reconsiderations. The formal denial process will be initiated only as a last resort for those cases in which the provider refuses to provide the necessary information. Moreover, payment will be made at any time during the 45-day period that the provider submits the required information. Once administrative and judicial appeal procedures are initiated, payment will be made only in accordance with the appeals process.

25. One comment expressed concern that the proposed rule lacks safeguards to ensure that physicians are not penalized if they meet their reporting requirements but the provider fails to report the required information to HCFA.

HCFA advises that payment to physicians will be denied only in cases where HCFA determines that the physician was not providing the necessary information to the provider. Where such a determination is made, HCFA will send a written notice to the physician, to which he or she may respond, stating the basis of HCFA's determination that the physician has failed to meet the reporting requirements.

26. One comment recommended that HCFA establish a clear procedure for late reporting so that physicians and providers could receive full payment after issuance of the 45-day notice that they failed to comply with the information collection requirements. The procedure was recommended because of a concern that registry information could get lost in the administrative process.

HCFA advises that the 45-day notice is intended to provide for late reporting. As noted previously, HCFA has not experienced any difficulties in receiving or processing this information since the agencies began collecting it more than a year ago.

F. Confidentiality

27. Two comments were received regarding proposed § 805.25 of FDA's regulations. One of the comments requested that FDA restrict from public use any information in the registry that identifies physicians. The other comment stated that proposed § 805.25 failed to adequately and expressly protect trade secret and proprietary information otherwise protected by the Freedom of Information Act (5 U.S.C. 552) and 21 CFR Part 20 (FDA's public information regulations). The comment suggested that the agencies revise § 805.25 to specifically provide that they will not disclose any information that constitutes a trade secret, confidential, commercial, or financial information, or proprietary data such as the names of physicians or hospitals.

Section 1862(h)(1)(D) of the Act prohibits the public disclosure of any specific information that identifies by name, or otherwise, a recipient of any pacemaker device or lead. The agencies do not believe that it is either necessary or appropriate to specify in the final rule any other information that may not be available for public disclosure. As stated in the preamble to the proposal (51 FR 16794), the public availability of any such information reported to the registry will be governed by the Freedom of Information Act, the Privacy Act of 1974 (5 U.S.C. 552a), and the public information regulations of HHS, FDA, and HCFA. To make these requirements clear, the agencies have changed final § 805.25(b) to make it consistent with the preamble to the proposed rule.

G. Return and Testing

FDA did not propose to establish regulations to implement certain provisions of section 1862(h) of the Act that are discretionary. In the preamble to the proposed rule (51 FR 16793), the agencies invited comments on the deferral of regulations implementing such discretionary provisions. These statutory provisions provide that the Secretary may establish regulations to: (1) Require the return by providers of removed pacemakers and leads to the manufacturer of the device (section 1862(h)(2)(A) of the Act), (2) require the testing of such returned devices by the manufacturer of the device and the sharing of test results with providers (section 1862(h)(3) of the Act), and (3) describe the circumstances under which FDA will participate in the testing (section 1862(h)(3) of the Act). The agencies specifically asked that any comments on the deferral of regulations implementing these provisions address: (i) The need for implementing either or both of these discretionary provisions and (ii) the nature and extent of the regulations that should be established.

28. The agencies received three comments on the deferral of regulations.

One comment urged the agencies to implement the discretionary provisions at the same time as the registry is established on the grounds that: (1) Deferral of testing that would be dependent on earlier registry data would result in a "lag-time" during which some models of pacemakers and leads might be discontinued, thus making testing of these models meaningless; (2) immediate implementation of the testing provision would save Medicare "thousands of dollars" because testing would provide the agencies with the data that would be required to pursue warranty reimbursements for defective devices; (3) testing would elevate the level of confidence that FDA has in the pacing industry: and (4) the industry, if faced with the prospect of having all explants tested and having to honor warranties, may be encouraged to define and implement a realistic, standardized warranty. The comment also suggested that, when the provision to require the testing of returned devices is implemented, it should provide for such testing by an independent testing facility approved by FDA, rather than by the manufacturer of the device, to eliminate a possible conflict of interest.

Two comments supported the deferral (perhaps indefinitely) of the implementation of the discretionary provisions of the Act. One of the comments gave the following reasons for deferral: (1) Manufacturers, on their own initiative, encourage physicians and hospitals to return explanted devices to them for testing; in fact, it is "fairly standard" in the industry for pacemaker warranties to require such return; (2) FDA's CGMP regulations, in 21 CFR 820.162, require manufacturers to conduct an investigation of any failed device; and (3) the MDR reports make device analysis information available to FDA. The comment believes that it is appropriate to implement the registry first and evaluate its usefulness in conjunction with these existing data sources before implementing provisions which, at the present time would increase registry costs with no commensurate benefit. If implemented in the future, this comment further believes that any regulations respecting the testing of returned devices should provide for such testing by the manufacturer of the device rather than any independent laboratory, FDA, or the hospitals, on the ground that only manufacturers have the facilities and expertise to do the testing.

The second comment favoring deferral believes deferral is appropriate in view of the current lack of information on the registry's actual functioning. Moreover, according to the comment, implementing the discretionary provisions could extend FDA's regulatory authority to providers, beyond the traditional scope of the agency's jurisdiction.

FDA agrees with the comments that favor deferral of the discretionary "return and testing" provisions of the Act although not necessarily with the reasons given in the comments. FDA continues to believe that it is not timely to establish "return and testing" requirements for the following reasons: (1) Data from the registry will be used to assist FDA in deciding if there is a need to implement return and testing provisions. To implement them at this time, when the agency is lacking data upon which to make such a decision, would involve an unnecessary and premature use of resources and would unduly delay implementation of the registry itself; (2) the means to implement these provisions, and the degree of specificity that is needed, will depend to a large degree on the actual functioning of the registry. The legislation itself recognizes this, in that it provides that once the registry is in operation, information derived from the registry will be used to identify pacemakers and leads which must be tested, and that information from the registry will be used to determine whether FDA personnel are to be present at the testing of specific pacemakers and leads.

29. One comment on proposed § 405.180(a) recommended that HCFA not establish regulations to require the provider to return to the manufacturer any pacemaker device or lead which is removed or to require the manufacturer to test the device or lead if FDA so requires under a subsequent regulation, because FDA has not decided to implement return and testing provisions. The comment argued that HCFA's proposed provisions are confusing and would lead to disjointed or conflicting provisions if and when FDA issues regulations to implement the discretionary provisions of the Act.

The agencies agree that the proposed provisions may be confusing and inappropriate at this time. Indeed, several other comments asked specific questions about the implementation of the "return and testing" provisions, apparently mistakenly believing that the agencies were proposing to implement them at this time. Therefore, we have removed all requirements regarding the return and testing of pacemaker devices from the final rule. Because the final rule does not implement the "return and testing" provisions of the Act, the agencies are unable to respond to the specific questions about such provisions raised in several comments. If FDA decides in the future to establish return and testing requirements, the agencies will proceed through notice and comment rulemaking, at which time interested persons will have the opportunity to comment on the proposal. The agencies urge those persons and organizations that submitted these comments to resubmit them, if still appropriate, and any other comments at that time.

H. Review Under the Paperwork Reduction Act

30. Two comments requested a review of the regulations under the Paperwork Reduction Act of 1980 within 1 year of implementation of the registry to examine how the registry is accomplishing its goals and to determine whether additional revisions could make it more workable.

The agencies will be monitoring and evaluating the implementation and operation of the registry on a regular basis. The agencies advise that revisions will be made as needed to assure compliance with the final rule and to assure that the registry is workable. Revisions will be submitted to the Office of Management and Budget for final review pursuant to the Paperwork Reduction Act.

I. Regulatory Impact Statement

31. One comment urged that the agencies reevaluate the estimates of the costs to hospitals of recordkeeping and reporting under the rule, once the agencies have had some experience with such reporting.

The agencies do not believe that a reevaluation is needed. The comment did not provide any data to show that the voluntary initial impact analysis that the agencies provided in the preamble to the proposal (51 FR 16794) was erroneous. Further, based on data collected for the registry from most hospitals for more than a year, the estimates have been found not to be erroneous.

32. One comment criticized as too low the estimate that "costs for collecting, processing, and transmitting data to the registry would equal approximately $750,000 per year" (51 FR 16795). The comment appeared to believe that this estimate represented costs to hospitals.

The estimate cited by the comment represents solely administrative costs to the Federal government that we estimate will be incurred by the Medicare program. Although we discussed in the preamble to the proposed rule factors that would affect

providers' administrative costs and gave reasons why we believed those costs would not be substantial (51 FR 16795), data were not available that would have enabled us to make a definitive estimate. Further, because hospitals differ greatly both in the number of implants performed and in their information management resources, an estimate of average or aggregate administrative costs to hospitals would have been of doubtful help to persons interested in commenting on the proposal. For this reason, we provided a formula for the expression of a hospital's administrative costs. The formula did not include the cost of returning devices to the manufacturer if required by subsequent FDA regulations. Although one comment suggested that HCFA might later assess hospitals' actual experience with the costs of recording and reporting required information, none of the comments submitted any data that would cause us to revise the amount set forth in the voluntary initial impact analysis.

33. Three comments recommended that the pacemaker diagnosis related groups, under which Medicare prospective payments are made for related inpatient hospital services, be readjusted, or that additional payments be made, so that hospitals could recover the recordkeeping costs incurred while complying with these regulations.

In Pub. L. 98–21, Congress established a new system for paying hospitals for services furnished to inpatients. This system was designed to replace the reasonable cost reimbursement system, under which hospitals were reimbursed on a dollar-for-dollar basis for their actual reasonable costs incurred in furnishing services to Medicare hospital inpatients. The new Medicare prospective payment system was implemented beginning October 1, 1983. Under the law, the amount of payment for operating costs of inpatient hospital services is based on prospectively determined rates. Section 1886(a)(4) of the Act defines operating costs as including:

> * * * all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services * * *. Such term does not include costs of approved educational activities, costs of anesthesia services provided by a certified registered nurse anesthetist or * * * capital-related costs * * *.

Costs of furnishing data for maintaining a pacemaker registry are clearly within the meaning of operating costs of inpatient hospital services, and we have therefore decided will not be reimbursed on a dollar-for-dollar pass-through basis.

IV. Technical Revisions

As part of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248), Congress authorized hospice care as a new Medicare benefit, effective November 1, 1983. Congress enacted the hospice benefit with a "sunset" provision that would terminate the benefit on September 30, 1986, unless further legislation were enacted. Section 9123 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) was enacted on April 7, 1986, just prior to the May 6, 1986, proposed regulations, and repeals the "sunset" provision of the Medicare hospice benefit. In accordance with this new legislation, we are removing from final § 805.3(g) the September 30, 1986, termination date for the hospice benefit, contained in proposed § 805.3(g).

We have, in addition, made changes in the regulations text to conform it to recent recodifications and to improve its clarity and consistency.

V. Regulatory Impact Statement

Executive Order 12291 requires Federal agencies to prepare and publish a regulatory impact analysis for any major rule. A major rule is defined as any rule that is likely to: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, and local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, we prepare and publish a regulatory flexibility analysis consistent with the Regulatory Flexibility Act (5 U.S.C. 601 through 612) unless the Secretary certifies that the rule would not have a significant economic impact on a substantial number of small entities.

In the preamble to the proposed rule published May 6, 1986 (51 FR 16794–16796), we set forth in some detail our reasons for determining that it was not necessary to prepare an analysis under either Executive Order 12291 or the Regulatory Flexibility Act. Nevertheless, we prepared a voluntary analysis of the effects we expected the creation of the pacemaker registry would have on beneficiaries, providers, physicians, manufacturers, and our own program and administrative expenditures. Our responses to the timely comments that dealt directly with the material discussed in that voluntary analysis are included in Section III of this preamble.

As noted in the preamble to the proposed rule, the impact of this rule will result primarily from the statutory mandate to establish a pacemaker registry. The pacemaker registry will impose costs on both providers of health care services and the Federal government. It may also provide benefit payment savings to the Medicare program by enabling purchasers of pacemakers and pacemaker leads to make more informed decisions. Private sector costs will arise from the requirement for physicians and health care providers to supply information for the registry regarding implanted, removed, or replaced pacemakers and pacemaker leads. Federal government costs will arise from the administration and data management of the registry. Any offsetting government savings from Medicare will depend on the content and functions of the registry and its impact on provider behavior.

Costs or potential savings cannot be estimated with any confidence. Both savings (that is, reductions of program expenditures) and the costs that will result from implementation of this final rule will be functions of the number of implants, removals, or replacements of pacemaker devices and leads.

As stated in the proposed rule, we believe that hospitals are able to maintain a relatively simple system of recordkeeping that requires minimum effort and facility expense. Some comments contested this (see, e.g., paragraphs 31 through 33 in this preamble), but our experience to date with collection of registry data supports us. The expenses incurred by hospitals in recording, maintaining, and reporting required data will be considered reasonable costs for hospitals paid on a cost basis. Hospitals under the prospective payment system are paid for such administrative expenses related to inpatient procedures under the prospective payment amount.

Although we expect the information concerning the ordering or implanting physicians to be supplied by hospitals to HCFA for the registry, if the surgeon or attending physician is found not to be supplying information necessary for the program to the hospital, authority exists to deny payment to the physician for each case. As in the case of hospitals, however, we expect physicians to comply. Therefore, the provision permitting denial of payment to physicians should not have any significant economic impact. Further, because the hospital will be

accumulating and reporting the data, we believe that physicians will not incur any significant additional administrative costs associated with the rule.

Beneficiaries will not be negatively affected by the registry requirements. If payment is denied to a hospital for noncompliance with the rule, the hospital is prohibited by § 489.21(g) from increasing charges to beneficiaries to recover denied payments. Although we do not expect implementation of this rule to have a financial impact on patients in the short term, potential long-term beneficial effects would include fewer complications and possibly fewer deaths associated with malfunctioning pacemaker devices. The magnitude of such effects can be determined only after the registry is implemented and we have a period of experience under the program.

In conclusion, this rule will require physicians and providers of services, all of which may be considered small entities under the Regulatory Flexibility Act, to submit to FDA and HCFA certain information regarding pacemakers and pacemaker leads.

Although this requirement will obligate hospitals to record and to report the information, we do not believe that it represents a significant increase in hospitals' overall paperwork or human resources requirements. To a large extent, much of this information is already kept by hospitals. Manufacturers of cardiac pacemaker devices and pacemaker leads may be required by subsequent FDA regulations to test and report on devices that are returned by providers of services. FDA will review the impact of any such regulations at the time that they are issued. Therefore, we have determined that this rule is not a major rule under Executive Order 12291. Further, we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities.

VI. Environmental Considerations

The agencies have determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Information Collection Requirements

21 CFR 805.10 of this rule contains information collection requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3507 of the Paperwork Reduction Act of 1980. These information collection requirements were approved and assigned OMB control number 0910–0234.

HCFA has already obtained OMB approval of Form HCFA–497, HCFA Pacemaker Related Data, which implements the collection of information requirements contained in this rule. The OMB control number, which reflects approval of that form, is 0938–0436. 42 CFR 409.19(a) and 410.64(a) do not establish any new information collection requirements. They only refer to 21 CFR 805.10, which as discussed above has been approved and assigned OMB control number 0910–0234.

List of Subjects in 21 CFR Part 805

Medical devices, Medicare records, Reporting and recordkeeping requirements.

List of Subjects

42 CFR Part 400

Grant programs—health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Medical and other health services, Medicare.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 498

Administrative practice and procedure, Appeals, Medicare, Practitioners, providers, and suppliers.

Therefore, under the Social Security Act and the Deficit Reduction Act, Title 21 and Title 42 of the Code of Federal Regulations are amended as follows:

TITLE 21—[AMENDED]

1. By adding new 21 CFR Part 805 to read as follows:

PART 805—CARDIAC PACEMAKER REGISTRY

Subpart A—General Provisions

Sec.
805.1 Scope.
805.3 Definitions.

Subpart B—Submission of Information

805.10 Submission of information by physicians and providers.
805.20 How to submit information.
805.25 Confidentiality.

Authority: Sec. 1862(h) of the Social Security Act and sec. 2304(d) of the Deficit Reduction Act, 98 Stat. 1068–1069 (42 U.S.C. 1395y(h), 1395y note); 21 CFR 5.10 and 5.11.

Subpart A—General Provisions

§ 805.1 Scope.

(a) This part provides for a nationwide cardiac pacemaker registry and requires any physician and any provider of services who requests or receives payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads to submit certain information to the registry. If the physician or the provider of services does not submit the information according to this part and 42 CFR 409.19(a) and 410.64(a), HCFA, which administers the Medicare program, will deny payment to the physician or the provider. FDA will use the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analyses regarding the use of the devices, and to transmit data to HCFA to assist HCFA in administering the Medicare program and to other Department of Health and Human Services' components to carry out statutory responsibilities.

(b) Information submitted to the registry by a physician or a provider of services (and any release by FDA or HCFA of that information) does not necessarily reflect a conclusion by the submitter, FDA, or HCFA that the information constitutes an admission that a pacemaker device or lead failed to operate within its performance specifications. A submitter need not admit, and may deny, that the information submitted to the registry constitutes an admission that the pacemaker device or lead failed to operate within its performance specifications.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 805.3 Definitions.

(a) "FDA" means the Food and Drug Administration.

(b) "HCFA" means the Health Care Financing Administration.

(c) A "pacemaker" or "pacemaker device" is a device that produces periodic electrical impulses to stimulate the heart. It consists of two basic components: a pulse generator and one or more leads. See § 870.3610 for a more detailed definition.

(d) A "pacemaker lead" is a flexible, insulated wire connected at one end to a

pacemaker's pulse generator and at the other end to the heart. It transmits electrical stimuli to and from the heart. See § 870.3680(b) for a more detailed definition.

(e) A "physician" is a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by applicable laws of the State in which he or she performs such function or actions. (This definition includes an osteopathic practitioner.)

(f) A "PRO" is a Utilization and Quality Control Peer Review Organization that contracts with the Secretary of Health and Human Services to review health care services funded by the Medicare program to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality which meets professionally recognized standards.

(g) A "provider" is a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or a hospice that has in effect an agreement to participate in Medicare.

(h) A "warranty" is an express or implied guarantee, under contract or State law, of the integrity of a pacemaker device or pacemaker lead and of the manufacturer's responsibility for the repair or replacement of defective parts of a pacemaker device or pacemaker lead.

(i) Any terms defined in section 201 of the Federal Food, Drug, and Cosmetic Act will have that definition.

Subpart B—Submission of Information

§ 805.10 Submission of information by physicians and providers.

A physician or a provider of services that requests or receives payment from Medicare for the implantation, removal, or replacement of a permanent cardiac pacemaker device or pacemaker lead shall submit the following information on a specified form to HCFA for inclusion in the pacemaker registry provided for by FDA under § 805.1:

(a) Provider number.

(b) Patient's health insurance claim number (HICN).

(c) Patient's name.

(d) Date of the procedure.

(e) Identification number (used by PRO's) and name of the physician who ordered the procedure.

(f) Identification number (used by PRO's) and name of the operating physician.

(g) For each device (pulse generator, atrial lead, ventricular lead) implanted during the procedure about which the report is being made: the name of the manufacturer, model number, serial number, and the warranty expiration date.

(h) For each device (pulse generator, atrial lead, ventricular lead) removed or replaced during the procedure about which the report is being made: the name of the manufacturer; model number; serial number; the warranty expiration date, if known; the date the device was initially implanted, if known; whether a device that was replaced was left in the body; if the device was not left in the body, whether it was returned to the manufacturer.

(Collection of information requirements in this section were approved by the Office of Management and Budget under OMB control number 0910-0234)

§ 805.20 How to submit information.

Information shall be submitted to the registry in the form and manner required under general instructions of the Medicare program (see 42 CFR 409.19(a) and 410.64(a)).

§ 805.25 Confidentiality.

(a) FDA and HCFA will keep confidential, and will not reveal to the public, any specific information that identifies by name a recipient of any pacemaker device or lead or that would otherwise identify a specific recipient.

(b) Public disclosure of all other information under this part will be governed by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act of 1974 (5 U.S.C. 552a), the Department of Health and Human Services' public information regulations (45 CFR Part 5), FDA's public information regulations (21 CFR Part 20), and HCFA's public information regulations (Subpart B of 42 CFR Part 401).

TITLE 42—[AMENDED]

PART 400—INTRODUCTION; DEFINITIONS

Subpart B—Definitions

2. The authority citation for 42 CFR Part 400, Subpart B, continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

3. In § 400.200 by adding the definition of "FDA" in alphabetical order to read as follows:

§ 400.200 General definitions.

* * * * *

"FDA" stands for the Food and Drug Administration.

* * * * *

PART 409—HOSPITAL INSURANCE BENEFITS

4. The authority citation for 42 CFR Part 409 is revised to read as follows:

Authority: Secs. 1102, 1812, 1813, 1861, 1862(h), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395x, 1395y(h), 1395hh, and 1395rr).

5. By adding new § 409.19, to read as follows:

§ 409.19 Services related to cardiac pacemakers and pacemaker leads.

(a) *Conditions.* Providers of services that request or receive payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit information required by FDA under 21 CFR Part 805 for the pacemaker registry to HCFA in the form and manner set forth in the general instructions of the Medicare program.

(b) *Denial of payment.* Notwithstanding any other provisions of this chapter, payment will be denied to a provider of services with respect to the implantation, removal, or replacement of any permanent cardiac pacemaker or pacemaker lead when, and for so long as, HCFA determines in accordance with the procedures established in paragraph (c) of this section that the provider has failed to submit information required by FDA (under 21 CFR Part 805) for the pacemaker registry.

(c) *Notice of denial of payment.* (1) Whenever HCFA determines that a provider of services has failed to meet any of the requirements contained in paragraph (a) of this section or 21 CFR Part 805, HCFA will send written notice of its determination to the provider at least 45 days before the determination becomes effective.

(2) The notice will state the reasons for the determination and its effective date, and will grant the provider 45 days from the date of the notice to submit to HCFA information or evidence to demonstrate that HCFA's determination is in error. The notice will also inform the provider of its right to a hearing.

(3) Following the expiration of the 45-day notice period provided in paragraph (c)(1) of this section, HCFA's determination and notice constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative and judicial appeal procedures specified in Part 498 of this chapter.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

6. The authority citation for 42 CFR Part 410 continues to read as follows:

Authority: Secs. 1102, 1832, 1833, 1835, 1861 (r), (s), and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 13951, 1395n, 1395x (r), (s), and (cc), 1395hh and 1395rr).

7. In § 410.10 by redesignating existing paragraph (n) as paragraph (o) and adding a new paragraph (n) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(n) Cardiac pacemakers and pacemaker leads.

* * * * *

8. By adding new § 410.64, to read as follows:

§ 410.64 Cardiac pacemakers and pacemaker leads.

(a) *Conditions.* Physicians and providers that request or receive payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads must submit to HCFA information required by FDA under 21 CFR Part 805 for the pacemaker registry in the form and manner set forth in the general instructions of the Medicare program.

(b) *Denial of payment.* Notwithstanding any other provisions of this chapter, HCFA will deny payment to a physician or provider who requests or receives payment from Medicare for the implantation, removal, or replacement of any cardiac pacemaker or pacemaker lead when, and for so long as, HCFA determines in accordance with the procedures established in paragraph (c) of this section that the physician or provider does not meet the reporting requirements in paragraph (a) of this section.

(c) *Notice of denial of payment.* (1) Whenever HCFA determines that a physician or provider has failed to meet any of the requirements contained in paragraph (a) of this section or 21 CFR Part 805, HCFA will send written notice of its determination to the physician or provider at least 45 days before the determination becomes effective.

(2) The notice will state the reasons for the determination and its effective date, and will grant the physician or provider 45 days from the date of the notice to submit to HCFA information or evidence to demonstrate that HCFA's determination is in error. The notice will also inform the physician or provider of the right to a hearing.

(3) Following the expiration of the 45-day notice period provided in paragraph (c)(1) of this section, HCFA's determination and notice constitute an "initial determination" for purposes of the administrative and judicial appeal procedures specified in Part 498 of this chapter.

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

9. The authority citation for 42 CFR Part 489 is revised to read as follows:

Authority: Secs. 1102, 1861, 1862(h), 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(h), 1395aa, 1395cc, and 1395hh) and sec. 602(k) of Pub. L. 98-21 (42 U.S.C. 1395ww note).

10. In § 489.21 by adding new paragraph (g) to read as follows:

§ 489.21 Specific limitations on charges.

* * * * *

(g) Items and services furnished in connection with the implantation of cardiac pacemakers or pacemaker leads when HCFA denies payment for those devices under § 409.19 or § 410.64 of this chapter.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM

11. The authority citation for Part 498 continues to read as follows:

Authority: Secs. 205(a), 1102, 1869(c), 1871, and 1872 of the Social Security Act (42 U.S.C. 405(a), 1302, 1395ff(c), 1395hh, and 1395ii), unless otherwise noted.

12. In § 498.3(b) by republishing the introductory text and adding new paragraph (b)(10) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

* * * * *

(10) Whether to deny payment under § 409.10 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare Hospital Insurance; and No. 13.774, Medicare Supplementary Medical Insurance.)

Dated: July 9, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

Dated: July 13, 1987.

William L. Roper,

Administrator of Health Care Financing Administration.

Dated: July 15, 1987.

Otis R. Bowen,

Secretary of Health and Human Services.

[FR Doc. 87-16592 Filed 7-22-87; 8:45 am]

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federal register

Thursday
July 23, 1987

Part III

Office of Management and Budget

5 CFR Part 1320

Controlling Paperwork Burdens on the Public; Regulatory Changes Reflecting Amendments to the Paperwork Reduction Act; Notice of Proposed Rulemaking

OFFICE OF MANAGEMENT AND BUDGET

5 CFR Part 1320

Controlling Paperwork Burdens on the Public; Regulatory Changes Reflecting Amendments to the Paperwork Reduction Act

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of proposed rulemaking.

SUMMARY: The recently enacted Paperwork Reduction Reauthorization Act of 1986 amended the Paperwork Reduction Act of 1980. In an amendment to 44 U.S.C. 3502(11), Congress clarified the applicability of the Paperwork Reduction Act to collections of information contained in proposed and current regulations. In amendments to 44 U.S.C. 3507, Congress sought to enable the public to participate more fully and meaningfully in the Federal paperwork review process. The Office of Management and Budget (OMB) is proposing to amend its existing paperwork clearance rules to reflect these legislative changes. In addition, consistent with the purpose of these legislative amendments, OMB is proposing (1) to have agencies include, in the **Federal Register** notice indicating submission of an agency's paperwork clearance package to OMB, an estimate of the average burden hours per response; (2) to have agencies publish, as part of the **Federal Register** notice, a copy of the collection of information, when agencies are seeking expedited OMB review; and (3) to have agencies indicate on each collection of information (or on any related instructions) the estimated average burden hours per response, together with a request that respondents direct any comments on the accuracy of the estimate to the agency and OMB.

DATE: Comments must be received on or before September 21, 1987.

ADDRESS: Please address all written comment to Jefferson B. Hill, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jefferson B. Hill, Office of Information and Regulatory Affairs, OMB, Washington, DC 20503 (202/395–7340).

SUPPLEMENTARY INFORMATION:

A. Background

The Office of Management and Budget (OMB) issued 5 CFR 1320—Controlling Paperwork Burden on the Public, on March 31, 1983 [48 FR 13666]. This rule implements provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511, 44 U.S.C. Chapter 35) concerning agency responsibilities for obtaining OMB approval of their collection of information, and other paperwork control functions.

The Paperwork Reduction Reauthorization Act of 1986 (Pub. L. 99–500 (October 18, 1986) and 99–591 (October 30, 1986), section 101(m)) amended the Paperwork Reduction Act of 1980, effective October 30, 1986. OMB is proposing to amend 5 CFR Part 1320 in order to reflect the legislative amendments to 44 U.S.C. 3502(11) and 44 U.S.C. 3507. In addition, consistent with the purpose of these legislative amendments, OMB is proposing (1) to have agencies include, in the **Federal Register** notice indicating submission of an agency's paperwork clearance package to OMB, an estimate of the average burden hours per response; (2) to have agencies publish, as part of the **Federal Register** notice, a copy of the collection of information, when agencies are seeking expedited OMB review; and (3) to have agencies indicate on each collection of information (or on any related instructions) the estimated average burden hours per response, together with a request that respondents direct any comments on the accuracy of the estimate to the agency and OMB.

B. 44 U.S.C. 3502(11)—OMB Clearance Procedures

Procedures by which OMB approves a collection of information—whether called for by a printed form, oral question, or a proposed or current rule—are set forth in the Paperwork Reduction Act, mostly in 44 U.S.C. 3507 and 3508. Collections of information contained in proposed rules published for comment in the **Federal Register** are also subject, in part, to clearance procedures set forth in 44 U.S.C. 3504(h).

The 1986 amendment to 44 U.S.C. 3502(11) states more explicitly the original intent of the Paperwork Reduction Act. This 1986 amendment clarifies that a "collection of information requirement" is a type of "information collection request." This clarification is intended to ensure that both an "information collection request" and a "collection of information requirement" are treated in the same manner under the Paperwork Reduction Act, except as, and only to the extent that, the generally applicable clearance procedures of the Paperwork Reduction Act are circumscribed by the clearance procedures in 44 U.S.C. 3504(h).

In other words, 44 U.S.C. 3504(h) sets forth specific clearance procedures for OMB paperwork clearance applicable to a collection of information contained in a proposed rule published for public comment in the **Federal Register**, otherwise, and unless circumscribed by the clearance procedures in 44 U.S.C. 3504(h), all the remaining provisions of the Paperwork Reduction Act apply to any collection of information, whether called for by a printed form, oral question, or a proposed or current rule. These provisions include: the basic legal authority in OMB to approve or disapprove the collection of information in 44 U.S.C. 3507(a) and 3508; the public protection provisions in 44 U.S.C. 3512; the minimum information that an agency must provide the public in its **Federal Register** notice in 44 U.S.C. 3507(a)(2)(B); the three-year limit on approval of a collection of information in 44 U.S.C. 3507(d); the legal reponsibility of agencies to display the OMB control number in 44 U.S.C. 3507(g); the fast-track, emergency clearance authority in 44 U.S.C. 3507(g); and the public disclosure provision in 44 U.S.C. 3507(h).

These various provisions of the Paperwork Reduction Act, working together, help the public participate more fully and meaningfully in the Federal paperwork review process. For example, the three-year limit to paperwork approval, combined with the notice provisions in the Act, gives the public the opportunity to comment on any collection of information (including any recordkeeping requirement) contained in a current rule every three years, not just when the rule was first issued. After a respondent has complied with a collection of information (including a recordkeeping requirement) contained in a current rule for several years, the respondent should have clearer knowledge of the burdens involved, and the agency more concrete experience with the practical utility of the information obtained. Through this iterative review process, the agency is able on a continuing basis to improve and reduce the burden of its collection of information.

In this notice, OMB has numbered its proposed amendments. Proposed amendments 4 and 5 would implement the 1986 amendments to 44 U.S.C. 3502(11) as it clarifies the applicability of the public protection provisions of 35 U.S.C. 3512. Proposed amendments 1, 3, 6, 8, 10, 11, 13, 14, 16, 17, 19, 21, and 23 would implement this legislative amendment for the remainder of 5 CFR Part 1320. Reference in existing 5 CFR Part 1320 to an "information collection request" or a "collection of information requirement" would be replaced with a reference to a "collection of information". Proposed amendment 8 would also clarify the defintion of

"collection of information" in § 1320.7(c).

C. 44 U.S.C. 3507—Public Notice

1. The Paperwork Reduction Act of 1980 requires each agency to give public notice in the **Federal Register** that it has submitted a paperwork clearance package to OMB. 44 U.S.C. 3507(a)(2)(B), as amended by the Paperwork Reduction Reauthorization Act of 1986, specifies what minimum information each agency should include in this notice. At a minimum, this **Federal Register** notice is to contain a title for the collection of information, a brief description of the need for the information and its proposed use, a description of the likely respondents and proposed frequency of response to the collection of information, and an estimate of the burden that will result from the collection of information. In describing likely respondents, OMB anticipates that agencies will use such categories as: individuals or households, State or local governments, farms, business or other for-profit institutions, Federal agencies or employees, non-profit institutions, and small businesses or organizations.

Proposed amendment 20 sets forth the content for this **Federal Register** notice. Proposed amendments 12, 15, and 18 would require agencies to provide this notice as part of the paperwork clearance process.

2. While the 1986 legislative amendment to 44 U.S.C. 3507(a)(2)(B) sets a statutory minimum for the information agencies are to provide in the **Federal Register** notice, agencies may include in their notice any additional information that would enhance the quality and quantity of such public comments. In the spirit of this legislative amendment, OMB is proposing, in amendment 20, that each agency disaggregate its estimate of total annual reporting and recordkeeping burden for each collection of information into discrete components applicable to each separate collection of information—the average hours per response, the frequency of response, and the likely number of respondents. Agencies will also be encouraged in this notice to explain the basis for estimating the average hours per response and to request comments on their overall accuracy.

OMB recognizes that an agency may, in its submission of collections of information for OMB review, seek approval for a group of related forms or other collections of information in a single package. Such packaging may facilitate agency implementation, and OMB review of related collections of information. OMB is not proposing to change this agency practice; OMB is, however, proposing that agencies estimate and give public notice of the reporting and recordkeeping burdens associated with each collection of information in such a packaged submission.

3. In amendment 20, OMB is also proposing that agencies publish in certain circumstances, as part of the **Federal Register** notice, a copy of the collection of information, together with any related instructions, for which OMB approval is being sought. Publication of the draft collection of information would occur when an agency, under existing § 1320.17(f), plans to request or has requested OMB to conduct its review on an expedited basis (a review faster than 60 days from the date of submission). Agencies would also include in this **Federal Register** notice the time period within which they are requesting OMB to approve or disapprove the collection of information. These requirements would not apply to collections of information contained in proposed rules published for public comment in the **Federal Register**; the instrument calling for the collection of information should already be published in the **Federal Register** as part of the proposed rule.

4. In amendment 22, OMB is likewise proposing that agencies include in the **Federal Register** notice the time period within which they are requesting emergency processing under § 1320.17.

5. More generally, it is the agency responsibility to develop and maintain an information collection management system that ensures that, to the extent practicable, the public receives adequate and appropriate notice. To this end, OMB is proposing, in amendment 3, that agencies indicate in their paperwork clearance packages, what practicable steps they have taken to consult with interested agencies and members of the public in order to minimize the burden of the collection of information.

6. The Paperwork Reduction Act of 1980 also requires OMB to make available to the public its decision to approve or disapprove an agency's collection of information. In an amendment to 44 U.S.C. 3507(b), the Paperwork Reduction Reauthorization Act of 1986 requires OMB to make its explanation thereof available to the public. Proposed amendment 9 would implement this legislative amendment.

7. In a new 44 U.S.C. 3507(h), the Paperwork Reduction Reauthorization Act of 1986 requires that:

> Any written communication of the Administrator of the Office of Information and Regulatory Affairs [in OMB] or any employee thereof from any person not employed by the Federal Government or from an agency concerning a proposed information collection request, and any written communication from the Administrator or employee of the Office to such person or agency concerning such proposal, shall be made available to the public. This subsection shall not require the disclosure of any information which is protected at all times by procedures established for information which has been specifically authorized under criteria established by an Executive Order or an Act of Congress to be kept secret in the interest of national defense or foreign policy.

OMB will comply with this statutory provision in a manner consistent with applicable law. OMB is aware, however, of public concerns suggesting that the first sentence of this amendment may act to inhibit possible whistleblowers—discourage public complaints or comments concerning specific collections of information. For example, a respondent may wish to express concerns about a collection of information imposed by a regulatory agency, or by an agency providing grants or other benefits. If the respondent's complaint is disclosed to the agency, the respondent may fear some form of reprisal, either, for example, through more intensified regulatory enforcement, through denial of a grant or other benefit, or other means.

OMB points out that one purpose of the Paperwork Reduction Act is "to ensure that the collection * * * of information by the Federal Government is consistent with applicable laws related to confidentiality" (44 U.S.C. 3501(6)), and that the authority of the OMB Director under the Paperwork Reduction Act is to "be exercised consistent with applicable law" (44 U.S.C. 3504(a)). If a complainant wishes to provide OMB comments about a specific collection of information on a confidential basis, the complainant should request such confidentiality. Consistent with the privacy functions of the OMB Director (see 44 U.S.C. 3501(6) and 3504(f)), OMB will seek to honor such a request to the extent that OMB is legally permitted (see 5 U.S.C. 552(b)).

D. New § 1320.21—Agency Display of Estimated Burden

OMB is proposing a new § 1320.21—Agency display of estimated burden. Proposed amendment 24 would require agencies to indicate on each instrument for the collection of information—whether set forth on a printed form, or contained in a proposed or current rule—the estimated average burden hours per response, together with a

request that the public direct any comments concerning the accuracy of this burden estimate to the agency and Office of Information and Regulatory Affairs in OMB.

In order to focus public comments, agencies may also, as part of the collection of information (or any related instructions), explain the basis for estimating the average hours per response. In addition, for example, if it is not practicable for an agency to indicate the burden estimate and request for comments on the front page of a printed form (or at the beginning of a proposed or final rule), the agency may indicate the burden estimate and request for comments at the beginning of any related instructions that accompany the collection of information (or of the preamble to the rule). Proposed amendment 24 also provides that if OMB determines that special circumstances exist, OMB may, at the request of the agency, exempt specific collections of information or categories thereof from the provisions of this proposal.

This proposal is intended to facilitate agency management of its collection of information and its efforts to reduce paperwork burdens on the public. Before an agency submits a collection of information for OMB review, an agency is obligated by the Paperwork Reduction Act to balance its need for the information, and the practical utility of the information, against the burden on respondents and costs involved. The purpose of this agency review is to encourage each agency to discipline itself to submit for OMB review the least burdensome alternative that will meet its need. A grossly underestimated or overestimated burden could adversely affect an agency's evaluation of the impact of alternative ways to collect the information. This proposal is also intended to encourage more meaningful public participation by eliciting public comment on the burdens actually imposed and the perceived practical utility of the information to be provided.

The Department of Interior has already initiated a pilot effort to implement this proposal. Specifically, that Department is developing internal guidance for its Information Collection Clearance Officers (ICCOs) that would require certain collections of information to include statements of etimated burden—either on the face of an individual form, or in a separate section of a rule containing a collection of information. An excerpt from this guidance follows:

Some forms impose approximately the same burden for all respondents. Examples are simple permit applications used by individuals or nontechnical surveys. For forms of this type, the following statement should be used:

Public reporting burden for this form [/information collection] is estimated to average *xx hours[/minutes]* per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the form[/information collection]. Direct comments regarding the burden estimate or any other aspect of this form [/information collection] to [insert title and address of bureau ICCO]; and Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Burden for some complex forms may vary widely. Examples include complex permit forms or applications completed by firms or organizations. On forms of this type, the following statement may be used:

Public reporting burden for this form[/information collection] is estimated to vary from xx to xx hours[/minutes] per response, with an average of *xx hours[/minutes]* per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the form[/information collection]. Direct comments regarding the burden estimate or any other aspect of this form[/information collection] to [insert title and address of bureau ICCO]; and Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Proposed amendment 24 would not require as specific a format as developed by the Department of the Interior. OMB, however, is considering whether such a specifically formatted statement should be required by rule. Consistent with the purposes of this proposal, OMB seeks comment concerning whether this format would provide information useful to the public, and what different or additional information would be more useful. OMB also seeks comment on the potential burdens and costs involved in including such a specifically formatted statement on agency forms, and on the degree of flexibility agencies need to tailor such a statement to their various kinds of forms and other types of collection of information.

E. Other Amendments

As amended in 1986, 44 U.S.C. 3501(5) states that a purpose of the Paperwork Reduction Act is "to ensure that automatic data processing, telecommunications, and other information technologies are acquired and used by the Federal Government in a manner which improves service delivery and program management, increases productivity, improves the quality of decisionmaking, reduces waste and fraud, and wherever practicable and appropriate, reduces the information processing burden for the Federal Government and for persons who provide information to and for the Federal Government." Agencies have been able to increase practical utility and reduce burden by automating or otherwise applying new forms of information technology to the collection of information; e.g., by receiving information electronically online or on magnetic tape or diskette. OMB is proposing, in amendment 7, to have all agencies, as part of the development of a collection of information, consider reducing the burden on respondents by use of automated collection techniques, or other forms of information technology.

Proposed amendments 2 and 25 are technical in nature, reflecting the fact that statutory amendment has taken place since implementation of these existing regulations.

Regulatory Impact and Regulatory Flexibility Act Analysis

OMB has analyzed the effects of this rule under both Executive Order No. 12291 and the Regulatory Flexibility Act. Copies of this analysis are available upon request. In summary, OMB has concluded that these amendments will have a salutary impact on small entities through the reduction of unnecessary paperwork and that, while the costs and benefits of procedural amendments such as these are largely unquantifiable, the amendments meet all the requirements of the Executive Order.

Issued in Washington, DC, July 16, 1987.

Wendy L. Gramm,

Administrator, Office of Information and Regulatory Affairs.

List of Subjects in 5 CFR Part 1320

Reporting and recordkeeping requirements, paperwork, collections of information.

PART 1320—CONTROLLING PAPERWORK BURDENS ON THE PUBLIC

For the reasons set forth in the preamble, OMB proposes to amend 5 CFR Part 1320 as follows:

1A. The authority citation for Part 1320 is revised to read as follows:

Authority: 31 U.S.C. Sec. 1111 and 44 U.S.C. Chs. 21, 25, 27, 29, 31, 35.

1. In the summary of the titles of the sections at the beginning of this Part, delete the titles for §§ 1320.12 to 1320.20 and replace them with:

1320.12 Clearance of collections of information.
1320.13 Clearance of collections of information in proposed rules.
1320.14 Clearance of collections of information in current rules.

1320.15 **Federal Register** notice of OMB review.
1320.16 Collections of Information prescribed by another agency.
1320.17 Interagency reporting.
1320.18 Emergency and expedited processing.
1320.19 Public access.
1320.20 Independent regulatory agency override authority.
1320.21 Agency display of estimated burden.
1320.22 Other authority.

2. In § 1320.1, after "1980" insert "as amended,"; replace "1950," with "1950"; and replace "1111," with "1111),".

3. At the end of § 1320.4(b)(3), replace the period with a comma, and add at the end of that sentence the following: "and shall indicate, in its submission of a collection of information for OMB review, what practicable steps it has taken to consult with interested agencies and members of the public in order to minimize the burden of that collection of information.". In § 1320.4(c)(2), replace "information collection request" each time the phrase appears with "collection of information". In § 1320.4(d), replace "§ 1320.19" with "§ 1320.20".

4. Remove §§ 1320.5(a) and 1320.5(b), and replace these paragraphs with a new § 1320.5(a), as follows: "(a) Notwithstanding any other provision of law, no person shall be subject to any penalty for failure to comply with any collection of information (1) that does not display a currently valid OMB control number; or (2), in the case of a collection of information required by law or to obtain a benefit which is submitted to nine or fewer persons, that fails to state, as prescribed by § 1320.4(a), that it is not subject to OMB review under the Act. The failure to display a currently valid OMB control number for a collection of information contained in a current rule does not, as a legal matter, rescind or amend the rule; however, its absence will alert the public that either the agency has failed to comply with applicable legal requirements for the collection of information or the collection of information has been disapproved, and that therefore the portion of the rule containing the collection of information has no legal force and effect and the public protection provisions of 44 U.S.C. 3512 apply.".

5. In § 1320.5, redesignated paragraphs (c) and (d) as paragraphs (b) and (c), respectively, and replace the first sentence in the new § 1320.5(b) with the following sentence: "Whenver an agency has imposed a collection of information as a means for providing or satisfying a condition to the receipt of a benefit or the avoidance of a penalty, and the collection of information does not display a currently valid OMB control number or statement, as prescribed in § 1320.4(a), the agency shall not treat a person's failure to comply, in and of itself, as grounds for withholding the benefit or imposing the penalty.". In the new §§ 1320.5(b)(1) and 1320.5(b)(2), replace "§ 1320.19" each time it appears with "§ 1320.20".

6. In § 1320.6(b), replace "an information collection request or requirement" with "a collection of information".

7. At the end of § 1320.6(j), replace the period with a comma and add after that paragraph the following new paragraph: "(k) Unless the agency has considered reducing the burden on respondents by use of automated collection techniques or other forms of information technology.".

8. In the first sentence of § 1320.7(c), after "questions,", insert "or identical reporting or recordkeeping requirements,". Replace the third sentence of § 1320.7(c) introductory text with the following: "In the Act, a 'collection of information requirement' is a type of 'information collection request.' As used in this Part, a 'collection of information' refers to the act of collecting information, to the information to be collected, to a plan and/or an instrument calling for the collection of information, or any of these, as appropriate."

In the second sentence of § 1320.7(c)(1), after "plans" insert "information collection requests, collection of information requirements,"; after "rules or regulations," insert "information collection requests or collection of information requirements contained in, derived from, or authorized by such rules or regulations,"; after "interview guides," insert "oral communications,"; and after "telephonic requests," insert "automated collection techniques,". In the first sentence of § 1320.7(c)(2), replace "by an agency or" with "by an agency for". In § 1320.7(c)(3), delete the word "also". In § 1320.7(f)(1), replace "information collection requests" with "collections of information," and "request" with "collection of information". In the first sentence of § 1320.7(u) introductory text, replace "an information collection request" with "a collection of information", and replace both "request" and "information collection request" with "collection of information". In § 1320.7(u)(2), replace "information collection request" with "collection of information". In § 1320.7, remove paragraphs (d) and (1); and redesignate paragraphs (e) to (k), and (m) to (u), as paragraphs (d) to (j), and (k) to (s), respectively.

9. At the end of § 1320.11(d), add a new sentence, as follows: "Any such determination and explanation thereof shall be publicly available.".

10. In § 1320.11(e), replace the third sentence with the following: "Agencies shall submit collections of information other than those contained in proposed rules published for public comment in the **Federal Register** or in current regulations that were published as final rules in the **Federal Register**, in accordance with the requirements set forth in § 1320.12.". In the fourth sentence of § 1320.11(e), replace "§ 1320.15" with "§ 1320.16". In the fifth sentence of § 1320.11(e), replace "information collection requests" with "collections of information", and replace "§ 1320.17" with "§ 1320.18." Replace the third sentence of § 1320.11(f) with the following: "Upon such notification, the agency shall submit the collection of information for review under the procedures outlined in §§ 1320.12 or 1320.14, as appropriate.". In the fifth sentence of § 1320.11(f), replace "information collection request" with "collection of information" and "request", the second time it appears, with "collection of information". In § 1320.11(h), replace "an information collection request or requirement" with "a collection of information".

11. In § 1320.12, replace the title with "§ 1320.12 Clearance of collections of information.". Replace the first sentence of § 1320.12 introductory text with: "Agencies shall submit all collections of information, other than those contained either in proposed rules published for public comment in the **Federal Register** or in current rules that were published as final rules in the **Federal Register**, in accordance with the following requirements:".

12. In the first sentence of § 1320.12(a), add after the word "shall" the following: ", in accordance with the requirements set forth in § 1320.15,".

13. In the second sentence of § 1320.12(a), replace "information collection request" with "collection of information". In § 1320.12(b), replace "information collection request" the first and third times the phrase appears with "collection of information"; replace "the request' with "the collection of information"; and replace "an information collection request" with "a collection of information". In § 1320.12(d), replace "No information collection request may" with "A collection of information may not".

14. In § 1320.13, replace the title with "*§ 1320.13 Clearance of collections of*

information in proposed rules.". In the first sentence of § 1320.13 introductory text, replace "collection of information requirements" with "collections of information". In the first sentence of § 1320.13(a), replace "collection of information requirements" with "collections of information".

15. In the first sentence of § 1320.13(a), after the word "include", insert ", in accordance with the requirements set forth in § 1320.15,"; and after the word "rule", insert ", and identified as such,".

16. In §§ 1320.13(d) through 1320.13(j), remove the word "requirement" each time it appears.

17. In the first sentence of § 1320.14 introductory text, replace "reporting and recordkeeping requirements" with "collections of information".

18. In the first sentence in § 1320.14(b), add after the word "shall" the following: ", in accordance with the requirements set forth in § 1320.15, ".

19. In the second sentence of § 1320.14(e), replace "§ 1320.7(f)(2)" with "§ 1320.7(e)(2)". In the third sentence of § 1320.14(g), replace "requirement" with "collection of information". In the second sentence of § 1320.14(i) remove "request or requirement" the first time it is used, and replace "request or requirement" the second time it is used with "collection of information".

20. Insert, after § 1320.14, a new § 1320.15, as follows:

§ 1320.15 Federal Register notice of OMB review.

Agencies shall publish the notices statement prescribed by §§ 1320.12(a) and 1320.14(b), and the statement prescribed by § 1320.13(a), in accordance with the following requirements:

(a) The notices and statement shall each set forth, at a minimum:

(1) The title for the collection of information;

(2) A brief description of the agency's need for the information to be collected, including the use to which it is planned to be put;

(3) A description of the likely respondents; and

(4) An estimate of the total annual reporting and recordkeeping burden that will result from each collection of information. This total burden for each collection of information shall also be disaggregated and set forth in terms of the estimated average burden hours per response, the proposed frequency of response, and the estimated number of likely respondents.

(b) If, at the time of submittal of a collection of information for OMB review in accordance with the requirements set forth in §§ 1320.12 or 1320.14, an agency plans to request, or has requested OMB to conduct its review on an expedited schedule (a review faster than 60 days from the date of receipt by OMB), the agency shall publish as part of this **Federal Register** notice the time period within which it is requesting OMB to approve or disapprove the collection of information, and a copy of the collection of information, together with any related instructions, for which OMB approval is being sought.

21. Redesignate existing §§ 1320.15 through 1320.19 as §§ 1320.16 through 1320.20, respectively. In the new § 1320.17, add, after the third use of the word "Act" the phrase "as amended,". In the first sentence of the new § 1320.18, replace "information collection requests" with "collections of information".

22. After the new § 1320.18(c), add the following new paragraph "(d) The agency shall set forth in the **Federal Register** notice prescribed by § 1320.15 a statement that it is requesting emergency processing, and the time period stated under § 1320.18(b).".

Redesignate paragraphs (d) to (f) in new § 1320.18 as paragraphs (e) to (g), respectively. In new § 1320.18(e), replace "§1320.17(b)" with "§ 1320.18(b)". In the new § 1320.19(b), replace "an information collection request" with "a collection of information".

23. In the third sentence of the new § 1320.20, replace "information collection requirement or collection of information request" with "collection of information".

24. In the new § 1320.19(b), after "used,", insert "the average burden hours per response,". Insert, after the new § 1320.20, a new § 1320.21, as follows:

§ 1320.21 Agency display of estimated burden.

(a)(1) Agencies shall display on each collection of information, as close to the current OMB control number as practicable, the agency estimate of the average burden hours per response.

(2) Agencies shall include with this estimate of burden a request that the public direct any comments concerning the accuracy of this burden estimate to the agency and the Office of Information and Regulatory Affairs.

(b) If it is not practicable to display the burden estimate and request for comments on the front page, or otherwise at the beginning of the collection of information (or for other good cause), the agency may display the burden estimate and request for comments at the beginning of the instructions that accompany the collection of information, or at the beginning of the preamble of a proposed or final rule that contains the collection of information.

(c) An agency need only display the burden estimate and request for comments on copies of the collection of information, or on its instructions, printed or otherwise reproduced (or newly communicated) after October 1, 1987.

(d) If an agency determines that special circumstances exist, OMB may, in consultation with the agency, exempt specific collections of information or categories of collections of information from the requirements of this section.

25. Redesignate existing § 1320.20 as § 1320.22. In the first sentence of the new § 1320.22(e), add after "1980" the following: ", the Paperwork Reduction Reauthorization Act of 1986,". In the second sentence of the new § 1320.22(e), replace the "or" with a ", " and after "Act" add the following: "of 1980, or the Paperwork Reduction Reauthorization Act of 1986".

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