

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-R-131]

**Agency Information Collection Activities: Proposed Collection; Comment Request****AGENCY:** Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Advance Beneficiary Notice; *Form No.:* CMS-R-131 (OMB# 0938-0566); *Use:* Physicians, practitioners, suppliers, and providers furnishing Part A or Part B items or services may bill a patient for items or services denied by Medicare as not reasonable and necessary if they informed the patient, before furnishing the item or service, that Medicare was likely to deny payment for the items or services and the patient, after being informed, agreed to pay for the items or services; *Frequency:* On occasion; *Affected Public:* Businesses or other for-profit, Individuals or households, Not-for-profit institutions; *Number of Respondents:* 1,028,585; *Total Annual Responses:* 19,660,110; *Total Annual Hours:* 1,638,345.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone

number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown, CMS-R-131, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: October 4, 2001.

**John P. Burke III,**

*Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-25686 Filed 10-11-01; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-2746 (formerly HCFA-2746)]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services ((CMS) formerly the Health Care Financing Administration), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification; *Form No.:* CMS-2746 (OMB# 0938-0448); *Use:*

This form is completed by all Medicare approved ESRD facilities upon death of an ESRD patient. The forms primary purpose is to collect fact and cause of death. Reports of deaths are used to show cause of death and demographic characteristics of these patients.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; Federal Gov't., Not-for-profit institutions; *Number of Respondents:* 4,000; *Total Annual Responses:* 56,258; *Total Annual Hours:* 9,564.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 27, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-25687 Filed 10-11-01; 8:45 am]

BILLING CODE 4120-03-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10026]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of

the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection*

*Request:* Reinstatement, without change, of a previously approved collection for which approval has expired.

*Title of Information Collection:*

Survey of Medicare Beneficiaries Who Involuntarily Disenroll from their Health Plan.

*Form No.:* CMS-10026 (OMB# 0938-0817).

*Use:* In January 2002, many managed care plans are expected to withdraw from Medicare or reduce their service area. This will continue a trend that began in January 1999. CMS wishes to survey approximately 3,600 affected beneficiaries in early 2002 to determine how they were impacted by the withdrawals and whether they received sufficient information about options for replacing their managed care coverage.

*Frequency:* Other: One-Time.

*Affected Public:* Individuals or Households.

*Number of Respondents:* 3,600.

*Total Annual Responses:* 3,600.

*Total Annual Hours:* 684.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 25, 2001.

**John P. Burke III,**

*CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.*

[FR Doc. 01-25688 Filed 10-11-01; 8:45 am]

**BILLING CODE 4120-03-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01N-0048]

**Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practice Regulations for Type A Medicated Articles**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practice Regulations for Type A Medicated Articles," has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 15, 2001 (66 FR 32628), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0154. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 5, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-25658 Filed 10-11-01; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01N-0176]

**Agency Information Collection Activities; Announcement of OMB Approval; Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Good Laboratory Practices (GLP) Regulations for Nonclinical Laboratory Studies" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 20, 2001 (66 FR 37977), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0119. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 5, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-25659 Filed 10-11-01; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01N-0277]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reports of Corrections and Removals**

**AGENCY:** Food and Drug Administration, HHS.