

language (e.g., Spanish, Arabic, Chinese, Haitian Creole, Korean, Russian, and Vietnamese) were used with consumers. *Form Number:* CMS-10632 (OMB control number: 0938—New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,460; *Total Annual Responses:* 3,460; *Total Annual Hours:* 1,176. (For policy questions regarding this collection contact Ashley Peddicord-Austin at 410-786-0757).

Dated: March 16, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-40B, CMS-43, CMS-1763, CMS-10174, CMS-10215, CMS-R-285]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 22, 2017.

ADDRESSES: When commenting, please reference the document identifier or

OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-40B Application for Enrollment in Medicare the Medical Insurance Program

CMS-43 Application for Hospital Insurance Benefits for Individuals with End Stage Renal Disease

CMS-1763 Request for Termination of Premium Hospital and Supplementary Medical Insurance

CMS-10174 Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment

CMS-10215 Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs

CMS-R-285 Request for Retirement Benefit Information

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Application for Enrollment in Medicare the Medical Insurance Program; *Use:* The CMS-40B form is used to establish entitlement to and enrollment in supplementary medical insurance for beneficiaries who already have Part A, but not Part B. The form solicits information that is used to determine enrollment for individuals who meet the requirements in section 1836 of the Social Security Act as well as the entitlement of the applicant or a spouse regarding a benefit or annuity paid by the Social Security Administration or the Office of Personnel Management for premium deduction purposes. The Social Security Administration will use the collected information to establish Part B enrollment. *Form Number:* CMS-40B (OMB control number: 0938-1230); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 200,000; *Total Annual Responses:* 200,000; *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Application for Hospital Insurance Benefits for Individuals with End Stage Renal Disease; *Use:* The CMS-43 application is used (in conjunction with CMS-2728) to establish entitlement to, and enrollment in, Medicare Part A (and Part B) for individuals with end stage renal disease. The application is completed by a Social Security Administration (SSA) claims representative or field representative using information provided by the

individual during an interview. The CMS-43 application follows the questions and requirements used by SSA to determine Title II eligibility. This is done not only for consistency purposes, but because certain Title II and Title XVIII insured status and relationship requirements must be met in order to qualify for Medicare under the end stage renal disease provisions. *Form Number:* CMS-43 (OMB control number: 0938-0800); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 10,400. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Termination of Premium Hospital and Supplementary Medical Insurance; *Use:* The CMS-1763 form provides us and the Social Security Administration (SSA) with the enrollee's request for termination of Part B, Part A or both Part B and A premium coverage. The form is completed by an SSA claims or field representative using information provided by the Medicare enrollee during an interview. The purpose of the form is to provide to the enrollee with a standardized format to request termination of Part B, Part A premium coverage or both, explain why the enrollee wishes to terminate such coverage, and to acknowledge that the ramifications of the decision are understood. *Form Number:* CMS-1763 (OMB control number: 0938-0025); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 101,000; *Total Annual Responses:* 101,000; *Total Annual Hours:* 16,867. (For policy questions regarding this collection contact Carla Patterson at 410-786-8911.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; *Use:* The collected information is used primarily for payment, but is also used for claim validation as well as for other legislated functions such as quality monitoring, program integrity, and oversight. *Form Number:* CMS-10174 (OMB control number: 0938-0982); *Frequency:* Monthly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 779; *Total Annual Responses:* 1,409,828,464; *Total Annual Hours:*

2,820. (For policy questions regarding this collection contact Ivan Iveljic at 410-786-3312.)

5. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicaid Payment for Prescription Drugs—Physicians and Hospital Outpatient Departments Collecting and Submitting Drug Identifying Information to State Medicaid Programs; *Use:* States are required to provide for the collection and submission of utilization data for certain physician-administered drugs in order to receive federal financial participation for these drugs. Physicians, serving as respondents to states, submit National Drug Code numbers and utilization information for “J” code physician-administered drugs so that the states will have sufficient information to collect drug rebate dollars. *Form Number:* CMS-10215 (OMB control number: 0938-1026); *Frequency:* Weekly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 3,910,000; *Total Annual Hours:* 16,227. (For policy questions regarding this collection contact Lisa Ferrandi at 410-786-5445.)

6. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Request for Retirement Benefit Information; *Use:* Section 1818(d)(5) of the Social Security Act provides that former state and local government employees (who are age 65 or older, have been entitled to Premium Part A for at least 7 years, and did not have the premium paid for by a state, a political subdivision of a state, or an agency or instrumentality of one or more states or political subdivisions) may have the Part A premium reduced to zero. These individuals must also have 10 years of employment with the state or local government employer or a combination of 10 years of employment with a state or local government employer and a non-government employer. The CMS-R-285 form is an essential part of the process of determining whether an individual qualifies for the premium reduction. The Social Security Administration will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. *Form Number:* CMS-R-285 (OMB control number: 0938-0769); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this

collection contact Carla Patterson at 410-786-8911.)

Dated: March 16, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1066]

Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting for Custom Device Exemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the annual reporting for custom devices.

DATES: Submit either electronic or written comments on the collection of information by May 22, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact