

Title of Information Collection: Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles; *Use:* We are renewing our request for approval for the collection requirements associated with the final rule, CMS-3017-F (71 FR 17021), which published on April 5, 2006, and became effective on June 5, 2006. The regulation CMS-3017-F finalized provisions set forth in the interim final regulation (70 FR 50940) which published on August 26, 2005. This final rule conforms our regulations to section 302(a)(2)(E)(iv) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This rule defines the term power mobility devices (PMDs) as power wheelchairs and power operated vehicles (POVs or scooters). It sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs. This rule also requires a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment (DME) suppliers maintain in their records and make available to us and our agents upon request. Finally, this rule discusses our policy on documentation that we and our agents may request to support a Medicare claim for payment. *Form Number:* CMS-10116 (OCN: 0938-0971); *Frequency:* Yearly; *Affected Public:* Private sector—business or other for-profits; *Number of Respondents:* 90,521; *Number of Responses:* 173,810; *Total Annual Hours:* 34,762. (For policy questions regarding this collection contact Susan Miller at 410-786-2118.)

Dated: September 3, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Extension of a Currently Approved Information Collection; Funding Opportunity Announcement and Grant Application Instructions Template for ACL Discretionary Grant Programs

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) 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 the information collection requirements relating to the standard Funding Opportunity Announcement and Grant Application Instructions template for ACL Discretionary Grant Programs.

DATES: Submit written or electronic comments on the collection of information by November 5, 2013.

ADDRESSES: Submit electronic comments on the collection of information to: lori.stalbaum@acl.hhs.gov.

Submit written comments on the collection of information to Lori Stalbaum, Administration for Community Living, Washington, DC 20201 or by fax to (202) 357-3466.

FOR FURTHER INFORMATION CONTACT: Lori Stalbaum at (202) 357-3452 or lori.stalbaum@acl.hhs.gov.

SUPPLEMENTARY 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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request 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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension, or update, of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Proposed Collection of Information

ACL plans to submit to the Office of Management and Budget for approval *Funding Opportunity Announcement and Grant Application Instructions Template for ACL Discretionary Grants Program*. The Funding Opportunity Announcement and Application Instructions provide the requirements and instructions for the submission of an application for funding opportunities of the Administration for Community Living. The Administration for Community Living (ACL) funds discretionary grants under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), which is administered by the Administration on Intellectual and Developmental Disabilities (AIDD) as well as the Older Americans Act, which is administered by the Administration on Aging (AoA). In addition, ACL is also responsible for administering other authorizing statutes relevant to older Americans and individuals with disabilities. Through its discretionary grant programs, the Administration for Community Living (ACL) supports projects for the purpose of developing and testing new knowledge and program innovations with the potential for maximizing the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers. The Funding Opportunity Announcement (FOA) template may be found on the ACL Web site at www.acl.gov/Funding_Opportunities/Announcements/docs/ACL_PA_Template_FINAL_8-12-13.doc.

ACL estimates the burden of this collection of information as follows: *Frequency*: Based on the budget authorization for that Fiscal Year, ACL publishes, on average, 15 to 20 FOAs annually. *Respondents*: States, public agencies, private nonprofit agencies, institutions of higher education, and organizations including tribal organizations. *Estimated Number of Responses*: 350 annually. *Total Estimated Burden Hours*: 16,800.

Dated: August 29, 2013.

Kathy Greenlee,
Administrator and Assistant Secretary for Aging.

[FR Doc. 2013-21654 Filed 9-5-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0523]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 7, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910-0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under § 314.81(b)(2)(ii)(b) (21 CFR 314.81(b)(2)(ii)(b)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Pub. L. 110-85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency

update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

In the **Federal Register** of May 10, 2013 (78 FR 27404), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR 314.81(b)(2)(ii)(b) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Submission of authorized generic drug information in each annual report. | 70 | 7 | 490 | 0.50 (30 minutes) | 245 |
| Submission of authorized generic drug information on first marketed generics in an annual report. | 20 | 1 | 20 | 1 | 20 |
| Submission of a copy of that portion of each annual report containing authorized generic drug information. | 70 | 7 | 490 | 0.05 (3 minutes) | 25 |
| Total | | | | | 290 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.