

Title of Information Collection: Request for Termination of Premium Hospital and Supplementary Medical Insurance; *Use:* The CMS-1763 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 (OCN: 0938-0025); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 14,000; *Total Annual Responses:* 14,000; *Total Annual Hours:* 5,833. (For policy questions regarding this collection contact Lindsay Smith at 410-786-6843.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Advantage Program Requirements; *Use:* Medicare Advantage (MA) organizations and potential MA organizations (applicants) use the information to comply with the application requirements and the MA contract requirements. We will use this information to: approve contract applications, monitor compliance with contract requirements, make proper payment to MA organizations, determine compliance with the new prescription drug benefit requirements, and to ensure that correct information is disclosed to Medicare beneficiaries (both potential enrollees and enrollees). *Form Number:* CMS-R-267 (OCN: 0938-0753); *Frequency:* Yearly; *Affected Public:* Individuals or households and Business or other for-profits; *Number of Respondents:* 18,043,776; *Total Annual Responses:* 21,935,728; *Total Annual Hours:* 8,529,541. (For policy questions regarding this collection contact Dana Burley at 410-786-4547.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicare Secondary Payer Information Collection and Supporting Regulations; *Use:* We are seeking to renew approval to collect information from beneficiaries, providers, physicians, insurers, and suppliers on health insurance coverage that is primary to Medicare. Collecting this information

allows us to identify those Medicare beneficiaries who are in situations where Medicare is statutorily required to be a secondary payer (MSP), thereby safeguarding the Medicare Trust Fund. Specifically, we use the information to accurately process and pay Medicare claims and to make necessary recoveries in accordance with § 1862(b) of the Act (42 U.S.C.1395y(b)). If an active MSP situation is identified and Medicare is inappropriately billed as primary, the claim will be rejected. The hospitals, other providers, physicians, pharmacies, and suppliers use the information collected (and furnished to them on the denial) to properly bill the appropriate primary payer. Completing an MSP questionnaire and making an accurate MSP determination helps hospitals, other providers, physicians, pharmacies, and suppliers to bill correctly the first time, saving the Medicare Program money and affording Medicare beneficiaries an enhanced level of customer service (which, again, is particularly important in Part D due to the real-time adjudication of claims and the complicated nature of its benefit administration). Insurers, underwriters, third party administrators, and self-insured/self-administered employers use the information to ensure compliance with the law by refunding any identified mistaken payments to Medicare. *Form Number:* CMS-250-254 (OCN: 0938-0214); *Frequency:* Occasionally; *Affected Public:* Individuals and Households, Private Sector, State, Local or Tribal Governments; *Number of Respondents:* 143,070,217; *Total Annual Responses:* 143,070,217; *Total Annual Hours:* 1,788,057. (For policy questions regarding this collection contact Ward Marsh at 410-786-6473.)

Dated: September 11, 2013.

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

[FR Doc. 2013-22515 Filed 9-16-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10069]

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 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.

DATES: Comments must be received by November 18, 2013.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). 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 <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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-10069 Medicare Waiver Demonstration Application

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 Collections

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Waiver Demonstration Application; *Use:* The currently approved application has been used for several congressionally mandated and Administration high priority demonstrations. The standardized format is not controversial and will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable us to select proposals that meet our objectives and show the best potential for success. *Form Number:* CMS-10069 (OCN: 0938-0880); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 6,000 (For policy questions regarding this collection contact Steven Johnson at 410-786-3332).

Dated: September 11, 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

Food and Drug Administration

[Docket No. FDA-2013-N-0662]

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; Patent Submission and Listing Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 17, 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 0910-0513. 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., PI50-400B, Rockville, MD 20850, PRAStaff@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 FDA Approval To Market a New Drug; Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed—(OMB Control Number 0910-0513)—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)(1)) requires all new drug application (NDA) applicants to file, as part of the NDA, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Section 505(c)(2) of the FD&C Act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the FD&C Act, we publish patent information after approval of an NDA in the list entitled "Approved Drug Products With Therapeutic Equivalence Evaluations" (the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the FD&C Act directs us to publish the information upon its submission.

FDA regulations at §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement, and require persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Forms FDA 3542 and 3542a.

The reporting burden for submitting an NDA, an amendment, or a supplement in accordance with § 314.50 (a) through (f) and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910-0001. We are not reestimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing, as explained in the following paragraphs, are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement