

performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures

that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on December 22, 2010 (75 FR 80542, pages 80542–80543).

This is a new collection of information. Respondents will be screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government. Below we provide CDC's projected annualized estimate for the next three years. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 13,933.

Type of collection	Number of respondents	Annual frequency per response	Average number of activities	Hours per response
Online surveys	20,000	1	2	20/60
In person interviews	120	1	2	60/60
Focus groups	120	1	2	90/60

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–276, CMS–339, and CMS–R–282]

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

AGENCY: Centers for Medicare & 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 & Medicaid Services (CMS), 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 function; (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.

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title:* Prepaid Health Plan Cost Report; *Use:* Health Maintenance Organizations and Competitive Medical Plans contracting with the Secretary under section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, interim final cost report, and a final certified cost report in accordance with 42 CFR 417.572 through 417.576. Health Care Prepayment Plans contracting with the Secretary under section 1833 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 417.810. CMS is requesting approval for the reinstatement with change of form CMS–276. The Cost Report outlines the provisions for implementing sections 1876(h) and 1833(a)(1)(A) of the Act. The purposes of the revisions are to implement certain changes associated with the Affordable Care Act, clarify instructions, and update outdated issues within the Cost Report and the Budget Report. *Form Number:* CMS–276 (OCN 0938–0165); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 77; *Total Annual Responses:* 106; *Total Annual Hours:* 4,372. (For policy questions regarding this collection contact Temeshia Johnson at 410–786–8692. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Provider Cost Report Reimbursement Questionnaire; *Use:* The purpose of

form CMS–339 is to assist the provider in preparing an acceptable cost report and to minimize subsequent contact between the provider and its Medicare Administrative Contractor (MAC). The form provides the basic data necessary to support the information in the cost report.

Exhibit 1 of form CMS–339 contains a series of reimbursement-oriented questions which serve to update information on the operations of the provider. It is arranged topically regarding financial activities such as independent audits, provider organization and operation, etc. The MAC is responsible for the settlement of the Medicare cost report and must determine the reasonableness and the accuracy of the reimbursement claimed. This process includes performing both a desk review of the cost report and an analysis leading to a decision to settle the cost report with or without further audit. The form provides essential information to enable the MAC to make the audit or no audit decision, scope of the audit if one is necessary, and to update the provider documentation (i.e., documentation to support the financial profile of the provider). If the information is not collected, the MAC will have to go onsite to each provider to get this information. Consequently, it is far less burdensome and extremely cost effective to capture this information through the form CMS–339.

Exhibit 2 of form CMS–339 is a listing of bad debts pertaining to uncollectible Medicare deductible and coinsurance amounts. Preparation of the listing is a convenient way for providers to supply the MAC with information needed to determine the allowability of the bad debts for reimbursement. Some items required to determine allowability that are included on this exhibit are patient's

name, dates of service, date first bill sent to beneficiary, and date the collection effort ceased. Supplying the MAC with this information may be all that is required for the MAC to determine whether or not the bad debt is allowable. This too may eliminate a visit to the provider to gather this needed data. *Form Number:* CMS-339 (OCN 0938-0301); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 23,391; *Total Annual Responses:* 23,391; *Total Annual Hours:* 75,625. (For policy questions regarding this collection contact Christine Dobrzycki at 410-786-3389. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Extension. *Title of Information Collection:* Medicare Advantage Appeals and Grievance Data Disclosure Requirements (42 CFR 422.111). *Use:* Section 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c)(3) require that Medicare Advantage (MA) organizations and demonstrations disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals to any individual eligible to elect an MA organization who requests this information. MA organizations and demonstrations remain under a requirement to collect and provide this information to individuals eligible to elect an MA organization, we continue to need the same format and form for reporting. *Form Number:* CMS-R-282 (OCN 0938-0778). *Frequency:* Annually and semi-annually. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 51,370. *Total Annual Responses:* 52,260. *Total Annual Hours:* 5,414. (For policy questions regarding this collection contact Stephanie Simons at 206-615-2420. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m.

on June 3, 2013. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: April 30, 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

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10146, CMS-10286, CMS-10308, and CMS-10339]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & 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 & Medicaid Services (CMS) 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection. *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage. *Use:* Section 1860D-4(g)(1) of the Social Security Act, requires that Part D plan sponsors who deny prescription drug coverage must provide a written notice of the denial to the enrollee. The written notice must include a statement, in understandable language, of the reasons for the denial and a description of the appeals process. The Part D denial notice has been revised for clarity and includes new optional language for Part D plan sponsors to use when explaining their denial rationale. Specifically, CMS

has added optional language in the denial rationale section of the notice to allow plans to populate text explaining that a drug denied under Part D may be (or is) covered under a different benefit, such as Part B. The instructions have also been changed to guide plans on when to use this optional text. CMS solicits feedback on this new addition as well as other situations where another benefit may cover a drug (i.e. employer group benefits) and what changes to the denial notice may be helpful in addressing those situations. CMS also seeks comment regarding the potential viability and usefulness of developing a combined notice for Part C and Part D, which would allow MA-PD plans that deny a drug under Part D to simultaneously issue an approval letter under Part B. *Form Number:* CMS-10146 (OCN 0938-0976). *Frequency:* Occasionally. *Affected Public:* Private sector (business or other for-profits). *Number of Respondents:* 596. *Total Annual Responses:* 1,497,929. *Total Annual Hours:* 374,482. (For policy questions regarding this collection contact Caroline L Baker at 410-786-0116. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved information collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable state or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the