Billing Code: 4120-01-U-P

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.

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 individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. Form Number: CMS-10286 (OCN: 0938-1077); Frequency: On Occasion; Affected Public: state, Local, or Tribal Governments, Private Sector; Number of Respondents: 2; Number of Responses: 2; Total Annual Hours: 0.5. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650. For all other issues call (410) 786-1326.)

3. Type of Information Collection Request: Revision of a currently approved collection. Title of Information Collection: Parts C and D Complaints Resolution Performance Measures. Use: CMS seeks to conduct a survey as part of the Part C and D Complaints Resolution Performance Measure project. The purpose of the project is to develop and support implementation of internal monitoring tools for the Medicare Advantage (Part C) and Prescription Drug (Part D) program that represents, from the beneficiary's perspective, the way in which plans handle complaints. The data collection is necessary because a survey is the only

way to collect information about the resolution process from the beneficiary's perspective. Currently, there is no other data source that collects such information for Part C and Part D Medicare plans. Form Number: CMS-10308 (OCN 0938-1107). Frequency: Yearly. Affected Public: Individuals or households. Number of Respondents: 18,210. Total Annual Responses: 18,210. Total Annual Hours: 3,035. (For policy questions regarding this collection contact Carolyn Scott at 410-786-1190. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Pre-Existing Health Insurance Plan and Supporting Regulations; Use: On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a ''temporary high risk health insurance pool program'' (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

We are requesting an extension of this package because this information is needed to assure that PCIP programs are established timely and effectively. This request is being made based on regulations and guidance that have been issued and contracts which have been executed by HHS with states or an entity on their behalf participating in the PCIP program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing state high risk pool programs. Form Number: CMS–10339 (OMB#: 0938–1100); Frequency: Reporting—On occasion; Affected Public: state governments;

Number of Respondents: 51; Total Annual Responses: 2,652; Total Annual Hours: 36,924. (For policy questions regarding this collection contact Laura Dash at 410–786–8623. 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 E-mail 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by **[OFR—insert date 60 days after date of publication in the Federal Register]**:

1. Electronically. You may submit 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) 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.

Dated: April 30, 2013 _____

Martique Jones,

Deputy Director, Regulations Development Group,

Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013-10522 Filed 05/02/2013 at 8:45 am; Publication Date: 05/03/2013]