Frequency of Response: 1.
Average minutes per response: 15.
Burden hours: 125.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Keith Tucker,

Paperwork Reduction Act Clearance Officer, Office of the Secretary.

[FR Doc. 2011–26319 Filed 10–11–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier CMS–10379]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and 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 and 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 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR 1320.13. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures in that public harm is reasonably likely to result if normal clearance procedures are followed as stated in 5 CFR 1320.13(a)(2)(i). The approval of this data collection process is essential to ensuring that consumers enrolled in individual and small group association products receive the consumer protections provided under Section 1003 of the Affordable Care Act. In absence of this change, a significant number of individual and small group rate increases for the 2012 plan year would not be subject to the review and public disclosure requirements of the rate review program and, instead, would be subject to rate increases that are largely unregulated.

1. *Type of Information Collection Request:* Revision of a currently approved; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements (45 CFR Part 154). *Use:* Under the Section 1003 of the Affordable Care Act (Section 2794 of the Public Health Service Act), The Secretary, in conjunction with the States, is required to establish a process for the annual review, beginning with the 2010 plan year, of unreasonable increases in premiums for health insurance coverage. Section 2794 directs the Secretary to ensure the public disclosure of information of unreasonable rate increases and justification for those increases.

On December 23, 2010, CMS published a proposed rate review regulation in the **Federal Register** for public comment (Rate Increase Disclosure and Review Rule, 75 FR 81004). CMS revised the proposed rule based on the public comments and published the final rate review regulation in the **Federal Register** on May 19, 2011. The final rule defines the unreasonable rate review process and issuer reporting and disclosure requirements (Rate Increase Disclosure and Review Rule, 76 FR 29964). The regulation establishes the following reporting requirements:

- *The Preliminary Justification:* This data collection is required of all health insurance issuers for all rate increases that exceed the ''subject to review''' reporting threshold as defined in the rule. This information will be posted on an HHS Web site.
- *Rate Review Final Determination:* This data collection requires States with effective rate review programs and CMS to report their review findings and unreasonable rate increase determinations on all rate increases that are subject to review. This information will be posted on an HHS Web site.
- *The Final Justification for An Unreasonable Rate Increase:* This data collection is required of health insurance issuers that elect to implement a rate increase that is determined to be unreasonable based on State or CMS review. This information will be posted on the Health Insurance Issuer's Web site and on a CMS Web site.

1. Preliminary Justification

The Preliminary Justification consists of three parts, Part I: Rate Increase Summary, Part II: Written Explanation of the Rate Increase, and Part III: Rate Filing Documentation. Issuers must complete Parts I and II for all rate increases that exceed the reporting threshold as defined in the rule. As described in the preamble of the rule, this information would be collected to provide consumers with basic information on all rate increases that are subject to review under the rate review program.

Under the rule, ''subject to review'' rate increases would be reviewed by either States or CMS, depending on whether a State has an effective rate review program. Issuers would only be required to submit Part III of the Preliminary Justification when CMS is conducting the review of a rate increase that is ''subject to review.'' Accordingly, Part III requires health insurance issuers to provide detailed rate data that would be used for the purposes of conducting thorough actuarial reviews and for making determinations about whether rate increases are unreasonable.

This Notice contains the following information about the Preliminary Justification:

- Preliminary Justification Issuer Instructions: health insurance issuer instructions for completing all three parts of the Preliminary Justification.
- Part I Worksheet: a standardized Excel worksheet that must be used to complete Part I of the Preliminary Justification.
- Sample internet display of the Rate Review Consumer Disclosure: Information provided in the Preliminary Justification would be posted on an HHS Web site. This sample display shows how the information contained in the Part I Worksheet would be displayed to consumers.

2. Rate Review Final Determination

Under the rule, States and CMS would have to provide a Rate Review Final Determination at the close of their review of all ''subject to review'' rate increases. The Rate Review Final

Determination must provide the State's or CMS' determination on whether a rate increases is 'unreasonable'. Section 154.301(a)(3) of the rule provides a list of actuarial review elements that must be taken into account as part of the rate review process. The Final Determination must provide a brief statement explaining how the review of elements set forth in § 154.301(a)(3) caused the State or CMS to arrive at its determination that the rate is unreasonable.

The Rate Review Final Determination will be entered into a data entry text box in the Rate Review Data Collection System. CMS is estimating that this statement would be approximately a paragraph in length. There is no specific form or set of instructions associated with this reporting requirement, apart from the reporting requirements provided in the rule. The information provided in the Rate Review Final Determination will be posted as part of the rate review consumer disclosure information on an HHS Web site.

3. Final Justification for An Unreasonable Rate Increase

The rule states that if a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, the health insurance issuer must provide a Final Justification for an Unreasonable Rate Increase. In the Final Justification, issuers would have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years.

In addition to the aforementioned requirements, we have revised the information collection request as a result of an amendment to the regulation discussed in the final rule that published September 6, 2011 (76 FR 54969). The amendment to the rate review final rule updated the applicability of the rate review requirements to include products that would be considered part of the individual or small group market had they not been sold through associations, including those that are consider to be large group products under State law or have been otherwise excluded from State's existing definitions for individual and small group products. This change will result in an increase in the total number of rate increases that are subject to the rate review reporting requirements. The amendment did not propose any changes to the information that issuers must submit for each rate increase. Thus, burden associated with each rate increase submission remains unchanged from the final rate review rule. *Form Number:* CMS–10379; (OCN: 0938–1141) *Frequency:* Annually; *Affected Public:* Private Sector and States; *Number of Respondents:* 452; *Number of Responses:* 1,201; *Total Annual Hours:* 15,213. (For policy questions regarding this collection, contact Sally McCarty at (301) 492–4489. For all other issues call 410–786–1326.)

CMS is requesting OMB review and approval of this collection by *October 31, 2011,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by October 21, 2011.

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.gov/PaperworkReductionActof1995/PRAL/list.asp* 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received via one of the following methods by October 21, 2011.

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.

3. *By E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: October 6, 2011.

Martique Jones,

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

[FR Doc. 2011–26344 Filed 10–7–11; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0694]

Guidance for Industry on Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This guidance is intended to assist applicants and reviewers in drafting the ''Warnings and Precautions, Contraindications, and Boxed Warning'' sections of labeling for human prescription drug and biological products. The recommendations in this guidance will help ensure that the labeling is clear, useful, informative, and to the extent possible, consistent in content and format.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.