

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10401]

**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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by March 9, 2018.**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. 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' website 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](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.**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-10401 Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

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 Collection**

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment; *Use:* The data collection and reporting requirements described below will be used by HHS to run the permanent risk adjustment program, including validation of data submitted by issuers, on behalf of States that requested HHS to run it for them. Risk adjustment is one of three (3) market stability programs established by the Patient Protection and Affordable Care Act and is intended to mitigate the impact of adverse selection in the

individual and small group health insurance markets inside and outside of the Health Insurance Exchanges. HHS will also use this data to adjust the payment transfer formula for risk associated with high-cost enrollees. State regulators can use the reporting requirements outlined in this collection to request a reduction to the statewide average premium factor of the risk adjustment transfer formula, beginning for the 2019 benefit year, and thereby avoid having to establish their own programs. Issuers and providers can use the alternative reporting requirements for mental and behavioral health records described herein to comply with State privacy laws. *Form Number:* CMS-10401 (OMB control number: 0938-1155); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 700; *Total Annual Responses:* 11,700,000,287; *Total Annual Hours:* 5,828,037. (For policy questions regarding this collection contact Ernest Ayukawa at 410-492-5213.)

Dated: January 2, 2018.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P****DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2011-N-0231]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Adverse Experience Reporting for Licensed Biological Products; and General Records****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 February 7, 2018.**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,