

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

[Document Identifier: CMS-10571]

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 February 13, 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.
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-10571 Limited Wraparound Coverage Reporting

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:* New collection of information request; *Title of Information Collection:* Limited Wraparound Coverage Reporting; *Use:* The Department of Treasury, the Department of Labor and the Department of Health and Human Services published final regulations on March 18, 2015 (80 FR 13995), amending the regulations regarding excepted benefits under the Employee Retirement Income Security Act of 1974, the Internal Revenue Code, and the Public Health Service Act to specify requirements for limited wraparound coverage to qualify as an excepted benefit. The final regulations include requirements that limited wraparound

coverage must satisfy in order to qualify as excepted benefits. One of them is a reporting requirement, for group health plans and group health insurance issuers, as well as group health plan sponsors.

A self-insured group health plan, or a health insurance issuer offering or proposing to offer Multi-State Plan wraparound coverage, is required to report to OPM information reasonably required to determine whether the plan or issuer qualifies to offer such coverage or complies with the applicable requirements. In addition, the plan sponsor of any group health plan offering any type of limited wraparound coverage is required to report to the Department of Health and Human Services (HHS), in a form and manner specified in guidance by the Secretary of HHS.

We seek comment on the content of the proposed collection form. We also seek comment on the impact that an extension of the limited wraparound pilot program would have on the number of employers/sponsors participating in the limited wraparound pilot program. In addition, if HHS extends the limited wraparound pilot program, we seek comment on when the limited wraparound pilot program should sunset, or whether the limited wraparound pilot program should be made permanent. *Form Number:* CMS-10571 (OMB control number: 0938-NEW); *Frequency:* Once; *Affected Public:* Private Sector; *Number of Respondents:* 8; *Number of Responses:* 8; *Total Annual Hours:* 24. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650).

Dated: December 12, 2017.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2017-N-0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to