

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-367a-d and CMS-10400]

**Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by *December 16, 2019*.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 *OR* Email: *OIRA\_submission@omb.eop.gov*.

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 website address at <https://www.cms.gov/>

*Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

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

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program; *Use:* Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. *Form Number:* CMS-367a, b, c, and d (OMB control number: 0938-0578); *Frequency:* Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 743; *Total Annual Responses:* 14,117; *Total Annual Hours:* 219,185. (For policy questions regarding this

collection contact Andrea Wellington at 410-786-3490.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Establishment of Exchanges and Qualified Health Plans; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that are certified as meeting certain standards.

As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange assumed responsibilities related to the certification and offering of QHPs. Under 45 CFR 156.280(e)(5)(ii), each QHP issuer that offers non-expected abortion services must submit to the State Insurance Commissioner a segregation plan describing how the QHP issuer establishes and maintains separate payment accounts for any QHP covering non-expected abortion services, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with PPACA section 1303 and applicable regulations. This segregation plan is used to verify that the QHP issuer's financial and other systems fully conform to the segregation requirements required by the PPACA. *Form Number:* CMS-10400 (OMB control number 0938-1156); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 210; *Number of Responses:* 210; *Total Annual Hours:* 580. For questions regarding this collection contact Michele Oshman at 410-786-4396.

Dated: November 8, 2019.

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

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