DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-304/-304a, CMS-367a – d, and CMS-368/-R-144]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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' Web Site address at Web Site address at:

   https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html

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*: Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS); *Use*: Form CMS-304 (ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (PQAS) is required only in those instances where a change to the original rebate data submittal is necessary. Effective July 1, 2021, the Medicaid Drug Rebate Program (MDRP) is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to

verbiage are applicable to Forms CMS-304 and -304a. Separately, we are also updating corresponding collection of information requests (OMB 0938-0578 and OMB 0938-0582) so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. *Form Number*: CMS-304 and -304a (OMB control number: 0938-0676); *Frequency*: Quarterly; *Affected Public*: Private sector (Business or other for-profits); *Number of Respondents:* 749; *Total Annual Responses:* 5,841; *Total Annual Hours:* 248,584. (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:* Medicaid Drug Rebate Program Labeler Reporting Format; *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. Effective July 1, 2021, the MDRP is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Forms CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), CMS-367c (Product Data), and CMS-367d (Manufacturer Contact Form). Separately, we are also updating corresponding collection of information requests (OMB 0938-0582 and OMB 0938-0676) so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. *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: 749; *Total Annual Responses*: 14,980; *Total Annual Hours:* 558,979. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Medicaid Drug Rebate Program State Reporting Forms; *Use*: Form CMS 368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP) and is required only in those instances where a change to the originally submitted data is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of these programs. Form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter. Effective July 1, 2021, the MDRP is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Form CMS-R-144. Separately, we are also updating corresponding collection of information requests (OMB 0938-0578 and OMB 0938-0676) so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. Form CMS-368 has been revised by removing the DUR State Contact information and description "Drug Utilization Review (DUR) Program." This information is now accounted for under OMB 0938-0659. *Form Number*: CMS-368 and -R-144 (OMB control number: 0938-0582); *Frequency*: Quarterly and on occasion; *Affected Public*: State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 290; *Total Annual Hours:* 13,669. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

Dated: February 17, 2021. _____

William N. Parham, III,

Director, Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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