of the drug under Medicare Part D. Per statute, drugs that are necessary for the palliation and management of the terminal illness and related conditions are not eligible for payment under Part D. The standard form provides a vehicle for the hospice provider, prescriber or sponsor to document that the drug prescribed is ''unrelated'' to the terminal illness and related conditions. It also gives a hospice organization the option to communicate a beneficiary's change in hospice status and care plan to Part D sponsors. *Form Number:* CMS–10538 (OMB control number: 0938–1269); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 424; *Total Annual Responses:* 376,487; *Total Annual Hours:* 31,374. (For policy questions regarding this collection contact Shelly Winston at 410–786–3694.)

6. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Good Cause Processes; *Use:* Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D–1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, dis-enrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. Consistent with these sections of the Act, subpart B in each of the Parts C and D regulations sets forth requirements with respect to involuntary dis-enrollment procedures at 42 CFR 422.74 and 423.44, respectively. In addition, section 1876(c)(3)(B) establishes that individuals may be dis-enrolled from coverage as specified in regulations. Thus, current regulations at 42 CFR 417.460 specify that a cost plan, specifically a Health Maintenance Organization (HMO) or competitive medical plan (CMP), may dis-enroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. Within these regulatory provisions, individuals dis-enrolled for nonpayment of premiums are afforded a grace period in which to request reinstatement. As part of the reinstatement request process, they must demonstrate good cause for failure to pay within the initial grace period that led to their involuntary dis-enrollment and pay all overdue premiums within three calendar months after the dis-enrollment date. *Form Number:* CMS–10544 (OMB control number: 0938–1271); *Frequency:* Reporting—Monthly; *Affected Public:* Private Sector (Business or other for-profit institutions); *Number of Respondents:* 10,008; *Total Annual Responses:* 10,008; *Total Annual Hours:* 6,665. (For policy questions regarding this collection contact Carla Patterson at 410–786–1000.)

Dated: June 5, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–12393 Filed 6–7–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10418]

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 August 7, 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 *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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–10418 Annual MLR and Rebate Calculation Report and MLR Rebate Notices

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 currently approved collection; *Title of Information Collection:* Annual MLR and Rebate Calculation Report and MLR Rebate Notices; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulation at 45 CFR part 158, a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing and regulatory fees, the amount of earned premium, and beginning with the 2014 reporting year, the amounts related to the transitional reinsurance, risk corridors, and risk adjustment programs established under sections 1341, 1342, and 1343, respectively, of the Affordable Care Act. An issuer must provide an annual rebate if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). Each issuer is required to submit annually MLR data, including information about any rebates it must provide, on a form prescribed by CMS, for each State in which the issuer conducts business. Each issuer is also required to provide a rebate notice to each policyholder that is owed a rebate and each subscriber of policyholders that are owed a rebate for any given MLR reporting year. Additionally, each issuer is required to maintain for a period of seven years all documents, records and other evidence that support the data included in each issuer's annual report to the Secretary. Based upon CMS' experience in the MLR data collection and evaluation process, CMS is updating its annual burden hour estimates to reflect the actual numbers of submissions, rebates and rebate notices.

The 2017 MLR Reporting Form and Instructions reflect changes for the 2017 reporting year and beyond. The 2017 MLR Reporting Form and instructions are also modified to eliminate the reporting elements that were required under the risk corridors data submission requirements in 45 CFR 153.530 for the 2014 through 2016 benefit years. For 2017, it is expected that issuers will submit fewer reports and on average, send fewer notices and rebate checks in the mail to policyholders and subscribers, which will reduce burden on issuers. In addition, issuers of qualified health plans will no longer have to submit on the annual report the data for the risk corridors program established under section 1342 of the Patient Protection and Affordable Care Act. *Form Number:* CMS–10418 (OMB control number: 0938–1164); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 522; *Number of Responses:* 2,138; *Total Annual Hours:* 170,589. (For policy questions regarding this collection contact Christina Whitefield at 301–492–4172.)

Dated: June 5, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–12394 Filed 6–7–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6730]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Malfunction Summary Reporting Program for Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 July 9, 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, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0437. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Reporting: Electronic Submission Requirements

OMB Control Number 0910–0437—Extension

The information collection associated with 21 CFR part 803 is approved under OMB control number 0910–0437. We request revision of the information collection approval as described in this document.

In the **Federal Register** of December 26, 2017 (82 FR 60922), FDA published a notification and request for comments entitled ''Center for Devices and Radiological Health; Medical Devices and Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers'' (the notification) which, among other things, proposed a program for manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form—the Voluntary Malfunction Summary Reporting Program. The proposed program would permit manufacturers of devices in certain product codes to report malfunctions for those devices on a quarterly basis and in a summary format (instead of reporting them as individual, 30-day reports), subject to certain conditions. Therefore, we have added a line item to the reporting burden table in OMB control number 0910–0437, ''Medical Device Reporting: Electronic Submission Requirements,'' for the proposed Voluntary Malfunction Summary Reporting Program.

FDA believes that submission of voluntary summary reports in the format described in this document would provide the most compact and efficient reporting mechanism for streamlining malfunction reporting that still provides sufficient detail for FDA to monitor devices effectively. The proposed Voluntary Malfunction Summary Reporting Program is meant to streamline the process of reporting malfunctions. It does not change regulatory requirements for MDR-related investigations or recordkeeping by manufacturers. The proposed program would neither apply to importers or device user facilities, nor affect