1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid and CHIP Program (MACPro); *Use:* The MACPro system is being transitioned to become the system of record that will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. Specifically, it will be used by state agencies to: Submit and amend Medicaid state plans, CHIP state plans and ADPs (Information System Advanced Planning Documents); submit applications and amendments for state waivers, demonstrations, and benchmark and grant programs; and submit reporting data. Among the collections submitted for approval under MACPro will be relevant collections that are currently approved under our generic umbrella information collection request (CMS–10398; OMB control number 0938–1148), certain collections approved as a regular stand-alone information collections, and upcoming collections. A list of those collections is included in our PRA package. *Form Number:* CMS–10434 (OMB control number: 0938–1188); *Frequency:* Monthly, yearly, quarterly, semi-annually, once, or occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 3,360; *Total Annual Hours:* 96,844. (For policy questions regarding this collection contact Annette Pearson at 410–786–6858).

Dated: August 12, 2019.

William N. Parham, III,

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

[FR Doc. 2019–17563 Filed 8–14–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–282, CMS–10638, and CMS–10338]

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 October 15, 2019.

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 the 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 N. 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–R–282 Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements under section 422.111.

CMS–10638 Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System.

CMS–10338 Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers.

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 with change of a currently approved collection; *Title of Information Collection:* Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements under section 422.111; *Use:* Part 422 of Title 42 of the Code of Federal Regulations (CFR) distinguishes between certain information a Medicare Advantage (MA) organization must provide to each enrollee (on an annual basis) and information that the MA organization must disclose to any MA eligible individual (upon request). This requirement can be found in § 1852(c)(2)(C) of the Social Security Act

and in 42 CFR 422.111(c)(3) which states that MA organizations must disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals, to any individual eligible to elect an MA organization who requests this information.

The appeals and grievance data form is an OMB approved form for use by Medicare Advantage organizations to disclose grievance and appeal data, upon request, to individuals eligible to elect an MA organization. By utilizing the form, MA organizations will meet the disclosure requirements set forth in regulations at 42 CFR 422.111(c)(3).

In an effort to identify opportunities to reduce burden for this collection, we compared data provided by plans to CMS in Part C reporting requirements (OMB 0938–1054) with the requirements to provide aggregate grievance and appeals data to MA eligible beneficiaries. We found that data reported to CMS in the Part C reporting requirements was data that would meet the disclosure requirements at § 1852(c)(2)(C) of the Social Security Act and 42 CFR 422.111(c).

We are proposing to revise this form by allowing plans to use data collected for Part C reporting requirements (OMB 0938–1054) that also meet requirements for this collection. This change merges and aligns the collection and reporting periods, so MA plans do not need to keep two separate sets of data and reports each year.

For CMS Part C reporting requirements, data is collected quarterly, but only reported annually. To match this and reduce plan burden, CMS is revising this form to use the data reported annually to CMS, and that data be valid for one year versus creating a new report every six months. Further, data provided to enrollees would be consistent with data provided to CMS. *Form Number:* CMS–R–282 (OMB control number: 0938–0778); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 733; *Total Annual Responses:* 59,133; *Total Annual Hours:* 5,405. (For policy questions regarding this collection contact Michele Hudson at 410–786–5490.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System; *Use:* Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the Medicare severity diagnosis-related groups (MS–DRGs); and the MS–DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87(b)). we are revising the estimated annual number of respondents from 32 to 62, based on the proposed alternative new technology add-on payment pathway for certain devices included in the FY 2020 IPPS proposed rule (CMS–1716–P). The existing regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

In the FY 2020 IPPS proposed rule (84 FR 19371–19373), we proposed an alternative new technology add-on payment pathway for certain devices. Specifically, for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, we proposed that a medical device that has received Federal Drug Administration (FDA) marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, the FDA) and that is part of the FDA's Breakthrough Devices Program would need to meet the cost criterion (that is, the medical device must be costly such that the DRG rate otherwise applicable to discharges involving the medical device is determined to be inadequate). To implement this proposal, we proposed to revise the existing regulations at 42 CFR 412.87. We use the application in order to determine if a technology meets the new technology criteria under the existing pathway, and would revise the application to reflect the information required to determine if a device meets the new technology criteria the proposed alternative pathway for certain devices. The revise application that would be used if the proposed alternative new technology add-on payment pathway for certain devices is finalized in the FY 2020 IPPS final rule, which is expected to be issued by August 1, 2019. *Form Number:* CMS–10638 (OMB control number: 0938–1347); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or Other for-profits, Not for-profit Institutions; *Number of Respondents:* 62; *Total Annual Responses:* 62; *Total Annual Hours:* 1,655. (For policy questions regarding this collection contact Michele Hudson at 410–786–5490.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* The information collection requirements ensure that claimants receive adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. Claimants need to understand plan procedures and plan decisions in order to appropriately request benefits and/or appeal benefit denials. The information collected in connection with the HHS-administered federal external review process is collected by HHS, and is used to provide claimants with an independent external review. *Form Number:* CMS–10338 (OMB control number: 0938–1099); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,711; *Total Annual Responses:* 4,711; *Total Annual Hours:* 1,195,626. (For policy questions regarding this collection contact Laura Byabazaire at 410–786–6650.)

Dated: August 12, 2019.

William N. Parham, III,

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

[FR Doc. 2019–17516 Filed 8–14–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1273]

Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final