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

guidance for industry entitled ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.'' The purpose of this guidance is to provide recommendations to industry for designing nonclinical bone quality studies to support the approval of drugs and biologics (*e.g.,* recombinant proteins and monoclonal antibodies regulated by the Center for Drug Evaluation and Research) intended for the treatment of osteoporosis.

DATES: The announcement of the guidance is published in the **Federal Register** on August 15, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1273 for ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Gemma Kuijpers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5336, Silver Spring, MD 20993–0002, 301–796–1243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.'' This guidance provides recommendations to industry for designing nonclinical bone quality studies to support the approval of drugs and biologics to treat osteoporosis. In addition to the pharmacology and toxicology studies required to support development of a new drug or biologic, long-term nonclinical studies, including bone-specific pharmacologic and toxicologic endpoints to evaluate the effects on bone quality, need to be conducted in appropriate animal models.

This guidance finalizes the draft guidance for industry entitled ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment'' issued in June 2016 (81 FR 38711). The main changes from the draft to final guidance include a modification of the recommended number of dose levels to be evaluated in the bone quality studies and the recommendation to use a multifactorial approach to determine the treatment duration in the conduct of the bone quality studies.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Osteoporosis: Nonclinical Evaluation of Drugs Intended for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: August 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17513 Filed 8–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements, OMB No. 0915–0307—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, included below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 15, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program (RWHAP) Core Medical Services Waiver Application Requirements, OMB No. 0915–0307—Extension

Abstract: Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (RWHAP), requires that grant recipients expend funds on core medical services including antiretroviral drugs for individuals with HIV who are eligible under the legislation. In addition, no less than 75 percent of the remainder of the total award amount after reserving statutory permissible amounts for administrative and clinical quality management costs are to be expended on core medical services.[1] For a grant recipient under the RWHAP Parts A, B, or C to be exempted from this requirement, a waiver must be requested from HRSA and submitted to the agency for review and approval in accordance with statute.

On October 25, 2013, HRSA published revised standards for core medical services waiver requests in the **Federal Register** (78 FR 63990). These revised standards allow grant recipients flexibility to adjust resource allocation based on the current situation in their local environments. These standards ensure that grant recipients receiving waivers demonstrate the availability of core medical services, including antiretroviral drugs, for persons with HIV served under the HRSA RWHAP. The core medical services waiver request process applies to RWHAP grant applicants and recipients under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services waivers are effective for a 1-year period. Grant applicants may submit a waiver request before, or with the annual grant application, and grant recipients can submit up to four months after the grant award has been made.

Need and Proposed Use of the Information: HRSA uses the documentation submitted in core medical services waiver requests to determine if the grant applicant or recipient meets the statutory requirements for waiver eligibility including: (1) No waiting lists for AIDS Drug Assistance Program services; and (2) evidence of core medical services availability within the grant recipient's jurisdiction, state, or service area to all persons with HIV identified and eligible under Title XXVI of the PHS Act.[2]

Likely Respondents: RWHAP Parts A, B, and C grant applicants and recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. Total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Waiver Request	20	1	20	5.5	110
Total	20		20		110

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance

[1] Sections 2604(c)(1), 2612(b)(1), and 2651(c)(1) of the PHS Act.

[2] Sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.